HELPING OBESE PREGNANT WOMEN ACHIEVE HEALTHY WEIGHT GAIN: IS PROVIDER INTERVENTION FEASIBLE?

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ABSTRACT

Mandy King Marshburn: Helping Obese Pregnant Women Achieve Healthy Weight Gain: Is Provider Intervention Feasible?
(Under the direction of SeonAe Yeo)

Problem Statement: Obesity rates among reproductive aged women are steadily rising. Obesity has significant health implications for pregnant woman and their babies. Obese pregnant women are more likely to gain excessive weight during pregnancy, further increasing health risks. While it is not possible to reverse obesity during pregnancy, it is possible to prevent excessive weight gain. Individualized counseling about physical activity and nutrition given by the primary obstetrical provider is the most effective intervention in helping obese pregnant women achieve healthy gestational weight gain (GWG). Providers may not find it feasible to offer individualized counseling when prenatal care visits are restricted to 10-15 minutes.

Purpose: The purpose of this DNP Project was to assess the feasibility of implementing the Clinician Lead Intervention of Daily Physical Activity and Healthy Eating (CINDHE) within a prenatal clinic in which a Certified Nurse Midwife (CNM) provides individual care for low-risk pregnant women. CINDHE is an evidence-based lifestyle intervention to assist obese pregnant women achieve healthy gestational weight gain.

Methods: Participants were given Fitbit activity trackers to track daily physical activity and nutrition data was obtained by having participants complete a nutrition survey at each prenatal visit. Physical activity and nutrition data were reviewed and individualized counseling on diet and nutrition was given during each visit. Feasibility of implementation was assessed by tracking time spent with patients in the exam room and weekly transcribed voice memos recorded by the

CNM. The effectiveness of the intervention was assessed by GWG, physical activity, and nutrition compared with historic matched cases.

Analysis: Descriptive data analyses and correlations were translated conservatively, taking into consideration the small sample size and study design. Descriptive statistics were used to calculate results of quantitative data (time of visits, weight gain, physical activity, nutrition). Qualitative data (provider perception and patient satisfaction) were coded, organized into common themes, and placed into table format to translate results.

Results: CINDHE proved feasible to implement. Data demonstrated that the intervention was effective in achieving healthy GWG. Participants demonstrated the ability to increase physical activity levels and make healthy food choices.

To my son, I thank you for inspiring me to be the best mom and role model that I can be. May you see that through hard work, dedication, and sacrifice anything is possible.

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I would like to thank Dr.'s Yeo, Leeman, and Belch for all of your guidance, feedback, and support that you provided throughout my DNP project and for helping me stay on track to attain my doctoral degree. I would also like to thank the patients who participated in my project. I thank you for placing your trust in me to care for you during your pregnancy. I consider it both an honor and a pleasure to provide maternity care to you and without your trust and support this project would not have been possible.

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LIST OF ABBREVIATIONS

AAP	American Academy of Pediatrics
ACOG	American Congress of Obstetrics and Gynecology
AMA	Advanced Maternal Age
CCHD	Craven County Health Department
CHAI Core	Communication for Health Applications and Interventions Core
CINDHE	Clinician Lead Intervention on Diet and Healthy Eating
CMA	Certified Medical Assistant
CNM	Certified Nurse Midwife
DHHS	Department of Health and Human Services
DNP	Doctor of Nursing Practice
ECWC	Eastern Carolina Women's Center
GWG	Gestational Weight Gain
IOM	Institute of Medicine
IRB	Institutional Review Board
IUFD	Intrauterine Fetal Demise
OB	Obstetrical or Obstetric
OB-GYN	Obstetrics and Gynecology
PA	Project Assistant
PAT	Physical Activity Trackers
PCP	Primary Care Provider
QNS	Qualtrics Nutrition Survey
RE-AIM	Reach Effectiveness Adoption Implementation Maintenance

TTM	The Transtheoretical Model
WHO	World Health Organization

CHAPTER 1: INTRODUCTION

Per the Institute of Medicine (IOM, 2009), about 4 million births occur in the United States annually and currently about 60% of women of childbearing age are either overweight or obese. Of greater concern is that obesity among women of reproductive age has continued to steadily rise over the last two decades with a corresponding increase in prevalence of class II and class III obesity (IOM, 2009). The American Congress of Obstetrics and Gynecology (ACOG, 2016b) recognizes that maternal obesity is associated with a significantly higher risk of early pregnancy loss, stillbirth, preterm delivery, gestational diabetes, preeclampsia, operative vaginal delivery, cesarean section, wound dehiscence, and venous thrombosis. Fetuses of overweight or obese women are more likely to develop macrosomia, impaired growth, and congenital anomalies. Postnatally, these children display a higher incidence of childhood obesity and long-term risk of developing dysmetabolic disorders. Kominiarek and Peaceman (2017) reported that women who are obese have a higher prevalence of gaining excessive weight during pregnancy. Gaining excessive weight during pregnancy significantly increases maternal morbidity for obese women as the same risks encountered upon onset of pregnancy are significantly increased. Also, obese women are more likely to retain pregnancy weight postpartum (Kominiarek & Peaceman, 2017). While it is not possible to reverse obesity during pregnancy, it is possible to prevent excessive GWG. Therefore, it is critical for obstetrical providers to implement evidence-based practice (EBP) interventions to assist obese pregnant women achieve healthy GWG gain during pregnancy to reduce adverse maternal and fetal outcomes.

A systematic review of the most current literature was recently conducted by Yeo, Walker, Caughey, Ferraro, and Asafu-Adjei (2017) to identify which lifestyle interventions targeting GWG are most effective in meeting GWG goals for obese pregnant women. The most effective intervention identified is for a woman's primary care provider (PCP) to offer individualized counseling on nutrition and physical activity. During pregnancy, the woman's PCP is her obstetrical (OB) provider. Yeo et al. (2017) also speculated that when a woman's PCP provides this specific type of counseling, obese pregnant women might become more motivated to modify their behavior in comparison to non-prenatal care providers providing this counseling.

Problem

One of the greatest challenges for providers to be able to effectively communicate and provide individualized counseling lies in the traditional model of prenatal care that is currently recommended by ACOG (American Academy of Pediatrics [AAP] and ACOG, 2012). The traditional model of prenatal care, according to ACOG's guidelines for routine OB visits for low-risk pregnancies, recommends that patients be seen once every 4 weeks until 28 weeks, every 2 weeks until 36 weeks, and weekly until delivery, allotting 10-15 minutes for each visit. Carter, Barbier, Sarabia, Macones, Cahill, and Tuuli (2017) calculated that the average patient who initiates prenatal care in the first trimester and does not deliver until 40 weeks would spend about 2 hours with her prenatal provider during the entire pregnancy in a traditional model format. The time in which the provider must assess the patient and fetus, offer counseling about routine screening and testing, and implement and interpret fetal surveillance leaves very little time for providers to offer individualized patient-tailored counseling. Unfortunately, when time spent between the patient and the provider is limited, patients have less of an opportunity to build a rapport with their provider. These time constraints can thus negatively impact information

exchange and result in poor communication between patients and providers (ACOG, 2016a).

Providers who engage their patients in dialogue and take the time to get to know them provides a good opportunity to exchange information and offer patients more appropriate counseling (ACOG, 2016a). Limited communication between the provider and patient can adversely affect the provider-patient relationship. ACOG (2016a) has recognized that sensitive and empathetic communication with patients is particularly important in obstetrics and gynecology. Within this specialty, patients may be more reluctant to discuss sensitive problems such as weight. Taking time to get to know the patient allows opportunity for providers to develop individualized counseling and treatment plans, which has been shown to improve patient adherence, long-term health, and satisfaction with their care (ACOG, 2016a; Fieril, Olsen, Glantz, & Premberg, 2017).

Purpose

Finding time to provide individualized counseling about diet and physical activity among a growing population of obese pregnant patients has been challenging for providers within the DNP project's practice site, as OB providers currently offer care within a traditional prenatal care model format. Therefore, the purpose of the DNP project was to test the feasibility of implementing an evidence based provider intervention to achieve healthy GWG throughout pregnancy for obese pregnant patients in order to improve maternal and fetal outcomes.

Clinical Question/Outcome Measures

The primary question that the DNP project sought to answer was: Is the EBP intervention feasible to implement within the project's practice site? Outcome measures that were also evaluated included: (a) patient satisfaction with care and (b) effectiveness of EBP intervention regarding physical activity, nutrition, and healthy gestational weight gain.

CHAPTER 2: REVIEW OF LITERATURE

There are many pregnancy-related factors such as psychosocial stress, fatigue, fluctuations in appetite, and maternal concern of fetal growth that may affect GWG (Kominiarek & Peaceman, 2017). The WHO (2014) and ACOG (2015) recommends that OB providers should offer obese pregnant patients advice on recommended GWG and offer counseling about healthy diet and exercise starting at the initial prenatal visit. The IOM (2009) has offered OB providers guidelines for informing patients what their recommended GWG should be based on their body mass index (BMI). Given that OB providers are PCPs for pregnant women, counseling obese pregnant women during routine prenatal visits is not only convenient, but improves access to individualized and tailored counseling about eating healthy and physical activity (Yeo et al., 2017).

There are many interventions documented throughout the literature that have been trialed to help pregnant women achieve and maintain healthy GWG. However, most of these interventions have proven to be inconsistent in their ability to help achieve healthy GWG, as these interventions have not demonstrated the same results across different patient populations and demographics (Merkx, Ausems, de Vries, & Nieuwenhuijze, 2017). The interventions that have proven to have inconsistent results include: general counseling on diet and exercise; providing education materials and newsletters about GWG, physical activity and diet; stepped-care approach; community-based lifestyle interventions; group sessions; self-graphing of weight; and online interventions.

Current literature cites a variety of behavioral and lifestyle interventions that demonstrate promise in assisting obese pregnant women achieve healthy GWG. Many of these studies conclude that a combination of individualized counseling and behavioral interventions focusing on physical activity and nutrition are the most effective strategies in preventing excessive GWG among obese pregnant women. In a large multi-center randomized control trial that enrolled 2,000 obese pregnant women in 8 inner-city hospitals throughout the UK, findings suggest that when women are counseled and offered specific recommendations about diet and physical activity, overall quality of diet and physical activity is improved and there is a reduction in total GWG (Poston et al., 2015). Washington Cole et al. (2017) demonstrated that individualized behavioral counseling about physical activity and nutrition offered during routine prenatal care is associated with lower pregnancy weight gain. Fieril, Olsen, Glantz, and Premberg (2017) demonstrated that when pregnant women feel supported and are given non-judgmental advice and recommendations for diet and physical activity, they are more likely to make recommended lifestyle changes that result in less GWG.

Being the prevalence of obesity has increased significantly over the past two decades, international and national organizations have issued recommendations and guidelines for health care providers who care for obese pregnant women. The Academy of Nutrition and Dietetics (2016) recommends that self-monitoring diet and physical activity, goal setting, regular weight monitoring, and receiving behavioral counseling during routine prenatal visits are the most effective strategies in preventing excessive GWG among obese pregnant women. Both ACOG (2015) and the WHO (2014) agree that all pregnant women should be counseled about weight gain, diet, and physical activity at the initial prenatal visit and periodically throughout pregnancy, and special attention should be given to obese pregnant women by providing patient tailored and

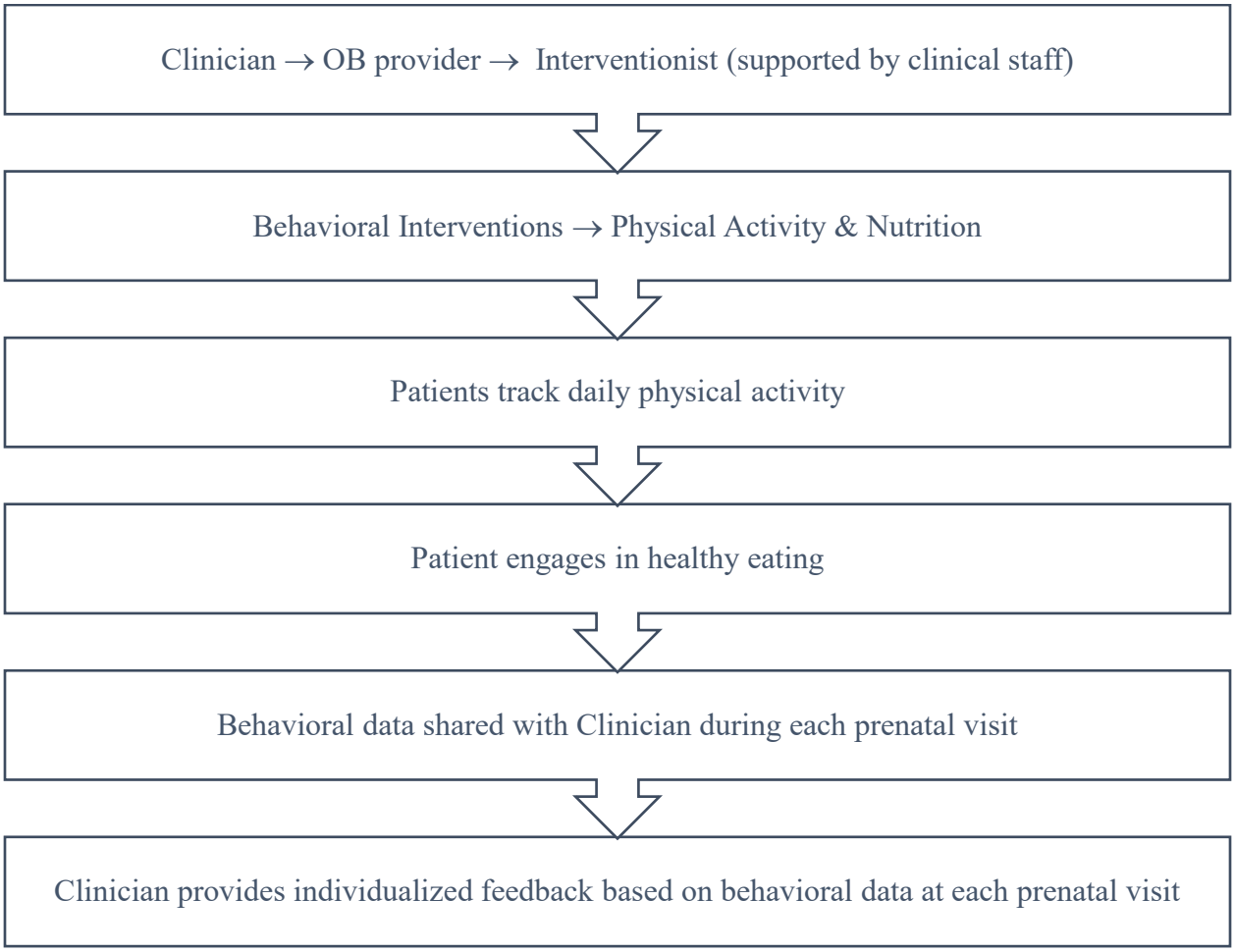
individualized counseling. The WHO (2014) has issued specific guidelines for health care providers to utilize when counseling pregnant women. These guidelines inform health care providers offer individualized counseling instead of general counseling, as every woman has different beliefs, personal factors and situations, and expectations. Therefore, for counseling to be more effective, providers must tailor counseling towards the specific needs of the patient (WHO, 2014).

