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The Behavioral Wellness in Pregnancy Study: a theory-based multi-component intervention to promote appropriate weight gain and healthy lifestyle behaviors in previously sedentary pregnant women

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The Behavioral Wellness in Pregnancy Study: A theory-based multi-component intervention to promote appropriate weight gain and healthy lifestyle behaviors in previously sedentary pregnant women

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The student author, whose presentation of the scholarship herein was approved by the program of study committee, is solely responsible for the content of this dissertation. The Graduate College will ensure this dissertation is globally accessible and will not permit alterations after a degree is conferred.

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LIST OF SYMBOLS OR ABBREVIATIONS

ACOG: American College of Obstetricians and Gynecologists

BMI: Body Mass Index

CDC: Centers for Disease Control and Prevention

EGWG: Excessive Gestational Weight Gain

GDM: Gestational Diabetes Mellitus

GWG: Gestational Weight Gain

HEI: Healthy Eating Index

IOM: Institute of Medicine

MI: Motivational Interviewing

MVPA: Moderate-Vigorous Physical Activity

NHANES: National Health and Examination Survey

OR: Odds Ratio

PA: Physical Activity

PRAMS: Pregnancy Risk Assessment Monitoring System

PPWR: Postpartum weight retention

RCT: Randomized-controlled trial

RDN: Registered Dietitian Nutritionist

SDT: Self-Determination Theory

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ABSTRACT

Obesity is the second largest modifiable cause of preventable death in the United States. Pregnancy is an ideal time to prevent the development of obesity as it offers the opportunity to influence the health of both the current and future generations. The Be-Well, Behavioral Wellness in Pregnancy, intervention is a randomized-controlled, multi-component self-determination theory (SDT)-based intervention designed to help pregnant women meet the current pregnancy weight gain guidelines through diet and physical activity (PA) modification.

Fifty-six women were randomized to either usual care (UC) or intervention; 48 (n = 23 intervention; n = 25 UC) completed the study. The intervention group met one-on-one with a Registered Dietitian Nutritionist monthly, beginning at weeks 8-14 gestation. Sessions discussed PA, diet, and the 2009 IOM pregnancy weight gain guidelines. Motivational interviewing (MI) was used to target the constructs of SDT and facilitate behavior change. The intervention group used a wrist-worn activity tracker to monitor daily step goals and followed an individualized meal plan designed to improve diet quality and modify carbohydrate intake.

The intervention group was significantly more likely to gain within the 2009 IOM guidelines (p = 0.019). Additionally, 36.4% were at or below pre-pregnancy weight at two months postpartum compared to 12.5% of UC (p = 0.05). The intervention group increased PA in mid-pregnancy (average step/day, p = 0.0002; moderate-vigorous PA in bouts of ≥30 minutes, p = 0.008) and improved diet quality (Healthy Eating Index-2010, p<0.01). Moreover, the intervention group had higher scores for perceived competence

for diet in late pregnancy (p = 0.0185) and perceived competence for PA in mid- and late-pregnancy (p = 0.0033 and p = 0.0019) compared to UC. Intervention group self-efficacy for diet increased from baseline to late-pregnancy (p = 0.0145) and was higher at two months post partum (p = 0.0041). Self-efficacy for exercise also increased in the intervention group from baseline to mid-pregnancy (p = 0.0362).

These findings support that GWG interventions can be effective at preventing EGWG and lays the foundation for future intervention research. Future work should identify how to conduct an intensive, comprehensive behavior change intervention in the clinical setting.

CHAPTER 1: GENERAL INTRODUCTION

Introduction

In society today, there are growing concerns about population health in both the short- and long-term. The burden of chronic disease impacts health care service, infrastructure, and economic cost. Our current model demonstrates a cycle of care for the treatment of chronic disease that, in many cases is preventable and a high cost to our nation. Obesity, a preventable condition, is considered a crisis in the United States today.[1] According to recent reports, more than two thirds of adults are considered overweight or obese.[2] It has been estimated that obesity accounts for almost 10 percent of the national health care budget and this estimate does not include the indirect costs associated with obesity such as cost of care for chronic disease associated with comorbidities of obesity such as diabetes, heart disease, and cancer.[3]

One possible strategy to shift the current dogma of treatment over prevention of obesity is the modification of obesity-causing behaviors during pregnancy. It is during this unique time in a woman's life that the health of one individual can influence the health of future generations. For many women pregnancy is a powerful motivator for positive behavior change. Pregnancy has commonly been referred to as a "teachable moment" in which women are more aware of personal risk, outcome expectations, and have a strong emotional response towards adopting risk-reducing behaviors.[4, 5] The combination of these characteristics, in addition to increased self-awareness, creates an ideal environment to facilitate behavior change.