The most current systematic review that identified EBP interventions utilized to reduce excessive GWG among obese pregnant women was conducted by committee chair, Dr. Yeo. In this systematic review and meta-analysis, 32 studies including 5,869 overweight and obese pregnant women were examined to determine the different types of interventions employed by prenatal care providers and non-prenatal care providers, the efficacy of these interventions, and how these interventions compared among obese and overweight women (Yeo et al., 2017). Researchers conducted a search through the MEDLINE (PubMed), EMBASE (Elsevier), and CINAHL databases. The search was restricted to the last 11 years and keywords that were used to conduct the search included: 'gestational weight gain', 'pregnancy', 'obesity', 'lifestyle modification', and 'randomized control trial'. Inclusion criteria included: randomized control trials, pregnant women with a BMI of 25 or greater, interventions implemented before the third trimester, and GWG reported or easily derived from available date. Studies that did not analyze or report GWG were excluded.

The results of Yeo et al.'s (2017) systematic review and meta-analysis determined that 28% (9/32) of the studies demonstrated a significant reduction in GWG because of the intervention. Of these nine studies, six (66%) demonstrated that the interventions were delivered by the PCP. Additionally, when interventions were delivered by the patient's PCP as opposed to

a non-PCP, there was a significantly greater reduction in GWG. The primary intervention employed by the PCP as having the most significant impact on GWG reduction was providing counseling about nutrition and physical activity. This systematic review led to the structure and process of the Clinician-Lead Intervention of Daily Physical Activity and Healthy Eating (CINDHE). The structure and process of CINDHE is represented in Figure 1.

Figure 1: Structure and Process of CINDHE



Yeo, Samuel-Hodge, Leeman, and Crandell (2017) reference and apply the CINDHE intervention in ongoing research targeting obese pregnant women in local health departments and CINDHE will be utilized by the DNP candidate as the intervention implemented within this DNP project.

CHAPTER 3: THEORETICAL FRAMEWORKS

Introduction

The DNP project was guided by two theoretical frameworks: one that guided the intervention and the other that guided the evaluation of whether the EBP intervention was feasible to implement within the project's practice setting. The Transtheoretical Model (TTM), also called the Stages of Change Model, served as the theoretical framework that guided the EBP intervention to motivate obese pregnant patients to achieve healthy GWG. Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework was used to evaluate the feasibility of implementing the EBP intervention within the project's practice site.

The Transtheoretical Model

The TTM was developed by Prochaska and DiClemente in the late 1970s through studies that examined smoking cessation (LaMorte, 2016). The investigators determined that people quit smoking only when they are ready to do so. Thus, the TTM evolved as a model of intentional change by focusing on the decision-making of the individual. The TTM applies different behavioral theories and constructs to five sequential steps: precontemplation, contemplation, preparation, action, and maintenance (Butts & Rich, 2015). This sequence of steps promotes successful behavior change, although people may not move through the steps in a linear fashion and may repeat stages based on their level of motivation and self-efficacy. The DNP project primarily focused on the preparation, action, and maintenance steps as outlined in Table 1.

Table 1: DNP Project Application of TTM

TTM Stages of Change	Stages of Change Aligned with the DNP Project
Preparation – planning for change	- Decision to enroll in project - Receipt of project training
Action – adopting new habits	- Engaging and tracking physical activity - Adopting healthy eating habits - Setting physical activity and nutrition goals
Maintenance – ongoing practice of new, healthier behaviors	- Meeting physical activity and nutrition goals - Compliance with project protocol for tracking physical activity - Completion of DNP project

The primary purpose for using the TTM as a theoretical framework to help guide the EBP intervention implemented during the DNP project is that it has proven useful in improving pregnant women's ability to achieve healthy GWG by applying general techniques for influencing behavioral changes related to diet and physical activity. Merkx et al. (2017) demonstrated this by utilizing the TTM framework to develop practical strategies to promote change based on consciousness-raising, tailoring, individualization, and self-re-evaluation.

RE-AIM

One of the goals of RE-AIM is to provide a practical means to evaluate the implementation of health interventions. RE-AIM was originally developed as a framework in 1999 for reporting research results and later was used to organize reviews of published literature on health promotion and disease management in a variety of settings. RE-AIM has been utilized in a variety of diverse fields, particularly dietary change, physical activity, women's health, quality improvement, weight loss, and practice-based research (RE-AIM, 2017). Therefore, it

was found to serve as a useful framework to guide the assessment of feasibility within the context of this DNP project.

Reach, Effectiveness, Implementation, and Maintenance were the primary components of RE-AIM that helped guide the evaluation of whether the EBP intervention was feasible to implement within the project's practice site. Reach relates to the population of patients that the intervention targeted (obese pregnant patients) and how those patients were recruited, how many were offered to participate, how many consented to participate, and how many completed the practice intervention. Implementation involved the protocol for delivering the components of the intervention and assessing whether the various intervention components were delivered as outlined in the DNP project's protocol. Maintenance applied to both the patients and the setting of the project's practice site. Maintenance has been defined as the long-term effects of a program on outcomes 6 or more months after the most recent intervention contact. Within the context of the DNP project, maintenance on an individual (patient) level was used to assess how likely patients are to continue healthy behaviors throughout the remainder of their pregnancy and how likely they are going to continue with lifestyle and behavior modifications (regarding physical activity and nutrition) after delivery. Evaluating maintenance within the practice setting was dependent upon data collected to assess feasibility. Based on data collected the interventionist had to determine what adjustments needed to be made to the project's protocol for all obstetrical providers within the project's practice site to adopt and implement the intervention.

CHAPTER 4: METHODOLOGY

Guided by the RE-AIM framework, the purpose of this project was to evaluate the feasibility of implementing the EBP intervention, CINDHE, by a Certified Nurse Midwife (CNM) in her prenatal care clinic at Eastern Carolina Women's Center (ECWC) in New Bern, NC. As previously mentioned within the Review of Literature section, CINDHE is an intervention adapted from a recently published systematic review that identified individualized nutrition and physical activity counseling provided by a woman's PCP as being the most effective intervention that facilitates clinicians helping obese pregnant patients maintain healthy GWG (Yeo et al., 2017).

Setting

ECWC is a private OB-GYN practice located in New Bern, NC, where the DNP candidate practices as a CNM. This practice services patients who reside in rural eastern North Carolina, primarily Craven, Jones, and Pamlico counties. Craven County has a population of 103,445 citizens. Jones County is a rural county that borders the western border of Craven County. It is comprised of four small townships with a population 9,845. Pamlico county is also a rural county that borders the middle eastern border of Craven County and has a population of 12,821 (United States Census Bureau, 2016). ECWC is the only private OB-GYN practice located in the three-county area. All OB patients who receive care through the practice are either insured through private insurance (BCBS, Medcost, Aetna, Cigna, and United Healthcare) or Federal Tricare (Standard and Prime). While ECWC does not accept Medicaid insured patients for routine OB care, the practice does offer collaborative and consultative care with the Craven

County Health Department (CCHD) for high risk OB Medicaid patients. The CCHD is also located in New Bern, NC and is the only public organization that is available to provide OB care to women in Craven, Jones, and Pamlico counties. There is a total of nine physicians who work alongside the CNM, seven of which provide OB care at ECWC.

Project site approval was granted from the lead physician within the practice site and was approved by the University of North Carolina's (UNC) School of Nursing. The DNP candidate also met with each OB provider within the practice to explain the context of the DNP project and to obtain feedback on their interest in implementing CINDHE into their own practice. All providers stated that they would implement CINDHE if it was deemed feasible and if it would not decrease their productivity. One physician within the practice site also agreed to serve as a committee member on the DNP candidate's project committee.

Participants

The prenatal care provider is a CNM with seven years' experience providing prenatal care, delivery, and postpartum care in New Bern. Soliciting the participation according to the IRB protocols, eight eligible pregnant women volunteered to participate in the DNP project. Inclusion criteria were (a) OB care provided at ECWC and care to be given primarily by the CNM, (b) recorded BMI of 30 kg/m^2 or greater at the initial OB visit, (c) gestational age less than 20 weeks, (d) able to communicate in English, (e) singleton pregnancy, (f) age greater than 18 years, and (h) owns a smartphone or computer with internet access. Patients were deemed ineligible to participate if they had preexisting type 2 diabetes requiring medication, chronic hypertension requiring medication, or other serious medical conditions as identified by completing the Exercise Readiness Assessment (Appendix A) with the CNM. Once consented, all participants received a Fitbit Flex physical activity tracker that they would be allowed to keep

upon completion of the project and a $50 Target gift card for project participation and completion.

Process of Patient Recruitment

Patients were identified and recruited by a trained registered nurse during the routine process for initiating prenatal care at ECWC. The routine process of initiating prenatal care requires the following:

1. To be established as a new OB patient, pregnancy is to be confirmed with urine pregnancy test at the clinic.
2. The new patient schedules to meet with a nurse for a maternal health history, social history (tobacco, alcohol, and recreational drug use), and family health history. During this visit, the nurse obtains baseline prenatal labs and vital signs to include blood pressure, temperature, pulse, respirations, height, weight, and BMI (based on current weight). A standardized BMI calculator is used to calculate BMI. Patients identified of having a BMI of 30 kg/m² or greater will have obesity listed on the prenatal chart under "risk factors".

   Specific to the DNP project, for any patient with a recorded BMI of 30 kg/m or greater and were interested in receiving care by the CNM received a "Welcome Letter" (Appendix B), information packet detailing project overview and protocol, and a consent form (Appendix C).
3. The patients were asked to review the letter and materials prior to their initial visit with the CNM. The nurse placed a colored sticker on the paper prenatal chart to alert the CNM that a patient had been given the materials.
4. The patient schedules for initial prenatal care visit with the CNM.

If eligible patients were already established at the prenatal care clinic, the CNM offered participation in the project and explained the context of the project during a routine visit.

Interested participants were given a consent form (Appendix C) to view and a copy of the proposed project protocol. Each of these patients were asked to review the consent form and protocol prior to their next appointment. Patients were informed that participating study should not result in longer or more frequent visits, except the first visit, which should be planned for an additional 20-30 minutes stay for screening, consenting, and orientation described in the following section.

Patient Orientation and Training

Fully informed and consented participants met with a project assistant (PA) who oriented and trained the participants. The protocol for orienting and training participants is outlined as follows:

- Each Fitbit was registered with a tracking number that would serve as the patient's identification number within Qualtrics and Communications for Health Applications and Interventions (CHAI) Core. Each participant signed a Fitbit Equipment Agreement (Appendix D) that acknowledged that the Fitbit was the property of UNC Chapel Hill, and should she not be able to complete the project the Fitbit would need to be returned to the practice site. Patients were informed that they would be allowed to keep the Fitbit upon project completion.
- The PA assisted patients in downloading the Fitbit app onto their smart phones, creating a Fitbit account, and taught them how to use and care for their Fitbit (Appendix E).
- The PA also assisted with creating a Validic account (Appendix F) to ensure that patients would be able to sync the Fitbit device and to collect physical activity data through CHAI Core servers. Patients were instructed on how and when to sync their Fitbit data with CHAI Core and how to access and complete the Qualtrics Nutrition Survey (QNS) (Appendix F)

upon arrival to prenatal visits.

Staff Orientation and Training

The DNP candidate held in-office education and training sessions for all clerical staff that are responsible for checking patients in and out and for all clinical office staff involved with providing patient care (medical assistants, nurses, and laboratory techs). A total of 17 staff members were provided education and training. The DNP candidate defined the role each staff member would serve in the implementation process of the DNP project as noted in Table 2. To prevent overtime, training sessions were held during the staff's lunch break and food was provided for them during these sessions. Each staff member was given a laminated card to use as a reference for what their project role entailed. The DNP candidate and her PA received training on Validic, CHAI Core, and Qualtrics in the SON at UNC Chapel Hill alongside Dr. Yeo and her research assistant. The training received is outlined in Appendices E, F, and G.

Validic (n.d.) is a healthcare technology platform that allows clinicians to access digital health data from remote monitoring devices, wearable physical activity trackers (Fitbits) and fitness equipment, and patient wellness apps. Validic enables clinicians the ability to control how health data is retrieved, displayed, analyzed, and shared. Health data that Validic provides includes data on fitness, weight, nutrition, sleep, biometrics, and diabetes. CHAI Core (2014) is a core facility, established in 2000 with support from the National Institute of Health (NIH) and funded by UNC's Gilling's School of Global Public Health, that functions as the primary resource for researchers at UNC to acquire services in behavioral intervention research, qualitative research, and web and mHealth intervention development. CHAI Core provided high quality graphical representations of weight, physical activity, and daily steps for project participants by linking with each participant's Validic and Fitbit accounts. Qualtrics, a secure

online survey platform, was used to build and share the nutrition survey. Qualtrics provides software to create and share surveys that automatically update in real-time. This software automatically builds data reports, offers a variety of graphical visualizations to view data, and analyzes responses to survey questions (Qualtrics LLC, 2017).

Table 2: Project Roles for Staff

Front Office Staff	1. Provide participants with project iPad upon check-in. If iPad is not available, contact PA or CNM's CMA immediately. 2. Ask patient if Fitbit is charged and if not have patient remove Fitbit from wrist. Fitbits that need charging are to be taken directly to the PA or CMA. 3. Instruct participant to complete QNS and to sync Fitbit with CHAI Core.
RN (Initial Visit)	1. Provide any patient who has a BMI of ≥ 30 kg/m² and is requesting to be seen by the CNM with a welcome letter (Appendix B) and project packet. 2. Explain to patient that she meets inclusion criteria for participating in a project being conducted by the CNM that is designed to help her achieve healthy GWG during her pregnancy. 3. Inquire if the woman is planning on moving out of the area during her pregnancy, if she has a smart phone, and whether she has access to Wi-Fi. 4. Provide reassurance to patients that participation is strictly voluntary and her desire to not participate will not affect the CNM or practice site's ability or willingness to provide her with prenatal care. 5. Encourage eligible patients to review "Welcome Letter" and project packet prior to initial visit with CNM.
Work-up Staff (Licensed Practical Nurses [LPN], Certified Medical Assistants [CMA], and lab techs)	1. Document weight in prenatal chart 2. Inquire if participants have completed QNS and been able to sync Fitbit with CHAI Core. 3. Alert CNM's CMA with problems

	encountered with accessing/completing QNS or synching of Fitbit. 4. Deliver iPad to CNM's CMA or PA once participant completes QNS and syncs Fitbit.
PA	1 Assist participants create Fitbit and Validic accounts. 2. Set-up Fitbits and sync Fitbit and Validic accounts. 3. Assess compliance with Fitbit use and functionality of Fitbit and charger by completing Fitbit usage log.
CNM's CMA	1. Review CNM's schedule on arrival to work to identify appointments with project participants. 2. Deliver project iPad to front office staff on days project participants are scheduled for appointments. 3. Retrieve data by logging into CHAI Core and Qualtrics prior to placing iPad in door basket. 4. Assess if Fitbit usage log has been completed by PA and if not complete this. 5. Alert CNM to any problems with Fitbit, charger, or CHAI Core/Qualtrics software that she is unable to troubleshoot.

CINDHE Implementation Process

The structure and process of CINDHE were derived based on Yeo, Walker, and et al.'s (2017) systematic review and meta-analysis. The provider was the interventionist supported by others (receptionist, staff nurses, and clinical staff). Participants wore a physical activity tracker (Fitbit) daily. They entered eating behavior into a designated project iPad upon arrival to each prenatal care visit. Physical activity and eating behavior data was arranged in graph and survey formats courtesy of Validic, CHAI Core, and Qualtrics. Reviewing and evaluating cumulative behavioral data enabled the CNM to share data with participants and offer individualized

recommendations about physical activity and healthy eating. An overview of the structure and process of implementing CINDHE is outlined in Table 3 and within the paragraphs that follow.

Table 3: Structure and Process of CINDHE

CINDHE Protocol	When	Who	How
Aptitude	Recruitment: • the initial prenatal visit • the visit after initial visit but < 20-week visit	RN CNM	"Welcome Letter" from CNM is given to patient waiting for the visit or by CNM during prenatal visit
Technical Training	Prenatal care visit 1 (after project enrollment, e.g. 12 weeks)	Project Assistant	Setting up Fitbit, Validic, & Qualtrics accounts
Self-monitoring physical activity	Daily between prenatal visits	Patient	Wearing Fitbit daily & Synching Fitbit
Self-monitoring nutrition	Prenatal care visits 2-9	Receptionist Patient CMA	• Receptionist gives patient iPad • Patient fills out QNS on iPad • Patient returns iPad to CMA
Feedback and goal setting	Prenatal care visits 2-9	CNM	Provide individualized counseling in the exam room

Check-in and preparing patient data in an iPad. Upon arrival to subsequent prenatal visits, a receptionist checking patients in upon arrival was alerted that the patient was a participant in the DNP project through a pop-up message seen immediately upon accessing the patient's chart in the EMR. The pop-up was utilized to alert staff to provide these patients with a project iPad. The project iPad was used to synchronize participant Fitbits with CHAI Core and to complete the QNS. Two iPads were utilized for data collection and retrieval within the practice

site. The CNM's CMA was responsible for ensuring that there was an iPad available for check-in staff to give to patients on days participating patients were presenting for prenatal visits. This was accomplished by the CMA reviewing the CNMs schedule at the beginning of each day. Time spent waiting to be called back by the nurse and time spent waiting to be placed in an exam room provided patients with the opportunity and time to synch their Fitbits and complete the QNS. Once participants finished synchronizing their Fitbit and completed the QNS, the iPad was given to the CNM's CMA or PA by the work-up staff. Upon placing the patient in the exam room, the CMA was responsible for asking the patient if they had any difficulty synchronizing their Fitbit with CHAI Core or completing the QNS. If there were any problems, the CMA was responsible for helping patients troubleshoot or alerting the CNM to any technical problems or issues. Once the patient was placed in the exam room and all troubleshooting issues were addressed, the CMA placed the iPad and patient's prenatal chart in a chart box located on the wall outside of the exam room door.

Clinician delivery of intervention. At outside the exam room where the project participant was waiting to be seen, the CNM recognized that the next patient was a study participant by the colored sticker (a red star) on the prenatal chart and a project iPad in the door basket. The CNM reviewed the patient's prenatal chart and retrieved data by logging onto CHAI Core and Qualtrics (Appendix G) on the project iPad. Physical activity data was summarized into graphical representations (Figure 1) by a web-based program developed by CHAI Core and patient responses to the QNS were accessible from Qualtrics. During each prenatal visit, the CNM shared physical activity (Figure 2) and weight graphs (Figure 3) and facilitated patients to evaluate and revise behavior goals for the next visit.

Figure 2: CHAI Core Physical Activity Graph

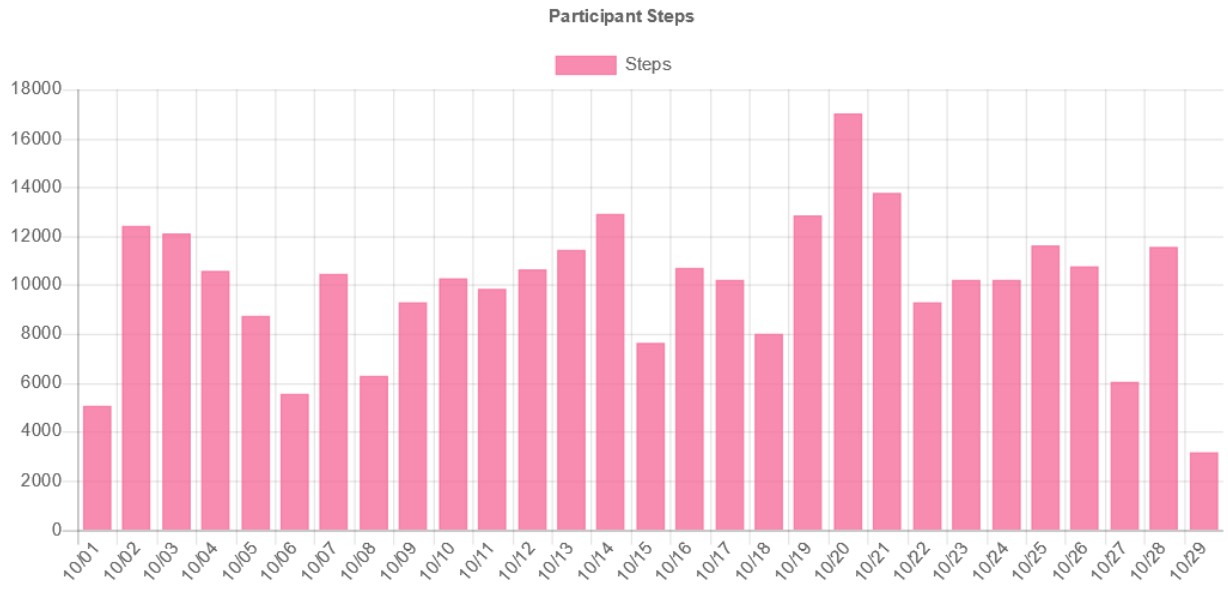
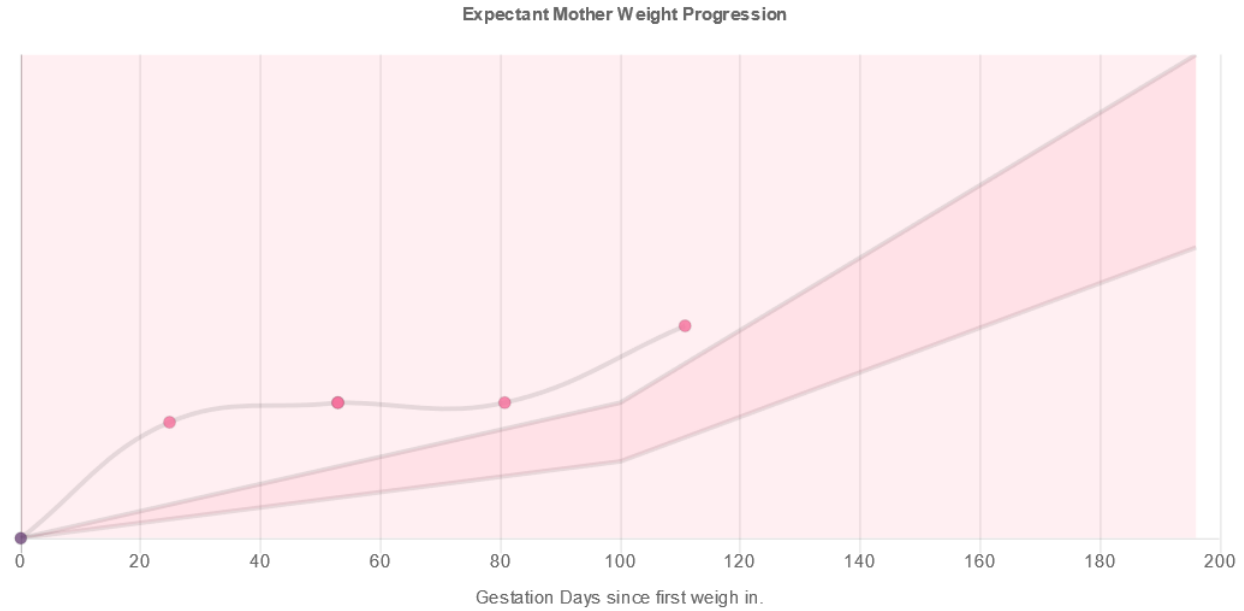


Figure 3: CHAI Core Weight Graph



Daily step goals varied among participants as level of physical fitness varied. Therefore, the CNM helped participants set daily physical activity goals based on recommendations offered by the United States Department of Health and Human Services (DHHS) guidelines for daily physical activity (DHHS, 2008). The standard formula used to help patients set daily step goals

required participants to assess daily steps taken daily and weekly. Participants were encouraged to add an additional 500 steps to the highest recorded steps taken on a single day to use as their step goal for the following week.

Assessment of patient maintenance. Individualized feedback on physical activity and setting daily step goals was based primarily on data obtained from patients wearing their Fitbits. At each prenatal visit, the CNM assessed patient compliance with tracking physical activity with the Fitbit tracker to identify if participants were wearing and synching the Fitbits daily, keeping the Fitbits charged, or having any problems with the functionality of the Fitbit trackers. This was assessed by completing the Fitbit Usage Log (Table 4) during each prenatal visit. These logs were placed inside each participants' prenatal chart and filled out by either the PA, CMA, or CNM.

Table 4: Fitbit Usage Log

Fitbit Usage Log Study ID:							
Date	Is she wearing the Fitbit always?	Is she syncing the Fitbit?	Is she keeping the Fitbit charged?	Is Fitbit synching with Fitbit app?	Is she keeping track of exercise?	Having any problems with the Fitbit?	Notes
							_____ _____ _____ _____

Data Collection

Table 5 represents an outline for data that was collected to assess feasibility of intervention implementation guided by the RE-AIM framework.

Table 5: Evaluation of Feasibility of Intervention Implementation via RE-AIM

Reach (Individual)	Effectiveness (Individual)	Adoption (Setting)	Implementation (Setting)	Maintenance (Individual)	Maintenance (Setting)
# of pts recruited =8 # of pts who consented= 8 # of pts who completed = 7 # of pts who did not complete = 1 Inclusion criteria Patient demographics	Total weight gain Physical activity (CHAI Core Data and Fitbit usage log) Nutrition (Qualtrics surveys) Patient satisfaction & perception of healthcare experience (response to open-ended surveys)	Providers who implemented = 1 (CNM) **Note**: Unable to assess within the context of this project being only one provider within the practice site piloted the intervention	**Feasibility Data**: Timeliness (time recorded on visit time log and transferred into Excel) Provider perception (weekly voice recordings of what works well, what doesn't) **Barriers to implementation:** How well did staff accept assigned duties? Did they follow protocol? Systems issues that led to breaks in protocol	How likely are patients going to continue tracking physical activity and diet t/o pregnancy? Did patients follow protocol (Fitbit usage logs)? Did patient satisfaction impact compliance with protocol?	(Ties into feasibility data) Changes that need to be made to project protocol to improve feasibility What changes to implementation delivery will impact sustainability of project intervention within the project site?

Feasibility: Timeliness

Feasibility of implementing CINDHE was primarily assessed based on "timeliness". Timeliness was assessed by determining whether providing individualized patient feedback on physical activity and nutrition during prenatal visits extended beyond the 15 minutes that were allotted for a prenatal visit. Time spent for prenatal visits was tracked by recording the time that the CNM spent in the exam room with each participant during each prenatal visit. Time was tracked with a cellular stopwatch. Prior to entering the exam room, the CNM activated her cellular stopwatch by pressing start and upon exiting the exam room at the end of the visit pressed stop. The CNM recorded the time of visit on a time log that was kept inside of participants' prenatal charts (Table 6). Data entered in the time logs were then transferred to an

Excel spreadsheet where times entered for each patient were summarized and averaged to obtain a mean visit time for each patient. When visits extended beyond the 15 minutes that were allotted for the prenatal visit, the CNM documented reasons that contributed to the longer visit beside the time entered on the visit log to identify whether these reasons were directly related to intervention delivery.

Table 6: Prenatal Visit Time Log

Project Participant #: _____	
Date:	Total Visit Time:

Provider Perception

Qualitative data to assess the CNM's perception of whether CINDHE was feasible to implement within the practice site were obtained through weekly voice memos that were recorded by the CNM onto her iPhone. The Transcribe app was used to transcribe the voice memos into text which were then transferred into a word document. Voice recordings included CNM feedback on what was working well with intervention delivery, technological problems affecting intervention delivery, and ideas to improve intervention delivery. Common themes were identified and placed into table format.

Effectiveness of Intervention

Three measures were used to assess whether CINDHE was an effective intervention to help obese patients maintain healthy GWG. These measures included physical activity, nutrition,

and healthy GWG. Physical activity was operationally defined as steps per day as recorded by Fitbit trackers worn by participants. CHAI Core computer software enabled the DNP candidate to later retrieve each patient's cumulative data on physical activity. This cumulative data was exported from CHAI Core to an excel spreadsheet. Qualtrics served the same purpose for collecting and analyzing data on nutrition. Cumulative data stored in Qualtrics were exported to an Excel spreadsheet.