Not only is pregnancy an important time to target behavior change, it is also an important time to target and prevent obesity. Data from the 2005-2014 National Health and Nutrition Examination Survey (NHANES) found that 37% of women between 20-39 years old are classified as obese.[6] This is of particular importance considering women who are categorized as overweight or obese are at an increased risk of gaining an excessive amount of weight during pregnancy as defined by the 2009 IOM weight gain guidelines.[7, 8] Gestational weight gain (GWG) is a concern to maternal and fetal health both during pregnancy and postpartum. The effects of excessive GWG (EGWG) in pregnancy are linked to cesarean delivery[9], large-for-gestational age infants (weight above the 90th percentile for gestational age)[10], macrosomia (>4000 grams weight at birth)[11], and childhood obesity[12, 13]. Furthermore, EGWG is strongly associated with maternal weight retention, a significant concern for women with an overweight or obese BMI. Women considered overweight or obese are already at increased risk for EGWG and in turn, increased retention of weight postpartum.[14, 15] A recent impact study provided powerful evidence to suggest the elimination of EGWG would result in a 10.7% and 9.3% reduction in midlife obesity for first and second time pregnant women, respectively.[16]

An increasing amount of research has explored how to effectively reduce the risk of EGWG and as a result, the risk of long-term health consequences to both mother and child. The Blossom Project is a research group that has collected observational data on pregnant women with the goal to better understand behaviors during pregnancy.

Results from the initial observational studies demonstrated that approximately 48% of pregnant women in central Iowa are exceeding the 2009 Institute of Medicine (IOM) weight gain guidelines, a percentage similar to the national trends.[8, 17] Furthermore, the same women were not meeting the current physical activity (PA) recommendations for pregnant women and spending a large portion of the day in sedentary activity.[18] The same observational data showed that the most significant predictors of GWG included carbohydrate intake in late-pregnancy and total metabolic equivalent of task (MET) minutes per day.

Findings from our observational work, in addition to the wealth of observational pregnancy literature, helped to inform the design of interventions to promote adequate weight gain during pregnancy. The Blossom Projects first randomized controlled trial (RCT), 'Moms to Move', aimed to promote adherence to the current PA guidelines by providing women with an overweight or obese BMI an at-home treadmill to use throughout pregnancy. The intervention was effective at increasing walking among intervention participants compared to the control however; there was no significant difference in GWG, postpartum weight retention, or infant body composition. The second RCT, 'The Blossom Project Online', used a behaviorally-based website specifically designed to increase exercise in previously sedentary pregnant women and in turn, prevent excessive gestational weight gain (EGWG). Similar to the first RCT 'Moms to Move', the intervention was successful at increasing intentional exercise but did not have an effect on prevention of EGWG. Post study analysis was conducted to determine a possible explanation for the lack of efficacy at preventing EGWG. Results showed that

although women in the intervention group increased physical activity, women compensated by eating significantly more total calories and spending more time sedentary. [19]

Both Blossom Project RCTs resulted in positive behavior change during pregnancy but did not answer the commonly asked GWG intervention question: how can we significantly reduce the proportion of women meeting the 2009 IOM weight gain guidelines? This question led to the development of the current RCT "The Behavioral-Wellness in Pregnancy" (Be-Well) study, designed using the successful pieces of the previous RCTs but modified to include effective components of behavior-change interventions in pregnant and non-pregnant populations.

A 2015 Cochrane systematic review concluded that the most effective RCTs at preventing EGWG included both diet and exercise behavior modification.[20] In addition to diet and exercise modification, weight interventions, in both pregnant and non-pregnant populations, are more successful at improving outcomes if a behavior theory and behavior change techniques are used to inform intervention design.[21, 22] Furthermore, the current recommendations for obesity prevention and treatment include the use of an individualized and intensive intervention.[23, 24]

The Blossom Project Be-Well study was developed in response to past evidence, both within and outside of the Blossom Project RCTs, and incorporated evidence-based practices to create an intervention that we hypothesized would increase the proportion of women meeting weight gain recommendations. Results from this study can be found in the third (efficacy of the intervention to promote adherence to weight gain

recommendations), the fourth (effect of the intervention to support healthy behavior change in previously sedentary pregnant women), and fifth chapters (impact of a theory-based RCT to modify psychosocial variables related to healthy behavior change during pregnancy) of this dissertation.

Dissertation Organization

This dissertation consists of six chapters including a general introduction, a review of current literature, three manuscripts and an overall conclusion. Chapter three is "The Behavioral Wellness in Pregnancy Study: a randomized trial of a multi-component behavioral intervention to prevent excessive gestational weight gain", a manuscript that will be submitted for publication to the *American Journal of Clinical Nutrition* (AJCN). The second manuscript, "Impact of a behaviorally-based randomized controlled trial on maternal healthy lifestyle throughout pregnancy," is found in chapter four and will be submitted for publication to *Medicine and Science in Sports and Exercise (MSSE).* The fifth chapter, "Efficacy of a theory-based intervention to modify psychosocial variables related to healthy behavior change during pregnancy," will be submitted to the journal of *International Society of Behavioral Nutrition and Physical Activity* (ISBNPA). The appendices of this dissertation include the recruitment documents, questionnaires used throughout the current study, and material developed for the intervention. The Institutional Review Board at Iowa State University approved all study documents.