Healthy weight gain was defined as total weight gained throughout pregnancy based on IOM's Weight Gain Recommendations for Pregnancy (Table 7). Baseline height and weight was obtained and recorded at the initial visit by the NOB nurse and BMI was calculated with a standard BMI calculator. The DNP candidate verified initial BMI by recalculating BMI at the initial visit. Weight was rechecked and recorded in the prenatal chart at each prenatal visit by the clinical staff. The CNM's CMA entered the recorded weight listed in the prenatal chart into the Chai Core App. Chart reviews were performed by the DNP candidate to collect data on recorded weight at each prenatal visit to compare with weight data that had been entered into CHAI Core. Weight graphs were utilized to provide data on cumulative weight gain and to determine if healthy weight gain was being maintained according to the IOM's Weight Gain Recommendations for Pregnancy.

Table 7: IOM Weight Gain Recommendations for Pregnancy

Prepregnancy Weight Category	BMI	Recommended Total Weight Gain Range (pounds)	Recommended Rates of Weight Gain Second and Third Trimesters (Mean Range, pound/week)
Underweight	Less than 18.5	28 – 40	1 (1 – 1.3)
Normal Weight	18.5 – 24.9	25 – 35	1 (0.8 – 1)
Overweight	25.0 – 29.9	15 – 25	0.6 (0.5 – 0.7)
Obese (all classes)	30.0 or greater	11 – 20	0.5 (0.4 – 0.6)

(IOM, 2009)

Patient Satisfaction

Data regarding patients' satisfaction with their health care experience was assessed by administering a survey that contained five open-ended questions (Appendix H). The questions were designed to not only assess satisfaction, but to provide insight on maintenance on the individual and setting levels as outline within the RE-AIM framework. The surveys were provided to patients at the end of the implementation phase of the project. Patients were asked to complete the survey at home and mail the survey back to the practice site within one week. Patients were instructed to keep surveys anonymous by not writing their name on the surveys. Addressed envelopes with postage was provided to each participant.

Data Analysis Plan

Descriptive data analyses and correlations were translated conservatively, taking into consideration the small sample size and study design. Descriptive statistics was used to calculate results of quantitative data (time of visits, weight gain, physical activity, nutrition). Qualitative data (provider perception and patient satisfaction) was coded, organized into common themes, and placed into table format enabling the DNP candidate to translate results.

CHAPTER 5: RESULTS

Recruitment

A total of eight patients were offered participation in the DNP project. All eight of those who were offered participation consented to enrollment. Of the eight participants who were initially enrolled, seven completed the project. The one patient withdrew from the project after the enrollment visit secondary to first trimester pregnancy loss.

Demographics

The mean age of project participants was 30.3 years (Range = 22-38; SD +/- 5.38). Seven of the participants were Caucasian and one was African American. All participants had health insurance that was provided through BCBS NC (4) or federal Tricare (3). All participants were married, had graduated from high school, and had either attended college or graduated from college.

Each participant shared the risk factor of obesity. Other risk factors that existed upon patient enrollment included advanced maternal age (AMA) as defined as maternal age of 35 or older, history of prior cesarean section, history of prior preterm delivery as defined as delivery prior to 37 gestational weeks, chronic hypertension (well-controlled without medication), prior history of preeclampsia, history of recurrent pregnancy loss as defined as three or more consecutive spontaneous first trimester pregnancy losses, history of intrauterine fetal demise (IUFD), and asthma (well-controlled). Risk factors that developed after onset of pregnancy included: iron deficiency anemia of pregnancy, gestational diabetes that was diet controlled

(Class A1), and marginal placenta previa (noted on first trimester ultrasound and was noted to resolve on second trimester ultrasound prior to project enrollment).

Feasibility of Implementation: Time Logs

Only three out of 28 (10.7%) total timed visits exceeded the 15-minute time frame. None of the reasons documented for exceeding the 15-minute time frame were directly related to the intervention delivery. Reasons documented for exceeding the 15-minute visit time-frame are included beside the time that exceeded 15-minutes under the "Notes" column in Table 8. The average mean time of visit for all patient visits was 12.11 minutes (Range = 7.17-22.32; +/- SD 2.15).

Table 8: Prenatal Visit Time Log Data

Study ID:	Date of Visit	Time of Visit (Minutes: Seconds)	Notes
#1	6/29/17	Enrollment	
	7/24/17	11:53	
	8/21/17	12:17	
	9/18/17	10:22	
	Mean:	11.5	
#2	7/21/17	Enrollment	
	8/14/17	10:26	
	9/11/17	12.51	
	10/13/17	13.10	
	Mean;	12.2	
#3	7/06/17	Enrollment	
	8/10/17	14:29	
	9/06/17	9:17	
	9/20/17	8:42	
	Mean:	10.77	
#4	6/29/17	Enrollment	
	7/21/17	14:15	
	8/18/17	20:01	Difficulty obtaining FHR due to maternal habitus and early GA
	9/13/17	13:39	
	9/27/17	14:39	
	10/13/17	12:23	
	Mean:	15	

#5	6/30/17	Enrollment	
	7/28/17	7:49	
	8/25/17	11:45	
	9/06/17	11:23	
	9/20/17	12:37	
	Mean:	10.88	
#6	7/14/17	Enrollment	
	8/09/17	8:36	
	9/08/17	22:32	Extra time spent troubleshooting Fitbit
	9/20/17	14:45	
	Mean:	15	
#7	6/12/17	Enrollment: Part1	
	7/07/17	Enrollment: Part 2	Patient accounts needed to be recreated to sync data with Validic and CHAI Core
	7/21/17	6:35	
	8/10/17	11:46	
	8/23/17	14:50	
	9/06/17	7:31	
	9/20/17	7:17	
	9/27/17	8:28	
	Mean:	9.42	
Participants 1-7	**Mean:**	12.11	Note: Mean time for all visits

Implementation: Provider Perception of Feasibility

A total of ten voice memos were recorded by the CNM throughout the course of project implementation. The CNM recorded voice memos only on weeks that she saw a project participant for prenatal care. Being the visit where patients enrolled in the project required additional time and project enrollment was done primarily by the CNM's student intern, voice recordings did not include feedback on the enrollment process.

Once voice memos were recorded by the CNM throughout the project, they were transcribed and placed in a Word document. Common themes were extracted to identify and extrapolate data on the CNM's perception of feasibility at the project site. Common themes that

were identified related to: (a) time it took to deliver the intervention, (b) common problems related to software and tracking devices, (c) staff compliance with following protocol, (d) patient compliance with protocol, and (e) feedback on suggestions for project improvement. Data regarding these themes are outlined in Table 9.

Table 9: Provider Perception of Feasibility on Intervention Implementation

Measure of Feasibility from CNM's Perspective	Provider Narratives
Timeliness of Intervention Delivery	"Providing individualized feedback did not increase time spent with patient" "Providing individualized feedback takes less time as CHAI Core graphs and access to QNS make it easier to devise feedback" "Reviewing patient data does not prolong time of patient visit with CNM" "Implementation of intervention is a more efficient way to counsel patients on weight, physical activity, and nutrition"
Common Problems Related to Computer Software and Fitbit	"Logging onto CHAI Core and Qualtrics to retrieve patient data slows down the CNM if this is not done by her CMA" "Fitbits were not always reliable in monitoring activity (if worn too tight, pushing a stroller, performing other physical activity such as swimming, cycling, yoga)" "Patients had to rely on looking at their smartphone to view daily steps as the Fitbit Flex itself did not display this data"
Advantages of Computer Software and Fitbit	"Effective in tracking, recording, and displaying data" "Graphs in CHAI Core and QNS are useful in helping tailor individualized feedback"
Staff Compliance with Protocol	"Staff sometimes forget to ensure patients have completed survey and synchronized device"

	"CMA does not always log CNM onto CHAI Core and Qualtrics to retrieve patient data (too busy, forgets, clinical staff place iPad in chart box instead of giving it to CMA)" "Big clinical staff turnover rate during project implementation" "Front office staff good at providing patients with iPads on arrival to visits"
Patient Compliance with Protocol Upon Arrival to Office	"Patients don't always have Fitbit charged upon arrival to visit" "Patients always complete QNS per protocol" "Patients always wear Fitbit to office visits"
Suggestions for Project Improvement	"Weekly reminders sent to clinical staff to remind to ask patients upon arrival to visits if they needed to charge their Fitbit Extra Fitbit charger was made available for patients to charge Fitbits if needed upon arrival to office" "Being prenatal charts are not electronic, printing out a paper version of the QNS would eliminate problems with data retrieval via Qualtrics" "Not all obese patients will own or purchase a PAT; therefore, project site must either invest in providing patients with some form of PAT or be creative in using what the patient has (smart phone, fitness apps)"

Effectiveness: Patient Satisfaction

All seven participants were provided with a survey to complete at their last visit of the project. Six out seven participants (85%) responded to and returned the survey as instructed to the project site. Participants were encouraged to answer openly and honestly, thus they were discouraged from including their name on the survey. Reponses to these surveys are recorded in Table 10.

Table 10: Participant Survey Responses

Question	Responses
How has participation in the healthy pregnancy weight gain project affected your ability to eat healthy and be physically active during your pregnancy?	"I definitely pay more attention to both counting steps and setting goals keep me motivated and moving." "It has made me rethink what I gravitate to when eating as well as how much I move throughout the day." "It made me more aware of what/how much I was eating and how active I was. I made better food choices and gave into cravings less." "More aware of activity and attempt to achieve goals." "It has helped me be mindful. I'm aware of my activity level/steps and more aware of my nutrition." "My activity level has not really changed. I have been making some healthier food choices."
Do you feel that the feedback you have received during your prenatal visits have been helpful in helping you achieve healthy weight gain? Why or why not?	"Yes. I'm educated on what foods are better to eat and which are not." "Yes. I feel more like a person than just a number when I get more personal feedback from the provider." "Yes, I do! I've been told my diet and weight gain has been pretty good so that has made me feel very positive. I watched what I ate more than I would have on my own." "Yes, by improving my attempt to increase physical steps." "Mostly, yes. Many ideas were shared to help me achieve my step goal and remain active, as

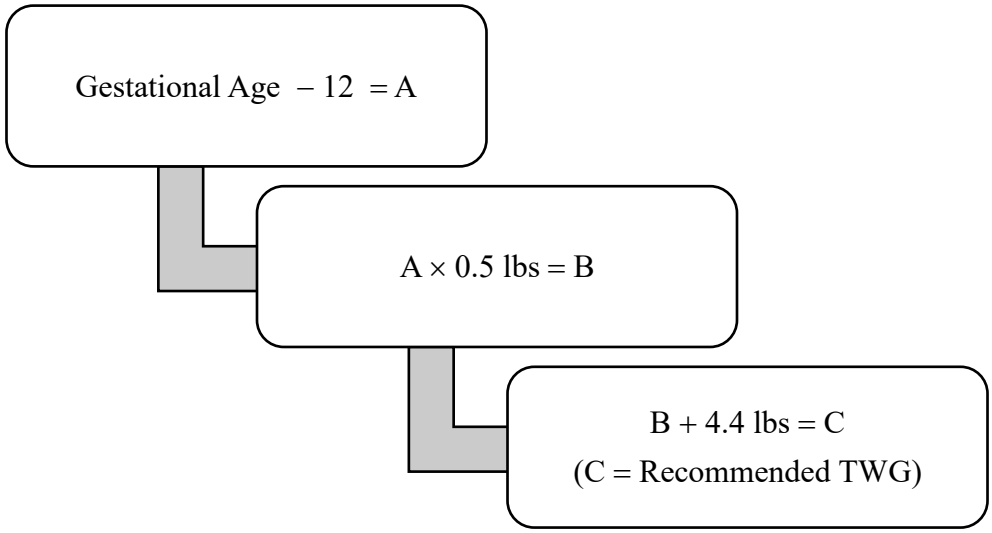
	well as alternative foods to choose. Discussing triggers for my unhealthy food choices (i.e. emotional or stress eating) might have been helpful as well." "Yes, the midwife always gives positive feedback on things I'm doing right and constructive feedback on some things to do better."
What do you consider to be most challenging in helping you maintain healthy weight gain during your pregnancy?	"Eating healthier choices and cutting down on bad choices (i.e. soda and sweet tea)." "Time management in preparing the healthy meals. Sometimes it is easier to pick something up than making it." "Hitting my step goal for sure! The farther along I get the harder it has been to meet my goal. The overall exhaustion and pain in my hips has been really hard to power through." "Cravings, heat, and pain" "Cravings and lack of self-control. Not thinking long-term about how difficult it will be to lose." "This pregnancy I have really had a sweet tooth and I am generally not a sweet food eater."
What has motivated you the most in trying to maintain healthy weight gain during your pregnancy?	"Just that. The less weight I gain, the less to lose." "Being able to lose the excess weight after pregnancy." "This is my second pregnancy, buy my only living child. I've been doing my best to make sure this little one has a healthy first home (me). Also, getting in the habit of being more active will be useful with trimming down after the baby." "Already being overweight and wanting to be healthier for the baby." "Setting attainable goals and realizing them."

	"My age. Knowing it won't be easy to take the weight off."
Overall, how have the interactions you have had with your provider during routine visits impacted your level of satisfaction with your prenatal care?	"I am satisfied. M. Marshburn gives feedback and allows time for me to voice my concerns at every visit. I never feel rushed!" "I have enjoyed the entire experience. No problems with anything." "I'm always a bit nervous going into appointments when I haven't been able to meet the goals. I'm worried of disappointing my midwife which is silly I know. I am completely satisfied with my prenatal care though!" "Great! Helpful tips to maintain health and make healthier choices." "Very good. I'm glad that weight gain and activity level are being discussed. I've not had providers discuss my weight or help me come up with a plan. If the provider won't address it with me – who will?" "Excellent! I love my health care provider."