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CHAPTER 2: LITERATURE REVIEW

Maternal Obesity

Overview of prevalence. Over the past two decades the prevalence of maternal obesity and excessive weight gain during pregnancy has dramatically increased, similar to the increasing prevalence of obesity.[1, 2] According to an Institute of Medicine (IOM) report in 2009, less than one-third of pregnant women gain within IOM guidelines for weight gain during pregnancy with 60-70% of overweight and obese women gaining in excess of the recommendations.[3] A recent National Health and Nutrition Examination Survey (NHANES) reported that more than half of women of childbearing age are classified as overweight or obese, putting them at higher risk for gaining excessive weight if and when they get pregnant.[4, 5] This is of specific concern considering that from 2005-2006 to 2013-2014 there was an increase in class 3 obesity for women between the ages of 20 to 39 years old.[4] Furthermore, if women who gain excessively during pregnancy do not successfully return to their pre-pregnancy body mass index (BMI) before their next pregnancy, they are at increased risk for excessive weight gain and in turn, deleterious effects for their offspring.[6-8]

The theory that nutrient and physiological factors alter fetal development was first proposed in 1967 by Barker et al., as the Developmental Origins of Health and Disease (DOHaD) theory. The theory hypothesized that an adverse intrauterine environment could affect disease initiation and progression in later life.[9, 10]

There is now research that suggests weight gain and pre-pregnancy BMI of expectant mothers influences the weight of their offspring, both in early infancy and later adolescence, prompting a vicious cycle of obesity (Figure 1). [11-14] Infants born to obese mothers are at increased risk for fetal macrosomia (birth weight of more than 4,000 grams) and early- or late-onset obesity in childhood.[11] Previous work examining overweight children demonstrates that BMI percentile and the severity of obesity are significant predictors of adult obesity in addition to elevated risk of cardiovascular disease, type 2 Diabetes Mellitus, and all-cause mortality both in childhood and in adulthood.[12, 13] Unfortunately, in our society today, obesity rates are high in adolescent groups, possibly as a result of the maternal factors including pre-pregnancy BMI and gestational weight gain (GWG).[15]

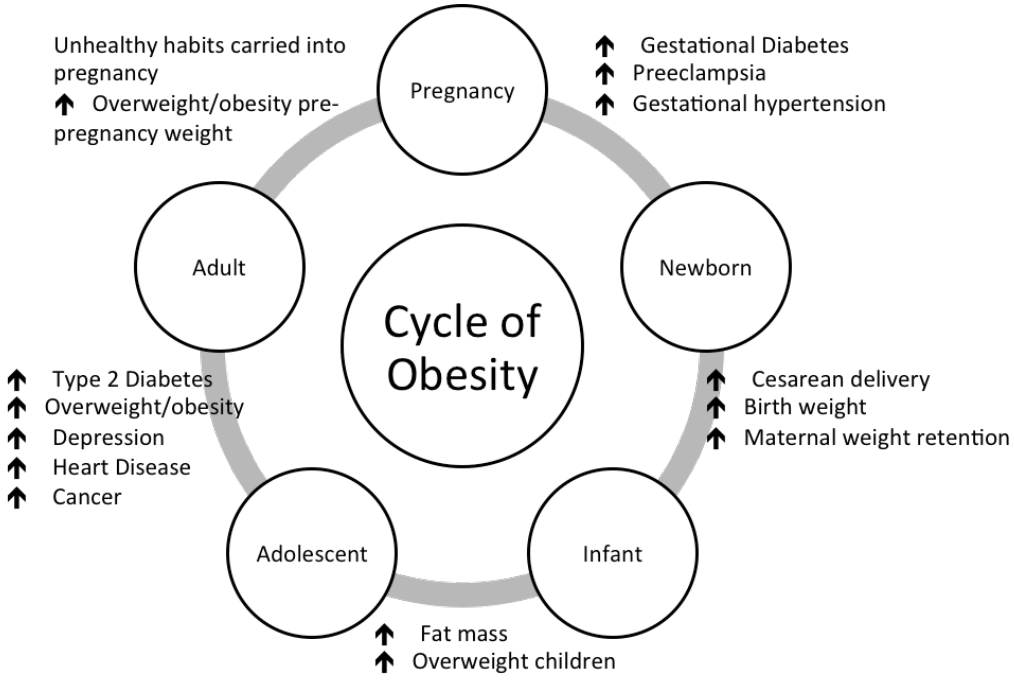

Figure 1. Cycle of obesity

Examination of a population-based cohort with 2,102,642 women between 2011 and 2012 observed that women who gained above the 2009 IOM guidelines had a 1.5 to 2.5-fold increased odds of being diagnosed with gestational hypertension, preeclampsia, or eclampsia compared to their pregnant counterparts that gained within the guidelines, regardless of BMI.[16] There continues to be a growing body of evidence to suggest that excessive weight gain during pregnancy puts offspring at risk of future overweight and obesity.[17] With increasing rates of obesity in women of childbearing age and the knowledge that women are gaining more than previously seen during pregnancy, in addition to retaining more post-pregnancy, it is a critical time to develop an approach to prevent excess weight gain during pregnancy as a means to interrupt this vicious cycle of obesity.