Effectiveness: Weight Gain

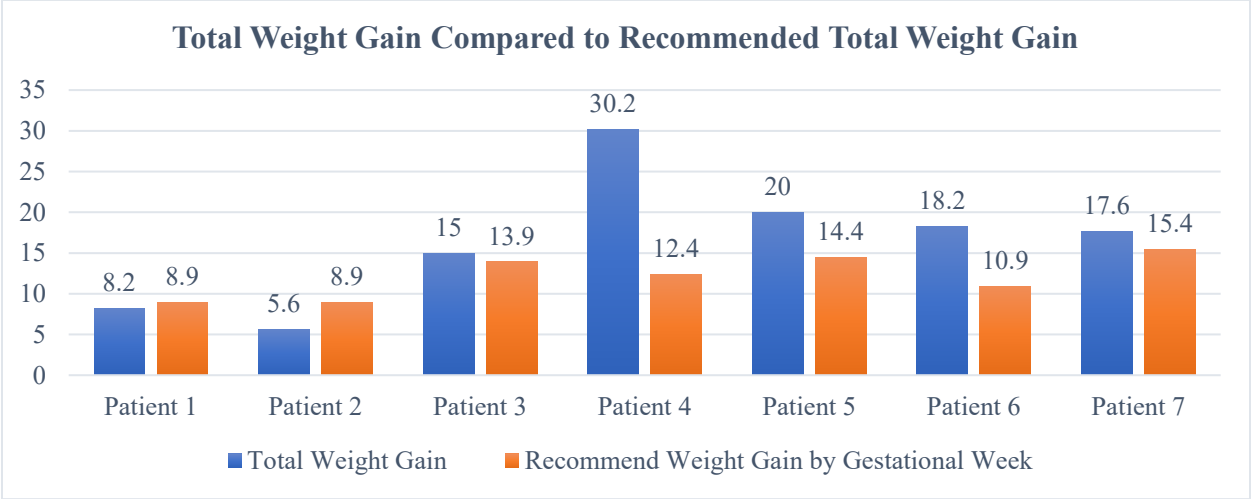
Healthy GWG was based on IOM's weight gain recommendations for pregnancy (Table 7). Being the project ended prior to being able to determine total weight gain (TWG) for the entire pregnancy, healthy GWG was determined by calculating what the recommended total weight gain was for gestational age at project end. The IOM's recommended rates of weight gain for second and third trimesters allow for a mean weight gain of 0.5 pounds per week during the second and third trimesters of pregnancy (≥ 13 weeks) and calculations assume a maximum of 4.4 pounds of weight gain for the first trimester (first 12 weeks of pregnancy). Figure 4 outlines how recommended total weight gain was calculated.

Figure 4: Recommended Total Weight Gain Calculation



Mean weight for project participants based on initial weight documented at the initial prenatal visit was 208.2 pounds (Range = 174.4-265; SD +/- 34.89). Mean total weight gain from weight recorded at the initial prenatal visit to project completion was 16.4 pounds (Range= 5.6-30.2; SD +/- 8.10). Figure 5 outlines participants' TWG and compares it to recommended TWG for the participant's gestational age based on IOM guidelines as outlined in Table 7.

Figure 5: Participants' Mean Total Weight Gain and Mean Recommended Weight Gain



To compare TWG for project participants (intervention group) with TWG for other obese pregnant women at the practice site who shared similar demographics (age, race, gestational age,

and risk factors), prenatal records were reviewed to identify seven patients to use as a comparison group. There were no patients with similar demographics who had their care solely provided by the CNM; however, all the patients included in the comparison group did see the CNM for at least one of their prenatal visits. Mean weight for the comparison group based on initial weight documented at the initial prenatal visit was 202.4 pounds (Range = 172.4 – 243.4; SD +/- 28.45). Mean total weight gain for patients in the comparison group was 22.5 pounds (Range = 8.6 – 32.7; SD +/- 8.45). Mean recommended total weight for the comparison group was 12.11 pounds (Range = 8.9 – 15.4; SD +/- 2.43). Figure 6 illustrates total weight gain and recommended weight gain for the comparison group. Figure 7 illustrates total weight gain for the participants (intervention group) and the comparison group (control group) to compare it to total recommended weight gain for both groups.

Figure 6: Comparison Group Total Weight Gain and Recommended Weight Gain

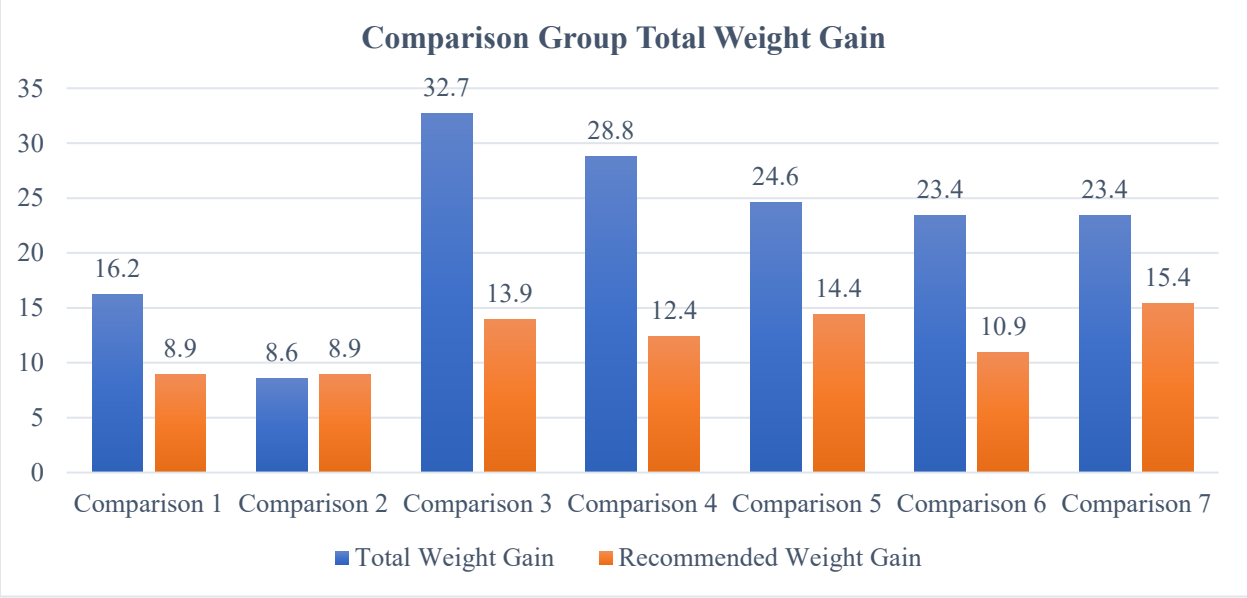
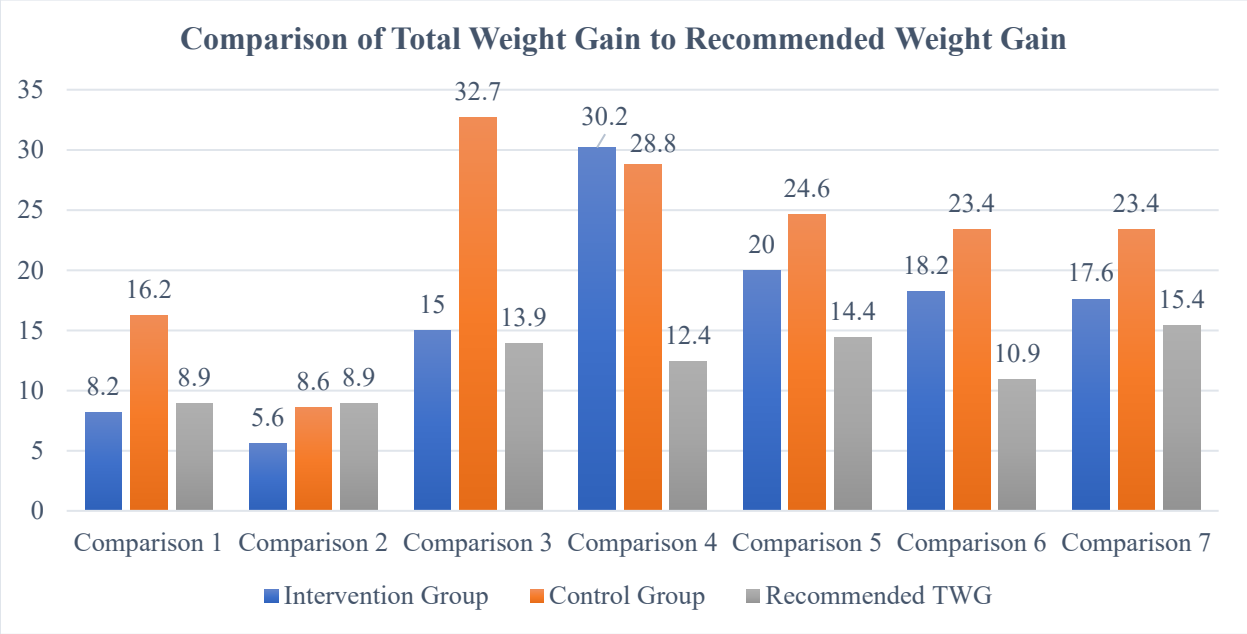


Figure 7: Total and Recommended Weight Gain for Intervention and Control Groups



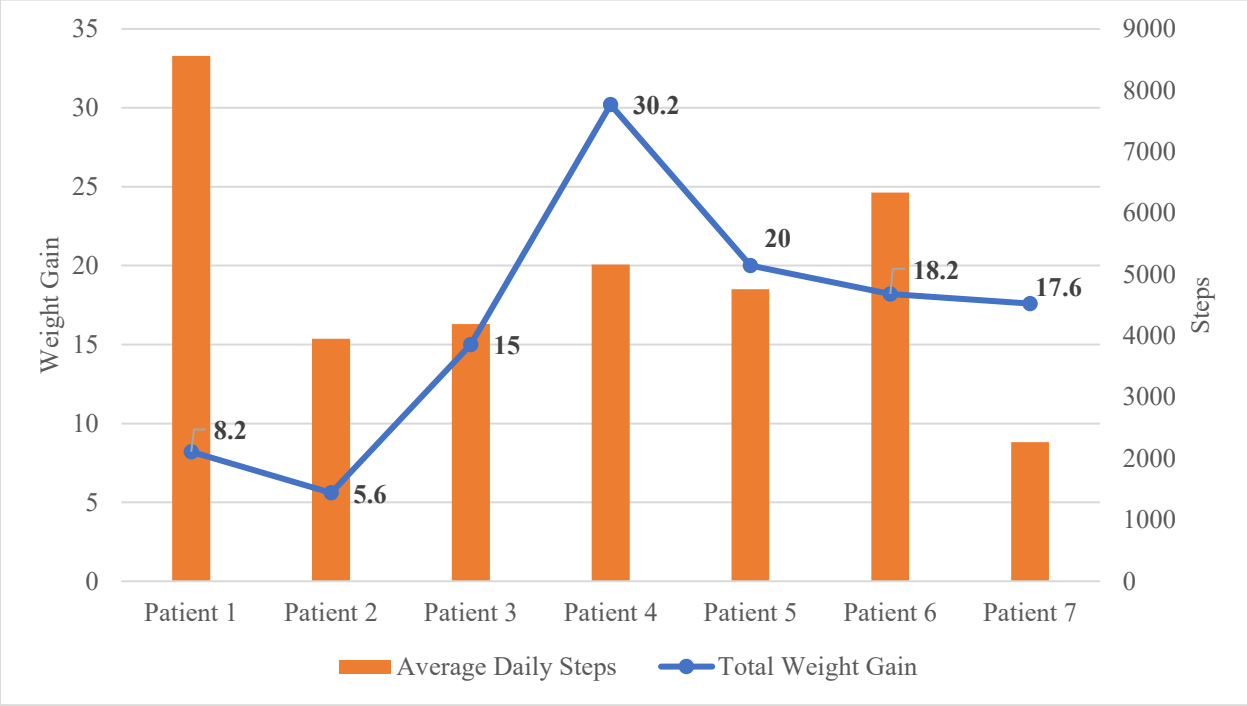
Effectiveness: Physical Activity

Physical activity data for each participant was calculated to obtain an average of daily steps taken throughout the course of the project. Average daily steps taken by each participant is summarized in Table 11 alongside average weight gain of each participant. Figure 8 offers a representation of how physical activity correlated to total weight gain for each participant.

Table 11: Average Daily Steps

Study ID #:	Average Number of Daily Steps	Total Weight Gain
1	8561	8.2
2	3949	5.6
3	4189	15
4	5163	30.2
5	4757	20
6	6336	18.2
7	2264	17.6

Figure 8: Correlation Between Steps and Weight Chart



Effectiveness: Nutrition

When participants were asked in the QNS about how they felt about their diet, all participants viewed their diet more favorably at completion of the project than they did upon project enrollment. At the time of enrollment 42.9% of participants viewed their diet as "not so good", 28.6% viewed diet as "ok", and 28.6% viewed their diet as "good". Upon completion of the project 28.6% of participants viewed their diet as "ok" and 71.4% viewed their diet as "good". All seven participants consumed at least three meals daily. Table 12 reflects daily eating habits in terms of meals per day, snacks per day, unhealthy foods that were limited on most days, unhealthy foods that were consumed most days, and average amount of weekly meals that were eaten out.

Table 12: Daily Meal Trends

Study ID:	Avg. Meals/ Day	Avg. Snacks/ Day	Unhealthy Foods Limited	Unhealthy Foods Consumed On Most Days	Avg. Weekly Meals Eaten Out
1	3	2.5	Breads	0	2.75
2	3	1.75	0	0	2.75
3	3	1.25	0	0	2.4
4	3.3	2	Desserts Sweets	Deli Meats Desserts Sweets	2.67
5	3	2.2	Fried Foods	Chips Pretzels	1.5
6	3	1.8	0	0	2.8
7	3	3.6	Desserts Sweets Chips Fries	Desserts Sweets Nuggets	1.11

Note: Unhealthy foods per QNS: Desserts/Sweets, Fries, Chips, Hot Dogs, Deli Meats, Nuggets, Other

Healthy diet in terms of self-reported intake of fruits, vegetables, dairy, whole grains, and following tables respectively (Tables 13, 14, and 15).