A "Teachable Moment." Pregnancy is a time in which many women are increasingly aware of their health and how their behaviors influence the well-being and the health of their offspring. This moment in time is often defined as a "teachable moment" or a moment in time when women are more likely and receptive to make healthy lifestyle changes.[18] Furthermore, women are in regular contact with their medical provider to monitor the progression of their pregnancy. Research shows that medical providers do not consider counseling on appropriate ways to gain weight during pregnancy as a high priority despite the urging of The American College of Obstetricians and Gynecologists (ACOG). It is recommended that health care providers to offer weight

gain recommendations based on the 2009 IOM guidelines at the initial prenatal visit and periodically throughout pregnancy. [19-21]

Despite medical providers assertion that they do not believe education on appropriate weight gain is important, over 50% of health care providers report that they counsel patients on appropriate pregnancy weight gain.[22,21] Furthermore, a survey conducted of 433 obstetric providers by ACOG's Research Department found that 80% of respondents had read the ACOG Committee Opinion, "Obesity in Pregnancy"[5] and 86% rated it as "helpful" or "very helpful".[19]

Although medical providers report that they believe counsel on appropriate weight gain is important, it is not consistent with the findings that only 10 to 40% of pregnant women report that their health care provider offered information on appropriate weight gain during pregnancy.[23, 24] Based on current qualitative research, there appears to be a disconnect between clinicians' and their patients perceived level of care related to GWG counseling.

Research shows that receiving no information or incorrect advice on appropriate GWG from medical providers is associated with excessive gestational weight gain (EGWG). The Center for Disease Control's (CDC) Division of Nutrition, Physical Activity, and Obesity report showed an association between women receiving no advice and EGWG.[20] The group of women who were not advised about GWG were twice as likely (OR 2.0, 95% CI 1.5-2.7) to gain excessively, compared to the women that were advised to gain within the 1990 IOM GWG recommendations. Women advised to gain more than

the recommendations were more than three times as likely to gain excessively (OR 3.6, 95% CI 2.4-5.5).[20]

The combination of medical providers lack of guidance and potentially inaccurate GWG recommendations puts women at increased risk of pregnancy complications, postpartum weight retention, and long-term complications for both mother and infant. While weight gain during pregnancy is expected and encouraged, expectant mothers need guidance on how to appropriately gain weight during pregnancy to prevent excessive gain and avoid the negative consequences of EGWG.

Without the proper information given or offered by their medical provider, many women seek out weight gain and nutrition-related recommendations through alternative sources. Women are more likely to turn to sources such as the Internet, books, and friends for this information.[24] More than 32% of women identified the Internet as their most important source of information related to weight gain and over 80% of women used the Internet to seek out the recommendations.[24]

Although research shows that pregnant women value information on GWG and counseling on how to gain the appropriate amount of weight to achieve a healthy pregnancy, it appears medical providers do not dedicate much time to counseling on appropriate weight gain.[25] Pregnant women are willing to seek out this information from non-clinical sources such as the Internet or media sources increasing the chance for obtaining inaccurate information. Given this, a strong need exists for improved

guidance within the health care setting and/or the use of high quality evidence-based media sources for prenatal care.

Gestational Weight Gain

Overview of GWG incidence and recommendations. Gestational weight gain is a modifiable risk factor for maternal and fetal health. Guidelines published by the IOM outline weight gain recommendations based on pre-pregnancy BMI. IOM has provided guidelines for recommended weight gain during pregnancy since the 1990's. In recent years the IOM has re-evaluated past standards in response to the increasing rates of overweight and obesity in women of childbearing age. The IOM identified the need to revise previous guidelines in order to prevent adverse maternal and fetal health outcomes including postpartum weight retention, cesarean delivery, gestational diabetes mellitus (GDM), pregnancy induced hypertension or preeclampsia, small or large for gestational age infants, preterm birth, and childhood obesity. A review of outcomes associated with the recommendations set forth by IOM confirms that the current recommendations are associated with the best outcomes for both mother and infants.[26]

Specifically, the 2009 revisions included weight gain recommendations based on pre-pregnancy World Health Organization body mass index (BMI) cutoff points: <18.5 kg/m^2 (underweight), 18.5-24.9 kg/m^2 (normal), 25-29.9 kg/m^2 (overweight), and ≥ 30 kg/m^2 (obese). Previously, IOM set weight gain recommendations were based on BMI

categories taken from the Metropolitan Life Insurance tables: <19.5 kg/m^2 (underweight), 19.8-26 kg/m^2 (normal), >26 kg/m^2 (overweight), and >29 kg/m^2 (obese).

Table 1: 2009 IOM Weight Gain Recommendations

Pre-pregnancy Body Mass Index (BMI)	Total weight gain range kg (lbs)	Rate of Gain per week of 2nd and 3rd trimesters*	
		Mean range in kg/wk	Mean range in lbs/wk
Underweight (<18.5 kg/m^2)	12.5-18 (28-40)	0.51 (0.44-0.58)	1 (1-1.3)
Normal weight (18.5 - 24.9 kg/m^2)	11.5-16 (25-35)	0.42 (0.35-0.50)	1 (0.8-1)
Overweight (25.0 – 29.9 kg/m^2)	7-11.5 (15-25)	0.28 (0.23-0.33)	0.6 (0.5-0.7)
Obese (≥ 30 kg/m^2)	5-9 (11-20)	0.22 (0.17-0.27)	0.5 (0.4-0.6)

*Adapted from [3] *Calculations assume a 0.5-2 kg (1.1-4.4 lbs) weight gain in the first trimester.*

A resource sheet released by the IOM in May of 2009 shows that trends in weight gain during pregnancy are significantly higher than the recommended guidelines for weight gain during pregnancy as reported in the Pregnancy Risk Assessment Monitoring System (PRAMS). Reports suggest that 50-70% of women in the United States are gaining in excess of the recommendations.[16, 27] Furthermore, recent research has found that more than 80% of the overweight (OW) category of women, classified as a BMI between 25.0-29.9 kg/m^2, gained in excess of the 2009 IOM recommended guidelines. [27-29] This is very concerning as excess weight gain during pregnancy is known to increase risk of future obesity and diabetes in both the mother and child.[12, 17, 30]

Normal pregnancy physiology and EGWG. It has been well established that weight gain is necessary in pregnancy to support growth and energy storage. According

to Lederman et al [31], "an optimum weight gain over the course of pregnancy is one that produces a healthy newborn and provides sufficient postpartum maternal fat stores to support lactation without increasing obesity risk." The placenta, fetus, and amniotic fluid, otherwise known as the products of conception, alone compromise 35% of total GWG.[32] Changes in total body water (TBW), fat-free mass (FFM, i.e. protein accretion), and fat mass (FM) are largely responsible for weight gain during pregnancy. Maternal tissue accretion accounts for approximately two-thirds of total gain with increases in uterine tissue, mammary mass, expansion of maternal blood volume, extracellular fluid, and maternal fat stores. TBW changes are controlled by hormonal changes necessary to support an increase in plasma volume of up to 50% by the third trimester.[33, 34]

In addition to TBW, lean body mass (LBM) includes the accrual of approximately one kg of lean mass as protein or FFM in late pregnancy. The remaining contributor of maternal weight gain is FM needed as an energy reserve either during pregnancy or lactation. For those women who gain in excess, the gains are primarily associated with maternal FM accrual. In a secondary analysis of 49 women enrolled in a randomized controlled trial found that EGWG is strongly correlated with fat mass change ($r=0.87$, $p<0.001$).[35] This is supported by additional studies reporting a positive correlation between GWG and FM accrual ($r=0.81$, $p<0.001$[31]; $r=0.76$, $p=0.001$[31, 36]).

Lederman et al[31] assessed the body composition of 196 women (including non-Hispanic white, non-Hispanic black, and Hispanic) at two points during pregnancy, weeks 12-16 and again during or after week 37 of gestation. Body composition was assessed using a four-compartment body composition model with body density measured by

hydrodensitometry. Total body weight was determined by the dilution of an orally administered dose of deuterium, and dual-energy absorptiometry was used to measure total body bone mineral mass.[31] After stratifying the women by pre-pregnancy BMI and weight gain category, results showed that FM gain was highest among the underweight (6.0 ± 2.6 kg gained within vs. 6.9 ± 3.5 kg gained above the IOM recommendations), followed by normal weight (3.8 ± 3.5 kg gained within vs. 6.0 ± 3.1 kg gained above the IOM recommendations), overweight (2.8 ± 4.1 kg gained within vs. 4.2 ± 6.9 kg gained above the IOM recommendations), and obese (-0.6 ± 4.6 kg gained within vs. 3.1 ± 3.9 kg gained above the IOM recommendations) in both women who gained within and above the IOM recommendations, respectively.[31]

Regardless of pregnancy, increased FM has negative consequences for long-term health. Women who gain in excess during pregnancy and increase their FM may be at higher risk of health conditions related to excess FM accrual. The same Butte et al.[37] group found that FM retention at 27 weeks postpartum was 5.3 kg higher in those who gained above the recommendations compared to a FM retention of 2.3 kg for those who gained within and a decrease of 0.5 kg FM for those who gained below the recommendations.

Consequences of EGWG. With an ever-increasing obesity rate, specifically in the United States, preventing excess weight gain during pregnancy is important in the prevention of lifelong overweight and obesity in pregnant women. Weight gain during pregnancy has strong implications on the health outcomes of both child and mother. Excessive gestational weight has been associated with failure to lose weight after

pregnancy and long-term obesity in women.[38-40] In addition, excess weight gain during gestation places women at higher risk for GDM, cesarean delivery, preeclampsia and pregnancy morbidities including macrosomia and congenital abnormalities.[41-43]

Fetal outcomes and GWG. Gaining in excess of the 2009 IOM guidelines has also been shown to have consequences on infant outcomes. Both pre-pregnancy BMI and gestational weight gain have been identified as modifiable determinants of infant size at birth.[29, 44, 45] There is well established research showing the strong associations between higher maternal BMI and poor outcomes specifically related to increased birth weight[45, 46], infant percentage of body fat[47, 48], primary cesarean section[45], and pre-eclampsia[49].