Table 13: Fruit and Vegetable Intake

Study ID:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**Fruit Total:**	**% of Fruit Consumed**
Apples	1	3	4	0	1	6	4	19	20.9%
Bananas	0	2	0	3	0	0	1	6	6.6%
Grapes	1	0	0	2	0	0	1	4	4.4%
Strawberries	3	2	5	2	4	4	4	24	26.4%
Blueberries	0	0	0	3	0	0	3	6	6.6%
Oranges	2	0	1	0	3	0	1	7	7.7%
Watermelon	1	0	0	0	1	1	0	3	3.3%
Pineapple	1	1	0	0	0	1	2	5	5.5
Peaches	1	0	0	0	0	2	5	8	8.8
Tomatoes	0	0	0	0	3	0	0	3	3.3%
Berries	0	0	0	0	1	0	0	1	1.1%

Pears	0	0	0	0	0	0	2	2	2.2%
Apricots	0	0	0	0	0	0	1	1	1.1%
Cantaloupe	0	1	0	0	0	1	0	2	2.2%
Total Participant Fruit Intake:	**10**	**9**	**10**	**10**	**13**	**15**	**24**	**91**	-
% of Total Fruit Intake per Participant	11%	9.9%	11%	11%	14.3%	16.5%	26.4%	**-**	-
Carrots	4	0	0	1	4	1	4	14	14.3%
Celery	1	0	0	0	0	0	0	1	1%
Broccoli	1	0	0	1	0	4	2	8	8.2%
Potatoes	1	1	0	0	0	0	3	5	5.1%
Onions	1	0	0	1	0	0	0	2	2%
Mushrooms	1	0	0	0	0	0	0	1	1%
Cabbage	2	0	2	0	0	0	0	4	4.1%
Zucchini	1	0	0	2	0	0	0	3	3.1%
Asparagus	1	0	0	0	0	0	0	1	1%
Lettuce	0	0	2	2	0	5	1	10	10.2%
Spinach	0	0	0	3	1	0	1	5	5.1%
Sweet Pot.	0	0	0	1	0	0	0	1	1%
Cucumbers	0	0	0	0	5	0	0	5	5.1%
Green Bean	0	0	5	0	3	3	6	17	17.3%
Corn	0	3	4	0	1	0	2	10	10.2%
Squash	0	0	0	0	1	0	0	1	1%
Collards	0	0	1	0	0	0	0	1	1%
Peas/Beans	0	5	0	0	0	0	3	8	8.2%
Cauliflower	0	0	0	0	0	0	1	1	1%
Total Participant Vegetable Intake:	**13**	**9**	**14**	**11**	**15**	**13**	**23**	**98**	--
% of Total Vegetable Intake per Participant	13.3%	9.2%	14.3%	11.2%	15.3%	13.3%	23.5%	**--**	--

Table 14: Grain and Dairy Intake

Study ID:	1	2	3	4	5	6	7	Total Type of Grain Consumed:
Crackers	2	0	0	1	1	0	3	**7**
Whole Wheat Bread	0	1	3	3	1	3	7	**18**
White Bread	0	2	2	2	0	3	0	**9**
Cereal Hot/Cold)	0	0	4	4	1	0	8	**17**
Pasta/Noodles	0	2	2	0	0	5	6	**15**
Corn Tortillas	0	0	0	0	0	1	0	**1**
Flour Tortillas	1	0	0	0	0	1	0	**2**
White Rice	0	2	2	0	0	1	0	**5**
Brown Rice	0	0	1	0	0	0	0	**1**
Granola	1	0	0	0	0	0	0	**1**
Pretzels	0	0	0	0	1	0	0	**1**
Total # of Grain Intake per Participant	**4**	**7**	**14**	**10**	**4**	**14**	**24**	**77**
Total % of Grain Intake per Participant	**5.2%**	**9.1%**	**18.2%**	**13%**	**5.2%**	**18.2%**	**31.2%**	—
Cheese	4	2	5	3	6	4	8	**32**
Non-Fat Milk	0	0	0	5	1	2	3	**10**
Low-Fat Milk	0	2	0	0	0	2	5	**10**
Whole Milk	0	1	5	0	0	2	0	**8**
Flavored Milk	0	1	1	0	0	0	0	**2**
Yogurt	0	1	3	2	0	5	7	**18**
Cottage	0	0	0	1	0	0	1	**2**
Total # of Dairy Intake per Participant	**4**	**7**	**14**	**11**	**7**	**15**	**24**	**82**
Total % of Dairy Intake per Participant	**4.9%**	**8.5%**	**17.1%**	**13.4%**	**8.5%**	**18.3%**	**29.3%**	--

Table 15: Beverage Intake

Study ID:	Water	Flavored Water	Milk	Juice	Tea	Coffee	Soda
1	4	3	0	0	3	1	1
% of Beverage Intake	33.3%	25%	0	0	25%	8.3%	8.3%
2	1	0	3	0	3	1	2
% of Beverage Intake	10%	0	30%	0	30%	10%	20%
3	1	3	5	0	2	0	4
% of Beverage Intake	6.7%	20%	33.3%	0	13.3%	0	26.7%
4	5	0	0	0	0	5	4
% of Beverage Intake	35.7%	0	0	0	0	35.7%	28.6%
5	6	3	3	0	0	4	0
% of Beverage Intake	37.5%	18.75%	18.75%	0	0	25%	0
6	5	0	4	5	4	0	0
% of Beverage Intake	27.8%	0	22.2%	27.8%	22.2%	0	0
7	7	3	4	7	0	0	0
% of Beverage Intake	33.3%	14.3%	19%	33.3%	0	0	0
% for all participants	26.3%	11.2%	17.6%	8.7%	12.9%	11.3%	11.9%

Note: Number reflects how many times participants reported drinking beverage

CHAPTER 6: DISCUSSION

Obesity has been defined as the most common health care problem among women of reproductive age (ACOG, 2015). Unfortunately, specific evidence based practice interventions that have been proven to make a significant impact on reducing the rates of obesity among women of reproductive age are lacking. Therefore, providers may overlook interventions that are targeted towards obese pregnant women that may prove to significantly impact healthy maternal and fetal outcomes during and after pregnancy. This often prompts providers to rely on offering generalized counseling about physical activity and nutrition to obese pregnant women instead of providing individualized and patient centered counseling (ACOG, 2016b). "One size fits all" is not the best motto when counseling obese pregnant women on behavioral change related to diet and physical activity. Fierel et al. (2017) demonstrated that what works for one simply may not work for another. Providing obese pregnant women with individualized counseling about physical activity and diet is the most effective intervention in helping them maintain healthy GWG, particularly when this counseling is given by their primary obstetrical provider (Yeo et. al, 2017). Obese pregnant women are extremely vulnerable to pregnancy risks and complications placing them and their babies at higher risks for stillbirth, preterm delivery, maternal cardiac dysfunction, gestational diabetes, preeclampsia, infection, operative vaginal delivery, higher C-section rates, impaired fetal growth and fetal congenital anomalies (ACOG, 2016). The primary goal of helping obese pregnant patients maintain healthy GWG is not reversing obesity, but to control a preexisting problem from spiraling out of control and reducing risk factors that may adversely affect maternal and fetal outcomes.

Reach

The DNP project was well-received by all patients who were approached to participate as evidenced by the fact that 100% of women who met inclusion criteria and were offered enrollment consented to enroll in the project. Of the eight patients that enrolled in the project, only one did not complete the project. Unfortunately, the reason this patient was unable to complete the project was because she experienced an early first trimester pregnancy loss secondary to having an ectopic pregnancy that was identified between the period she initially presented for OB care and her next follow-up visit. It was interesting to note that among the eight participants, only three (37.5%) were recruited in the first trimester. Ideally first trimester enrollment for all participants would have allowed more time for the intervention to impact total weight gain. However, due to the time line for recruiting patients, providing training, and implementing the intervention within the context of this project the sample size of participants would have been far smaller. All seven project participants have agreed to continue tracking physical activity and monitoring nutrition until the end of their pregnancies so that more long-term data can be collected.

Effectiveness: Patient Satisfaction

All participants who completed the participant survey (6/7) at the end of the project viewed participation in the project favorably and reported that they were satisfied with the care that the CNM provided. Participant responses demonstrated that the provider allowed time for patients to voice concerns without being made to feel rushed. Participants appreciated that the CNM discussed weight gain and activity level, as this was the first time a provider had ever discussed this or helped formulate a plan to help them achieve healthy weight gain. The CNM also demonstrated the ability to offer helpful advice on making healthier choices in terms of

nutrition and physical activity. Five out of six respondents felt that the feedback they received during their prenatal visits was helpful in helping them achieve healthy weight gain. One respondent answered that the feedback was "mostly helpful" in that many ideas were shared to help achieve physical activity goals, remain physically active, and choosing healthier food choices. However, she stated that "discussing triggers for my unhealthy food choices (i.e. emotional or stress eating) might have been helpful as well." This statement raises an interesting question for future research: how can providers help patients identify and reduce triggers that lead to unhealthy habits related to diet and physical activity? Another interesting statement made by one participant was that she always feels "a bit nervous going into appointments" when she hasn't met her goals because she is worried about disappointing the CNM. Statements like this convey that the provider-patient relationship can have a significant impact on patient compliance and adherence to healthcare recommendations, particularly when a patient has a good rapport with their provider.

Effectiveness: Weight Gain

Among project participants, 28.6 % (2/7) demonstrated the ability to maintain healthy GWG as defined by IOM guidelines for recommended weight gain during pregnancy (IOM, 2009) as compared to 14.3% (1/7) of patients within the comparison group. Mean total weight gain among project participants (16.4 pounds) was 6.1 pounds less than mean total weight gain of patients in the comparison group (22.5 pounds). These data suggest that the intervention has the potential to be an effective intervention in helping obese pregnant women achieve healthy GWG. However, effectiveness of the project's intervention regarding weight gain will be best determined by assessing total weight gained at the end of each participants' and comparison patients' pregnancy.

Effectiveness: Physical Activity

All participants demonstrated a willingness to set daily step goals and made efforts to follow recommendations and feedback given during their prenatal visits. In review of cumulative data collected on physical activity, the physical activity levels varied among project participants. The mean number of daily steps taken by all participants was 5,031 steps with a range of 6,297 steps (SD +/- 1,991). The one participant who averaged the most daily steps was also one of the participants who did not exceed the IOM's weight gain recommendations for gestational age. Class of obesity also appeared to play a role in physical activity. Two out of seven participants met criteria for Class I obesity. The average daily steps taken by these participants was 6,255 steps (Range = 4,612; SD +/- 3,261). Both participants also gained the least amount of weight. Two out of seven participants met criteria for Class II obesity and average daily steps taken for these two participants was 4,676 steps (Range = 974; SD +/- 689). Three participants who met criteria for Class III obesity averaged 4,452 steps daily (Range = 2264-8561; SD +/- 2,053).

Effectiveness: Nutrition

All seven participants completed the QNS at every prenatal visit following enrollment and answered all questions within the survey at each visit. Based on participant responses, all participants demonstrated the ability to choose healthy food choices by selecting a variety of fruits, vegetables, dairy, and whole grain foods. The primary beverage for project participants was water (26.3% of total beverage intake). Towards the end of the project, participant responses demonstrated more variety in their food choices regarding fruit and vegetable intake. All patients demonstrated the ability to limit or avoid unhealthy food choices such as desserts and sweets by choosing healthier options for snacks. Upon completion of the project, 71.4% of participants viewed their diet as "good" as opposed to only 28.6% at time of enrollment.

Implementation (Setting)

The key element to implementation was feasibility of intervention delivery regarding timeliness. The problem that many obstetrical providers face is believing that there is not enough time to offer patients individualized counseling when they are allotted only 15 minutes to spend with a patient. How can providers find the time to do this and maintain productivity when crowded schedules have them seeing a different patient every 10-15 minutes? In piloting the CINDHE in her OB practice in New Bern, NC, the DNP candidate demonstrated that it is indeed possible, and the intervention was even perceived to save time and improve efficiency during prenatal visits.

Based on data collected on time spent with project participants during their prenatal visits, the CINDHE proved to be feasible in relation to timeliness. Providing patients with individualized feedback on physical activity and nutrition did not increase the amount of time that the CNM spent in the exam room with patients. The mean time spent with participants during all prenatal visits was 12.11 minutes (Range = 9.42-15; +/- SD 2.15). There were three visits out of 27 (11.1%) that extended beyond the 15-minute time-frame allotted. However, none of those three visits were directly related to providing the patient with individualized feedback on physical activity and nutrition. The CNM found that she felt that the intervention made her "more productive and efficient" in terms of whether the intervention had saved her time in the exam room.

Weekly voice memos recorded by the CNM offered insight into how consistent staff were in following protocol, challenges that were faced in the clinical setting that had the potential to affect the CNM's ability to deliver the intervention, and what modifications would be necessary to help implement the intervention within the project's practice site. Overall, staff carried out their assigned roles efficiently, particularly regarding providing participants with the

iPad at check-in allowing participants to complete the QNS, obtaining and recording data on weight, and handing over the iPad to the CNM's CMA in a timely manner. The biggest break in protocol occurred when the CNM's CMA was too busy to log into CHAI Core and Qualtrics to retrieve data for the CNM. Having to log into two different software programs to retrieve two sets of data was "cumbersome and time consuming". When the CNM had to take time to retrieve physical activity and nutrition data or troubleshoot computer software and tracker problems she perceived this as being a barrier to intervention delivery and that the delay had the potential to decrease her productivity and efficiency. Therefore, finding alternative ways to collect and retrieve data will be critical should the provider be solely responsible for data retrieval.

Maintenance (Individual)

All participants have agreed to continue tracking physical activity and providing input on nutrition at each remaining prenatal visit until they deliver. In review of Fitbit usage logs kept on each participant's prenatal chart, all patients used their Fitbits as instructed, kept them charged most of the time (97.3%), and synchronized data daily. The longest that any participant went without logging any steps was 3 days and reasons given all related to forgetting to charge the Fitbit tracker. All participant survey respondents reported some form of motivation to maintain healthy GWG. The top three motivating factors included: 1) concern for not being able to lose pregnancy weight; 2) less weight gained during pregnancy equates to less weight to lose postpartum; and 3) concern for fetal well-being.

Maintenance (Setting)

Maintenance of the project within the project's practice site ties directly into feasibility of intervention delivery and what changes need to be made to the project's protocol to improve feasibility. The computer software programs CHAI Core and Qualtrics will not be utilized

outside the context of this project and outside of Dr. Yeo's current research. Therefore, the practice site will have to use an alternative way to collect and retrieve patient data. Also, the practice site will not provide patients with Fitbit trackers, therefore, alternative ways to have patients collect data on physical activity will need to be explored. Therefore, providers within the practice site will need to creatively utilize different methods of technology that are at their disposal (i.e. physical activity trackers or pedometers, fitness and nutrition apps, dietary surveys, weight graphs). Creativity and technology can provide innovative ways to track patients' physical activity and dietary habits so that providers may provide clear, concise, simple feedback that will address each patient's individual needs.

Sustainability

It is highly probable that the intervention that was implemented within the context of this DNP project will be able to be sustained within the project's practice site. Sustainability will weigh heavily upon whether other providers within the practice site will adopt the intervention. Prior to project implementation, all OB providers acknowledged that they would be willing to implement the intervention within their own practice should it not adversely affect their productivity regarding extending length of time spent with patients.

Another aspect of sustainability that must be considered is patients' willingness to provide the necessary data that providers will need to provide them with individualized feedback. This will require that providers counsel patients starting at the initial OB visit on what maternal and fetal health benefits the intervention may provide and helping patients explore ways to provide this data by allowing patients to use devices and resources at their disposal. Thus, providers must and be willing to review data in various formats.

It is time providers relinquish some control and authority by sharing accountability and responsibility with patients about the lifestyle choices they make that impacts their health and their baby's health. Providers must allow patients to be active participants in their own care. It is impossible to provide individualized counseling when there is no data to review regarding what patients are eating, how much they are eating, and how physically active they are. Empowering patients with the ability to be active participants in their care and offering them with encouragement and guidance is imperative to reducing their risks and improving birth outcomes for both mom and baby. Therefore, it is time we talk with our patients instead of just talking to them.