The use of pre-pregnancy BMI and weight gain during pregnancy are valid predictors for large for gestational age babies (LGA).[29] The HAPO study cohort demonstrated the relative odds of birth weight being greater than the 90th percentile gradually increased with both 75-gram dose oral glucose tolerance test (OGTT) glucose levels and maternal BMI. Compared with women who are normal or underweight with a normal glucose response, the relative odds of birth weight exceeding the 90th percentile was 2.58 for women with GDM and 2.07 for obese women with a normal glucose response ($p<0.001$).[50]

Research done by Hull et al[48] showed an interactive effect between GWG and pre-pregnancy BMI on infant body composition. Specifically, differences were found between both appropriate and excessive GWG groups and BMI categories.[48] Women who gained appropriately by 2009 IOM guidelines but were obese, as determined by

their pre-pregnancy BMI, had infants with significantly greater fat mass (472.9 g ± 56.0) and percent body fat (14.6% ± 1.4) than overweight (303.6 g ± 46.1 fat mass, p<0.018; 9.2% ± 1.1 percent body fat, p<0.002) and normal weight (355.5 g ± 20.1 fat mass, p=0.041; 11.2% ± 0.5 percent body fat, p=0.014) mothers. Women who exceeded the 2009 IOM guidelines and were categorized as normal weight had infants with significantly lower fat mass (388.9 g ± 21.9) and percent body fat (11.8% ± 0.5) than infants born to overweight and obese mothers (484.4 g ± 28.8, p=0.004 and 486.4 g ± 33.5, p=0.012; 13.7% ± 0.7, p=0.019 and 14.2% ± 0.8, p=0.011, respectively). Overall, newborn infants of women who gained in excessive of the guidelines and/or are considered obese had a significantly greater fat mass and percent body fat compared to women who gained within the guidelines and had a normal or overweight BMI.

An interesting finding from this study was that overweight mothers who gained excessive weight had infants with a significantly greater fat mass than infants born to overweight mothers who gained appropriately (484.4 g ± 28.8 vs. 303.6 g ± 46.1; p =0.001). Furthermore, overweight mothers who gained appropriately did not have infants with fat mass or percent body fat that differed significantly from normal weight mothers who gained appropriately (9.2% body fat vs. 11.2% body fat, respectively).[48] However overweight women who gained excessively did have infants with significantly different fat mass and percent body fat than normal weight mothers who gained excessively (13.7% ± 0.7 body fat vs. 11.8% ± 0.5 body fat, respectively; p=0.019).

The timing of weight gain is also an important factor in neonatal outcomes. A retrospective study on 172 healthy pregnant women evaluated how the timing and

amount of maternal weight gain effects neonatal adiposity at birth. Using the 2009 IOM weight gain guidelines, the researchers concluded that infant birth weight increased with increasing maternal BMI (birth weight >4,000 g in 5.2%, 12.1%, and 28.5% in normal, overweight, and obese mothers respectively).[51] Furthermore, infants born to women who gained excessively in the first half of their pregnancy, between 16-20 weeks gestation, were larger and had excessive body fat at birth compared to the women who gained appropriately (3,918 g ± 265 vs. 3,159 g ± 300 neonatal weight, $p<0.05$; 17.5% ± 3.1 vs. 13.2% ± 4.1 percent body fat, $p<0.01$).[51] Infants of women who gained excessively in the first half of pregnancy had increased risk of elevated percentage body fat compared to women who gained in excess, regardless of timing (OR 2.64, 95% CI 1.35-5.17 v OR 1.49, 95% CI 0.80-2.79). These same findings were not exhibited in women who gained appropriately prior to week 20 and excessively in late pregnancy (week 20 – delivery).

Outcomes from this study suggest the need to target pre-pregnancy BMI and the timing of weight gain when considering the optimal time to prevent development of obesity. Early intervention to prevent EGWG has the potential to promote the best outcomes regarding infant fat mass and percent body fat based on the fact that infants of mothers who gain excessively are more likely to have more fat mass compared to infants whose mothers gain appropriately.

Maternal postpartum weight retention. An important contributing factor to the weight gain in women of childbearing age is sustained postpartum weight retention (PPWR). A strong predictor of PPWR is EGWG, with women retaining a substantial

amount of the excessive weight gained 12 plus months postpartum. Siega-Riz[8] et al reported a shift in 4% of normal weight and 40% of overweight women to the obese BMI category at 12 months postpartum.[8] Furthermore, two large prospective studies, a 10 and 15 year follow-up found that weight gain, leading to classification of overweight status were both related to weight gain during pregnancy and the year after childbirth.[6, 7] In a 21-year post pregnancy follow-up, women who gained outside of the 1990 IOM recommendations had an increased BMI of 3.72 kg/m^2 as well as increased odds of being overweight (OR: 2.15; 95% CI: 1.64, 2.82) or obese (OR: 4.49; 95% CI: 3.42, 5.89) suggesting that weight gain and PPWR contributes to the rising prevalence of obesity.[52]

Recent research has also found a link between PPWR and number of previous live births.[53] To prevent PPWR in both nulliparous and parous women, it is important for mothers to gain the appropriate amount of weight during each pregnancy. Appropriate weight gain will reduce the risk of PPWR and the short- and long-term effects of EGWG.

Gestational diabetes mellitus, pre-eclampsia, and gestational hypertension. The increasing prevalence of obesity is also associated with rising risk for gestational hypertension[54], preeclampsia[49, 54], and GDM[38, 42, 55] during pregnancy as well as hypertension, cardiovascular disease, and diabetes mellitus later in life.[56, 57] The increased risk of developing these specific disease states is also associated with adverse pregnancy outcomes when weight gain exceeds 2009 IOM recommended levels.

Gestational diabetes mellitus is of significant concern due to the increasing diagnosis rates, which puts women at greater risk for development of type 2 Diabetes

Mellitus post-pregnancy.[30, 58] The Kaiser Permanente of Colorado GDM Screening Program found GDM prevalence among their large cohort doubled from 1994 to 2002.[42] The increasing rates of GDM diagnosis have strong implications on future prevalence when we examine the relationship between weight classification and the risk for a GDM diagnosis. A recent large retrospective study on the relationship between BMI and maternal outcomes found that the risk of GDM increases across the overweight and obese BMI categories at an odds ratio of 8.5 (99% CI; 5.7-12.9).[59] This is of particular concern considering the most recent NHANES data showing obesity rates have significantly increased in the last 10 years in women of childbearing age.[4]

Gestational Diabetes Mellitus is characterized by a maternal decrease in insulin sensitivity or increased insulin resistance. The manifestations of these alterations results in decreased glucose uptake in skeletal muscle, white adipose tissue, and liver, decreased suppression of hepatic glucose production, the inability of insulin to suppress lipolysis and results in a decreased ability of insulin to suppress amino acid turnover.[60] In women with GDM, by late pregnancy whole body insulin sensitivity is decreased by 40% more than normal pregnancy.[61] These changes result in alterations in normal fasting, postprandial, and 24-hour concentrations of amino acids, glucose and lipid concentrations. Women with GDM have a three-fold increase in plasma triacylglycerol, plasma fatty acids, and delayed clearance of fatty acids.[61]

The insulin resistance observed in women with GDM is indicative of the typical type 2 diabetes mellitus abnormalities in glucose metabolism. The specific mechanism by which insulin sensitivity decreases and insulin resistance increases is unknown;

however, the metabolic effects of several hormones and cytokines that are elevated in maternal blood during pregnancy may enhance a genetic susceptibility to insulin resistance.[62] Normal glucose metabolism in pregnant women progressively changes during pregnancy. Unlike normal pregnancy, β-cell function of women with GDM is 30% to 70% lower compared to normal pregnancy. The dysfunction of β cells in GDM leads to defective insulin action resulting in increased hepatic glucose production and in turn, higher blood glucose levels.[60] In addition to alterations of maternal metabolism, GDM influences fetal metabolism. One of the defining characteristics of GDM is fetal overgrowth resulting from maternal metabolic imbalance. Maternal-fetal glucose regulation is altered in GDM as evidenced by higher fetal glucose levels at birth compared to infants of mothers with glucose levels in a normal range.[63]

The risk of adverse outcomes is also linked to PPWR such that with increasing weight retention, the likelihood of poor outcomes in a subsequent pregnancy increases. Villamor and Cnattinguis[38] found that risks of pre-eclampsia, gestational hypertension, and GDM increase with an increase in 1 kg/m^2. The reverse was seen in risk for pre-eclampsia when women lost more than 1 kg/m^2 between pregnancies.[38]

There also appears to be a link between EGWG and the development of pre-eclampsia and gestational hypertension. Gestational hypertension is defined as the new onset of hypertension after 20 weeks of gestation and is associated with pre-eclampsia, characterized by proteinuria. As pre-pregnancy BMI increases, the risk of developing gestational hypertension or pre-eclampsia also increases.[64, 65] Haugen et al.[65] showed that both nulliparous and parous overweight women who gained in excess of the IOM

recommendations had increased odds for development of gestational hypertension (OR 1.55; 95% CI: 1.03, 2.32 nulliparous; OR 1.14; 95% CI 0.71, 1.83 parous), preeclampsia (OR 2.87; 95% CI: 1.96, 4.88, OR 1.5; 95% CI: 1.01-2.24) and emergency cesarean section (OR 1.42 95% CI: 1.14, 1.77, OR 1.95; 95% CI: 1.41,2.69). These findings were similar in a large study on 24,241 nulliparous women examining the risk of pre-pregnancy BMI with risk of pre-eclampsia. According to their finding, women classified as "Class 3 Obese" are at the highest risk of pre-eclampsia (OR 7.2; 95% CI: 4.0, 11.2) followed by women who are categorized as class I and II obese (OR 3.1; 95% CI: 2.8, 3.5) and overweight women (OR 1.6; 95% CI: 1.2, 1.8) as compared to women with a normal BMI.[64]