Limitations

Limitations of this project include the sample being restricted to a predominantly Caucasian population of middle-class, college educated, population of women with ages that ranged from 22-38 years old. The small sample size limited the ability to examine statistical significance of CINDHE's effectiveness when compared to a historic matched comparison group. The short length of time available for project implementation limited the ability to track long term maternal and fetal outcomes and total GWG for participants throughout the entire pregnancy. Another limitation of this project is the risk of perceived bias regarding the CNM's perception of feasibility being she was also the DNP candidate implementing the project.

Use of the TTM as a framework for the DNP project has limitations as well. LaMorte (2016) acknowledge that the model ignores the social context in which change occurs, such as socioeconomic status and income, and the lines between the stages can be arbitrary. There are no set criteria of how to determine a person's stage of change and there is no clear sense for how much time is needed for each stage, or how long a person can remain in a stage. The TTM

assumes that people make clear and reasonable plans in their decision-making process when this is not always true. Regarding RE-AIM, since only one obstetrical provider implemented the intervention within the context of this project, little was learned about "Adoption".

Implications for Practice

Fortunately, all participants within the project will continue tracking physical activity and nutrition throughout the remainder of their pregnancies according to the same protocol as outlined in this project. The CNM will continue to provide individualized feedback on physical activity and nutrition as this pilot feasibility study is also included as "Aim 3" of Yeo, Samuel-Hodge, Leeman, and Crandell's (2017) ongoing research study, "Integrating Weight-Wise Program in Health Departments to Prevent Gestational Diabetes".

This project has brought awareness to the challenges health care providers face in motivating patients to make behavioral changes regarding physical activity and nutrition among obese pregnant women. Motivating patients to eat healthier seemed less challenging than motivating participants to increase daily physical activity. Therefore, providers must consider effective ways to motivate patients to increase physical activity during pregnancy. Motivational counseling tools such as the 5 A's (Ask, Advise, Assess, Assist, and Arrange), which was originally developed for smoking cessation counseling, have proven to be effective in counseling patients on both diet and physical activity (ACOG, 2015; Fieril et al., 2017). Also, OB providers must acknowledge that the primary determinant of adhering to physical activity guidelines during pregnancy is based on pre-pregnancy frequency of physical activity level (Santo, Forbes, Oken, and Belfort, 2017). Therefore, providing preconception counseling on increasing physical activity for overweight and obese women is likely to improve physical activity levels during pregnancy.

Conclusion

This feasibility study that piloted an EBP provider intervention among obese pregnant women receiving their prenatal care at ECWC in New Bern, NC proved the EBP intervention to be feasible to implement regarding timeliness and the implementing provider's perception. In terms of effectiveness, CINDHE proved to be an effective intervention for helping private and Tricare insured obese, predominantly White (Non-Hispanic) pregnant women maintain healthy GWG during pregnancy when prenatal care is primarily provided by their PCP. The intervention helped motivate participants to eat healthier; however, providing feedback on physical activity had less effect in helping participants meet daily physical activity goals. Project participants reported that they were satisfied with their prenatal care and provided useful feedback on what their challenges and barriers were in terms of nutrition and physical activity. Ongoing intervention delivery by the CNM and data collection among project participants and patients selected for the comparison group throughout the remainder of pregnancy will provide a better representation of effectiveness of the intervention in terms of total weight gain, physical activity, and nutrition. Future research involving a larger sample size is needed to determine if the effectiveness of the EBP intervention on TWG, physical activity level, and nutrition is statistically significant when compared with a control group of equal size.

APPENDIX A: EXERCISE READINESS ASSESSMENT

EXERCISE READINESS ASSESSMENT

SEREAS is a guideline for health screening prior to participation in **WWP intervention**, which consists of a 30-minute of prescribed stretching exercise 5 days a week.

Healthy women with uncomplicated pregnancies can integrate physical activity into their daily living and can participate without significant risks either to themselves or to their unborn child, according to American College of Obstetricians and Gynecologists (ACOG). ACOG recommends prenatal care providers to develop "An exercise program that leads to an eventual goal of **moderate-intensity** exercise for at least 20-30 minutes per day on most or all days of the week with the patient and adjusted as medically indicated." (Committee Opinion on Physical Activity and Exercise During Pregnancy and the Postpartum Period, No. 650, December 2015).

While the prenatal care providers counsel patients to this end, your patient has signed up for a study that encourages her to engage in a 30-minutes of stretching exercise five days a week. The stretching exercise consists of large muscle group stretching guided by a study video. Stretching exercise is considered as light exercise, not endurance training or aerobic exercise. This intervention is not a replacement of ACOG guidelines but supplement to the guidelines. When your patient feels too tired to engage in moderate intensity exercise, she is encouraged to engage in stretching exercise. When she is able to engage in moderate intensity exercise, your patient is encouraged to add stretching exercise. The study is to examine whether stretching exercise can produce protective effect against developing late onset preeclampsia.

The safety of prenatal stretching exercise depends on an adequate level of maternal-fetal physiological reserve. SEREAS is a checklist for use by prenatal care providers to evaluate pregnant patients who plan to enter in SLOPE intervention program and for ongoing surveillance of stretching pregnant patients.

Instructions for use of the SEREAS are following:

1. The patient should fill out the section on PATIENT INFORMATION and the SEREAS HEALTH CHECKLIST (PART 1, 2) and give the form to the health care provider monitoring her pregnancy.

2. The health care provider should check the information provided by the patient for accuracy and fill out SECTION on CONTRAINDICATIONS based on current medical information.

3. If no exercise contraindications exist, the HEALTH EVALUATION FORM (p.3) should be completed, signed by the health care provider, and given by the patient to the study coordinator.

The study will not provide physical activity recommendations other than stretching exercise to your patient.

PATIENT INFORMATION and PRE-EXERCISE CHECKLIST should be completed by the patient before the appointment with the health care provider.

PATIENT INFORMATION

NAME _____

ADDRESS _____

EMAIL _____ PHONE _____

BIRTHDATE _____/ _____/ _____

PRE-EXERCISE HEALTH CHECKLIST

PART 1: GENERAL HEALTH STATUS

In the past, have you experienced:

1. Miscarriage in an earlier pregnancy? Y / N
2. Other pregnancy complications? Y / N
3. I have completed SEREAS within the last 30 days Y / N

If you answered YES to question 1 or 2, please explain:

____

____

Number of previous pregnancies: ________________

PART 2: STATUS OF CURRENT PREGNANCY

Due Date: ______/_____/______

During this pregnancy, have you experienced:

1. Marked fatigue? Y / N
2. Bleeding from the vagina (spotting)? Y / N
3. Unexplained faintness or dizziness? Y / N
4. Unexplained abdominal pain? Y / N
5. Sudden swelling of ankles, hands or face? Y / N
6. Persistent headaches or problems with headaches? Y / N
7. Swelling, pain or redness in the calf of one leg? Y / N
8. Absence of fetal movement after 6th month? Y / N
9. Failure to gain weight after 5th month? Y / N

CONTRAINDICATIONS TO EXERCISE

To be completed by your health care provider

ABSOLUTE CONTRAINDICATIONS

Does the patient have:

1. Ruptured membranes, premature labor? Y / N
2. Persistent second or third trimester bleeding/ placenta previa? Y / N
3. Pregnancy-induced hypertension or preeclampsia? Y / N
4. Incompetent cervix? Y / N
5. Evidence of intrauterine growth restriction? Y / N
6. High-order pregnancy (e.g., twins, triplets)? Y / N
7. Uncontrolled Type I diabetes, hypertension or thyroid disease, other serious cardiovascular, respiratory or systemic disorder? Y / N

RELATIVE CONTRAINDICATIONS

Does the patient have:

1. History of spontaneous abortion or premature labor in previous pregnancies? Y / N
2. Mild/moderate cardiovascular or respiratory disease (e.g., chronic hypertension, asthma)? Y / N
3. Anemia or iron deficiency? Y / N
4. Malnutrition or eating disorder (anorexia, bulimia)? Y / N
5. Other significant medical condition? Please specify

____

STRETCHING RECOMMENDATION

☐ Recommended ☐ Contraindicated ☐ Don't know

- ✂ -

SEREAS- HEALTH EVALUATION FORM

(To be completed and given to the study coordinator after obtaining medical clearance to stretching exercise)

I, _______________________ (please print patient's name), have discussed my plans to participate in the SLOPE intervention during my current pregnancy with my health care provider and I have obtained his/her approval to begin participation.

PATIENT SIGNATURE

_____ DATE _____

NAME OF HEALTH CARE PROVIDER

_____

PHONE _____

HEALTH CARE PROVIDER SIGNATURE

_____

HEALTH CARE PROVIDER COMMENTS:

_____

_____

This form was adapted from PARmed-X for Pregnancy developed by Canadian Society for Exercise Pregnancy (2015).

APPENDIX B: WELCOME LETTER

Eastern Carolina Women's Center has two locations:
801 McCarthy Boulevard, New Bern, NC 28562
200 Stonebridge Square, Havelock, NC 28532
Call Us Today! (252) 633-3942

Dear Expecting Mom,

We are always trying to improve patient care here at Eastern Carolina Women's Center. My care team recently helped me go over all my patient charts to find patients who might need extra help in making lifestyle changes related to healthy eating and exercise during pregnancy. We think you might be one of those patients.

I am happy to say that I now have found a tool that I feel will let me help patients reach their own health and wellness goals. The tool that I plan on using to help patients reach their own health and wellness goals is currently being implemented in a research study being conducted through the school of nursing at the University of North Carolina Chapel Hill entitled "Integrating Weight-Wise Program in Health Departments to Prevent Gestational Diabetes". This tool is simply giving patients individualized advice about physical activity and diet at each prenatal visit based on information I gather from participating patients. Information about physical activity will be obtained from steps recorded on a Fitbit that participating patients will be given to wear. Information about diet will be collected from answers to questions patients will be asked at each visit. I will then use this information and weight taken at each visit to provide patients feedback that will help them maintain healthy weight gain during pregnancy.

Participation is voluntary and is not required as part of your routine prenatal care. You will not be expected to have more visits and time commitment outside of the office setting will require you to wear the provided Fitbit daily and synch the Fitbit daily with the free Fitbit app that you will be asked to download on your smart phone. If you decide to participate, you will be provided with hands on training and assistance with using the Fitbit, how to create a Fitbit account, how to download and use the free Fitbit app, and how to complete the diet questionnaire. This training will take place during one of your prenatal visits and most likely will extend your visit by an additional 20 minutes.

I love seeing my patients in the office; talking to patients is one of the reasons I chose to be a Certified Nurse Midwife. Unfortunately, our visits never seem long enough to discuss all the right plans for a healthy lifestyle and how to best make those changes. Therefore, your participation will allow me to determine if providing you with individualized feedback is possible to do at each visit, regarding the time we will be allotted to spend together at each visit. I will be providing you more information about the research study during your first visit and I will be happy to talk about any concerns or answer any questions you might have during your first visit. Any questions or concerns that you may have after that first visit with me can be directed by the research staff within the office.

I am here to help you reach your best health during your pregnancy and I look forward to seeing you soon.

In Good Health,

Mandy Marshburn, CNM, MSN

APPENDIX C: CONSENT FORM

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants: Pregnant Participants for Pilot Study

Consent Form Version Date: June 1, 2017
IRB Study # 14-3211
Title of Study: Integrating Weight-Wise Program in Health Departments to Prevent Gestational Diabetes
Principal Investigator: SeonAe Yeo
Principal Investigator Department: School of Nursing
Principal Investigator Phone number: (919) 843-1245
Principal Investigator Email Address: syeo@email.unc.edu
Co-Investigators: Carmen Samuel-Hodge, Jennifer Leeman, Jamie Crandell

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What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.
You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to understand better how pregnant women can safely increase physical activities and healthy eating, and manage stress and worries to achieve healthy weight gain during pregnancy in order to avoid diseases such as gestational diabetes.

You are being asked to be in the study because you are eligible.

Are there any reasons you should not be in this study?

You should not be in this study if your doctor, nurse, or midwife, who provides you prenatal care, objects your participation. You should not be in this study if you will move out of this area before the baby is due.

How many people will take part in this study?
A total of approximately 20 pregnant women at one Health Department and one clinic will take part in this study.

How long will your part in this study last?
You will be in the study while you are pregnant up to 34 weeks gestation. You will meet with a clinician throughout the duration of your prenatal care. This will entail 8-10 prenatal care visits, but this may also vary according to your needs. Each prenatal care visit will entail 15-minute face-to-face sessions. At each visit you will be asked to complete a survey on your eating habits.

Aside from these interactions we also ask that you sync your fit bit data on a weekly basis.

What will happen if you take part in the study?
You will be asked to spend 15 minutes for each visit. During this visit, you will:

- Take a survey on your eating habits.
- Weigh in and check the height.
- Receive feedback and instruction from the clinician on your eating and physical activity.

You will be required to create a fitbit account and to sync this device daily for the duration of this study to give researchers access to your physical activity habits throughout the week.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be motivating you to achieve your goals in active lifestyle and healthy eating.

What are the possible risks or discomforts involved from being in this study?
The risks associated with participation in the behavioral lifestyle intervention are minimal. Pregnant women will remain under the medical supervision of the healthcare providers and any contraindications to the physical activity recommendations of the intervention will be screened for during enrollment. Permission from a health care provider will be required for pregnant women who may be at risk for complications related to physical activity.

A remote possibility exists that a regular exercise program for 30 minutes a day may cause unfavorable outcomes of pregnancy. Potential risks associated with the exercise program during pregnancy may include cardiovascular-related problems such as abnormal blood pressure, fainting, irregular, fast or slow heart rhythm, and, in rare instances, heart attack, stroke, or death, and pregnancy-related problems such as musculoskeletal injuries, premature labor, hypoglycemia, or intrauterine growth retardation. However, to date no report substantiates these potential risks when pregnant women perform low to moderate intensity exercise. In addition, the risks that women may encounter during supervised exercise sessions will be no more than the risks when they perform exercise at home alone.

It is theoretically possible that diet changes and self-monitoring of physical activities and weight may cause stress and anxiety during pregnancy. Again, however, to date no report substantiates these potential risks.

Contraindications and warning signs against engaging in physical activity are specified by the American Congress of Obstetricians and Gynecologists (2002). The American College of Obstetricians and Gynecologists (ACOG) specifies the following symptoms as "warning signs" to stop exercise or not to start exercise: vaginal bleeding, dizziness or feeling faint, increased shortness of breath, chest pain, headache, muscle weakness, calf pain or swelling, uterine contraction, decreased fetal movement, or fluid leaking from the vagina. When these symptoms are observed during exercise sessions, the instructor will assist the participant to slowly stop the exercise, and encourage the participant to contact her care provider immediately. If the instructor judges that the participant cannot initiate communication with the care provider because of medical conditions such as unconsciousness or too much pain, the instructor will contact the provider or the emergency room listed on the emergency contact list for evening or weekend classes. According to a default procedure, a staff member on site will call 911/ambulance, will stay with the woman until emergency medical personnel arrives. This procedure may be modified to better fit to each HD.

If participants experience these symptoms at home alone, they will be instructed to contact their care provider. On rare occasions when medical urgency and complexity indicate a clear need for the HD staff to communicate with care providers directly, the staff member(s) will communicate with care providers in the HDs or designated referrals. The written consent to the study states this possibility. However, participants will be informed that the study will not provide medical care or advice.

What are the risks to a pregnancy or to a nursing child?

Regular physical activity and healthy eating are believed to promote heath for pregnant mother and the fetuses.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

The potential risks to participants are no more than minimal. There will be some risk associated with breach of confidentiality but the likelihood is 'rare'. All survey administration will be conducted either by phone or online. For phone surveys, administration will take place in a private place where conversations cannot be overheard; no names will appear on survey forms. Online survey administration is protected by security safeguards present in the University-supported software and IT data security systems. Fitbits will bear no personal identification.

Only investigators listed on this consent form and a limited number of UNC students/fellows will have access to individually identifiable data. Only ID numbers will be used except when UNC research assistants communicate with you. The linkage file that assigns numbers to name will be kept in a locked file of the principal investigator.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?

Upon completion of this study, you may receive a $50 gift card and a fitbit.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent

APPENDIX D: FITBIT EQUIPMENT AGREEMENT

UNC-CH Research Study

Fitbit Equipment Agreement

To participate in this research study, you must agree to the following policy:

I understand that the fitbit flex used for this research study belongs to the University of North Carolina – Chapel Hill. If at any point I decide to withdraw from this research study, I agree to return the fitbit flex to my clinician immediately. I understand that failure to return the fitbit flex upon my withdrawal will be considered theft. I am personally responsible if it is lost, stolen, or damaged.

I also recognize that upon successful completion of this research study, the ownership of this fitbit flex will be transferred from the university to me as part of my compensation.

My fitbit number:

_____ _____

Participant Signature Date

_____

Participant Printed Name

_____ _____

Witness Signature Date

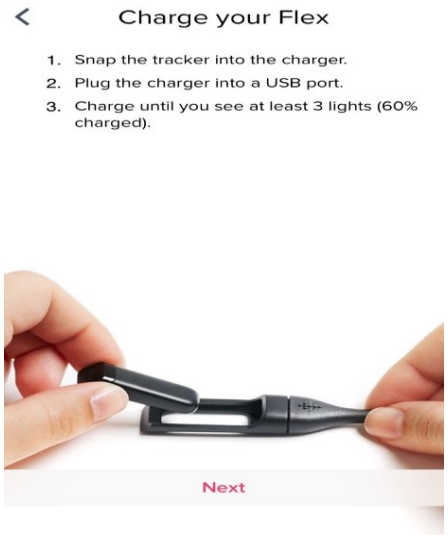
_____

Witness Printed Name

APPENDIX E: FITBIT SET-UP AND USER GUIDE

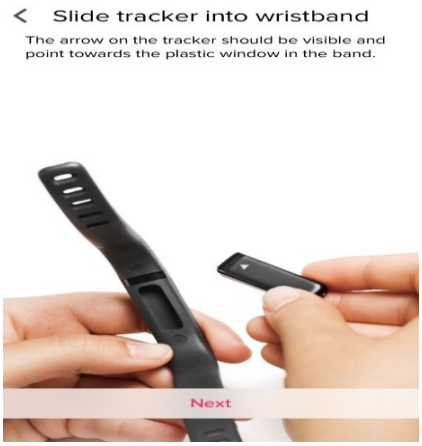
The patient will create a Fitbit account at the clinic. This will be done to ensure that she will be able to sync her device and to collect physical activity data through CHAI CORE servers.

1. Must download Fitbit app first
2. After opening app, the screen will prompt you to two options: join Fitbit or log in
3. Click “Join Fitbit”
4. Fitbit will now ask which tracker you are setting up. Select “Flex” and then “Set Up Your Fitbit Flex”
5. The following screens will ask for your height, gender, weight, and birthday.
6. To create an account, you will need to enter in your first name, last name, email, and a password.
7. Must agree to the Fitbit Terms of Service and Privacy Policy.
8. You will need to allow Fitbit to access the Bluetooth function on your phone in your phone settings.
9. Carefully remove the tracker from the wristband.
10. Follow screen instructions to charge the flex tracker:
    a. Snap the tracker into the charger
    b. Plug the charger into a USB port
    c. Charge until you see at least 3 lights (60% charged)

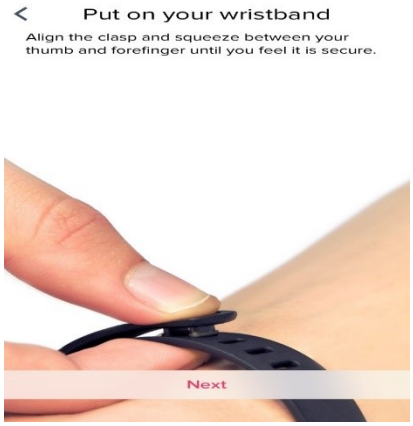


11. Select the wristband that fits you best. If using the small wristband, use the clasp from the large wristband.

12. Slide tracker into wristband. The arrow on the tracker should be visible and point towards the plastic window in the band.



13. Put on your wristband. Align the clasp and squeeze between your thumb and forefinger until you feel it is secure.



14. Care and Wearing Tips:
    Clean and dry the flex regularly – particularly under the band.
    Wear your flex band loosely enough to allow air circulation.
    Use skin care product sparingly on the areas of the wrist covered by the flex.
    If you notice any signs of skin irritation or experience any discomfort, please discontinue use.

15. Lastly, you will need to verify your email address with the link that Fitbit will send you. Click “Verify Your Email.” This will finish setting up your Fitbit account.

16. You will need to sync the Fitbit to the app now. Keep the app and the device close to each other and ensure that Bluetooth is on. This process may take up to 10 minutes.

17. Need to deliver instructions to the subject on how to sync the fitbit and phone. Should sync at least once a day.

APPENDIX F: INSTRUCTIONS FOR CREATING VALIDIC ACCOUNT AND FOLLOW-UP VISIT PROTOCOL FOR PARTICIPANTS

Initial Visit- Creating Validic Account

1. Go to https://chai-nudge-prod.bioinf.unc.edu/bootstrap/docs/site/gest.html
2. Type in de-identified ID, their initial weight, and select whether they are overweight or obese.
   Click "Create New User" and then click "Show Users"
3. Once new user appears in the list of users, select "Validic Login"
4. This will open a new page from Validic. Browse the apps until you see "Fitbit" and then click "Connect +"
5. Now the user will be prompted to log into fitbit with their fitbit username and password
6. Agree to terms of use with UNC
7. Once the account has been linked, go back to the gestational website. Hit "Sync Data."

Follow-up Visits

1. Check In
2. Set up anonymous survey link – this should be prepared in advance, so that participant may take the survey while waiting in the waiting room
   a. Participant must enter in their name for each survey. They must enter in the same name for each survey entry to track longitudinal progress.
3. Pregnant woman will go with workup nurse to measure vital signs, height, and weight
4. Pregnant woman will go with the lab technician to collect samples
5. Lab technician will take measurements chart to the provider nurse or intern.
   The provider nurse or intern will enter in the weight and open Qualtrics for the clinician to review data.

APPENDIX G: PROTOCOL FOR VIEWING PHYSICAL ACTIVITY DATA AND QNS RESULTS

Fitbit Data Retrieval:

a. Enter password
b. Select username
c. Enter weight for patient in lbs.
d. Click on "sync data." Graphs should now appear to show patient their health information.

QNS Data Retrieval:

a. Log-in to Qualtrics
b. Go to "WWP Pilot Study" Project
c. To view participant responses, you will need to go to the top menu and click on "Data & Analysis"
d. To only view the individual participants' responses over time, you will need to "Add Filter" by "Q1. Name" and type in the participants name when the text box prompts you to do so.
e. Now you should be able to see only the participants' responses. Select a date to see the participant's responses for that day.

APPENDIX H: PARTICIPANT SURVEY

1. How has participation in the healthy pregnancy weight gain project affected your ability to eat healthy and be physically active during your pregnancy?

2. Do you feel that the feedback you have received during your prenatal visits have been helpful in helping you achieve healthy weight gain? Why or why not?

3. What do you consider to be most challenging in helping you maintain healthy weight gain during your pregnancy?

4. What has motivated you the most in trying to maintain healthy weight gain during your pregnancy?

5. Overall, how have the interactions you have had with your provider during routine visits impacted your level of satisfaction with your prenatal care?

REFERENCES

Academy of Nutrition and Dietetics. (2016). Position of the Academy of Nutrition and Dietetics: Obesity, reproduction, and pregnancy outcomes. *Journal of the Academy of Nutrition and Dietetics, 116*(4), 677-691. Retrieved from http://doi.org/10.1016/j.jand.2016.01.008

American Academy of Pediatrics and American College of Obstetrics and Gynecology. (2012). *Guidelines for Perinatal Care.* (7th ed). Retrieved from http://www.acog.org/Resources-And-Publications/Guidelines-for-Perinatal-Care

American College of Obstetrics and Gynecology. (2016a). Improving access to quality health care for women. Retrieved from http://www.acog.org/Resources-And-Publications/Special-Issues-in-Womens-Health/Improving-Access-to-Quality-Health-Care-for-Women

American College of Obstetrics and Gynecology. (2016b). Obesity in pregnancy [Practice Bulletin]. Retrieved from http://www.acog.org/Resources-And-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Obstetrics/Obesity-in-Pregnancy

American College of Obstetrics and Gynecology Committee Opinion No. 650. (2015). Physical activity and exercise during pregnancy and the postpartum period. American College of Obstetrics and Gynecology. Washington, DC.

Butts, J. B. & Rich, K. (2105). *Philosophies and theories for advanced nursing practice.* (2nd ed) Sudbury, Mass.: Jones and Bartlett Publishers.

Carter, E. B., Barbier, K., Sarabia, R., Macones, G. A., Cahill, A. G., &Tuuli, M. G. (2017). Group versus traditional prenatal care in low-risk women delivering at term: A retrospective cohort study. *Journal of Perinatology*, *37*, 769–771. doi:10.1038/jp.2017.33

Communications for Health Applications & Interventions Core. (2014). Delivering innovative solutions for intervention research. Retrieved from http://www.chaicore.com/home

Fieril, D. P., Olsen, P. F., Glantz, D., & Premberg, D. A. (2017). Experiences of a lifestyle intervention in obese pregnant women - A qualitative study. *Midwifery, 44*, 1-6. doi:S0266-6138(16)30192-9

Institute of Medicine. (2009). Weight gain during pregnancy: Reexamining the guidelines. National Academies Press*: Washington, DC*

Kominiarek, M. A. & Peaceman, A. M. (2017, May). Gestational weight gain. *American Journal of Obstetrics and Gynecology.* doi:10.1016/j.ajog.2017.05.040

LaMorte, W. W. (2016). Behavioral change models: The Transtheoretical Model (Stages of Change). Boston University School of Public Health. Retrieved from http://sphweb.bumc.bu.edu/otlt/MPH-Modules/SB/BehavioralChangeTheories/BehavioralChangeTheories6.html

Merkx, A., Ausems, M., de Vries, R., & Nieuwenhuijze, M. J. (2017). Come on! Using intervention mapping to help healthy pregnant women achieve healthy weight gain. *Public Health Nutrition*. doi:10.1017/S1368980017000271

Poston, L., Bell, R., Croker, H., Flynn, A. C., Godfrey, K. M., Goff, L., . . . UPBEAT Trial Consortium. (2015). Effect of a behavioural intervention in obese pregnant women (the UPBEAT study): A multicentre, randomised controlled trial. *The Lancet.Diabetes & Endocrinology, 3*(10), 767-777. doi:10.1016/S2213-8587(15)00227-2

Qualtrics LLC. (2017). Qualtrics Research Core. Retrieved from https://www.qualtrics.com/research-core/

RE-AIM. (2017). About RE-AIM. Retrieved from http://re-aim.org/about/

Santos, E. C., Forbes, P. W., Oken, E., & Belfort, M. B. (2017). Determinants of physical activity frequency and provider advice during pregnancy. *BMC Pregnancy and Childbirth*, *17*, 286. Retrieved from http://doi.org.libproxy.lib.unc.edu/10.1186/s12884-017-1460-z

United States Census Bureau. (2016). QuickFacts. Retrieved from https://www.census.gov/quickfacts/fact/table/jonescountynorthcarolina,pamlicocountynorthcarolina,cravencountynorthcarolina/PST045216

United States Department of Health and Human Services. (2008). *2008 Physical Activity Guidelines for Americans*. Retrieved from https://health.gov/paguidelines/

Validic. (n.d.). How it works. Retrieved from https://validic.com/how-it-works/

Washington Cole, K. O., Gudzune, K. A., Bleich, S. N., Bennett, W. L., Cheskin, L. J., Henderson, J. L.,…Roter, D. L. (2017). Influence of the 5A's counseling strategy on weight gain during pregnancy: An observational study. *Journal of Women's Health, 26*(10), 1123-1130. doi:10.1089/jwh.2016.6115

World Health Organization. (2000). Obesity: Preventing and managing the global epidemic. Report of a WHO consultation. Geneva. Retrieved from http://www.who.int/nutrition/publications/obesity/WHO_TRS_894/en

World Health Organization. (2013). *Counselling for maternal and newborn health care: A handbook for building skills*. (NLM classification: WA 310). Retrieved from World Health Organization website: http://www.who.int/maternal_child_adolescent/documents/9789241547628/en/

Yeo, S., Samuel-Hodge, C., & Leeman, J. (2017). Integrating the weight-wise program in health departments to prevent gestational diabetes. Manuscript in preparation.

Yeo, S, Walker, J. S., Caughey, M. C., Ferraro, A. M., & Asafu-Adjei, J. K. (2017). What characteristics of nutrition and physical activity interventions are key to effectively reducing weight gain in obese or overweight pregnant women? A systematic review and meta-analysis. *Obesity Reviews, 18*(4), 385-399. doi: 10.1111/obr.12511