Childhood obesity. The consequences of EGWG on infant outcomes persist into adolescence, with the children of mothers with EGWG being at greater long-term health risk, specifically obesity. In the Growing Up Today Study cohort (GUTS; n= 11,305 aged 9-14), offspring of the women who participated in the Nurses Health Study II (NHS II), had higher z-scores (0.14, 95% CI: 0.09-0.18) and higher odds of overweight (1.27, 95%CI: 1.12, 1.44) and obesity (1.42, 95% CI; 1.19-1.70) if they were offspring of women who gained above the 1990 IOM guidelines compared to the offspring of women who gained appropriately.[44] This is supported by a number of long-term follow-up studies that further provide evidence that children of women who gain excessive weight have a greater likelihood of becoming obese toddlers[66] and adults[67]. Toddlers born to mothers who gained above the 2009 IOM recommendations in the Pregnancy Infection and Nutrition (PIN 3) study had higher weight-for-age (WAZ), length -for-age (LAZ) and

weight-for-length (WLZ) z-scores at birth (WAZ, LAZ, and WLZ, p<0.001) and at 3 years old (WAZ p=0.01, LAZ, p=0.03).[28]

The consequences of GWG on offspring not only include greater risk of overweight/obesity, EGWG in pregnancy puts children at greater risk of asthma, sleep disorders, high blood pressure, type 2 Diabetes, early growth and puberty, and psychological disorders including depression and anxiety.[68, 69]

Diet During Pregnancy

Dietary intake plays an important role in the management of GWG. The amount and type of food have both been shown to impact the amount of weight gained during pregnancy.[70-72] The expectation is that women will gain weight while pregnant and as such, should increase their caloric intake to achieve the recommended gains. However, in our society, we commonly hear the term "eating for two", suggesting that a pregnant woman should double her normal food intake. However, the expectation is not that women double their intake but rather recommendations provided by the Food and Agriculture Organization/World Health (FAO/WHO/UNU) recommend no increases in energy intake during the first trimester, an increased energy intake of 340 kilocalories per day in the second trimester, and 452 kilocalories per day in the third trimester to support fetal growth and increasing maternal BMR.[73,74, 75]

By the second trimester, energy needs increase in response to the growing needs of the fetus. Energy needs also increase to support changes in maternal basal metabolic rate (BMR) and total energy expenditure (TEE). Throughout pregnancy,

regardless of BMI, BMR increases by a mean rate of 10.7 kilocalories per week of gestation and TEE increases by a mean of 5.2 kilocalories per gestational week.[76]

Several observational studies suggest that there is an association between macronutrient intake (fats, carbohydrates, and protein) and GWG. Specifically, diets high in total fat and protein were positively associated with GWG (+2.6 kg per 1 s.d. of total fat intake, $p<0.001$; + 3.1 kg per 1 s.d. of protein intake; $p<0.001$).[72] Diets with a higher glycemic load have also demonstrated a positive association with EGWG ($\beta=0.16$; 95% CI 0.4-0.29, $p<0.05$).[77] Furthermore, a study on the Danish National Birth Cohort found that higher rates of GWG were observed in women in the higher quintiles of glycemic load ($p<0.001$).[78]

Olafsdottir et al.[71] showed that only the women who gained in excess of the IOM guidelines increased their energy intake as the pregnancy progressed (108 ± 672 kilocalories per day, $p=0.010$). Overweight women who gained excess weight were found to increase their percentage of energy from fat (1.2% ± 6.3 total energy) and decrease their percentage of energy from carbohydrates (-0.7% ± 6.4 total energy) throughout the pregnancy. Overweight women who gained excessively also decreased their intake of fiber whereas overweight women who gained appropriately increased their fiber intake (-1.4 ± 5.8 vs. 3.4 ± 7.5 g per 2390 kilocalories, respectively). Furthermore, there was a positive relationship between high intake of sweets in early pregnancy (OR = 2.52, 95% CI = 1.10-5.77, $p=0.029$), increased energy intake in late pregnancy (OR = 2.04, 95% CI = 1.17-3.58, $p= 0.012$) and milk consumption (OR = 1.82, 95% CI = 1.08-3.06, $p= 0.024$) in late pregnancy and EGWG.[71]

In a cohort of 342 obese pregnant women, intake of added sugars was positivity associated with GWG (+2.8 kg, 95% CI 0.8-4.9, p= 0.02). Sweets, snacks (e.g., chips, salted peanuts, popcorn), cakes and ice cream were relatively strong predictors of GWG (RR = 1.84, 95% CI 1.14-2.96, p<0.0006), with increased frequency of intake associated with greater relative risk of EGWG (as defined as >9kg weight gain).[79] Based on current research findings, diet is known to be a predictor of GWG, specifically type and composition of diet. Special attention and education may be necessary for groups at higher risk of EGWG, specifically women with an overweight BMI. Future dietary interventions should utilize the information on the relationship between dietary intake and EGWG to inform how diet modification and management is used within the interventions.

Physical Activity During Pregnancy

Adherence to physical activity guidelines during pregnancy has the potential to positively impact maternal and fetal outcomes. Along with dietary intake, physical activity has been identified as a modifiable variable during pregnancy that may aid in meeting weight gain recommendations. Physical activity is important during pregnancy not only to potentially control weight gain but also minimize gains in fat mass. Previous research has demonstrated the need for physical activity to manage the elevated state of insulin resistance present in late gestation.[80, 81]

Specific guidelines for physical activity during pregnancy were first introduced in 1985 by American College of Obstetricians and Gynecologists (ACOG).[82] The original

published guidelines have been updated and adapted to reflect what is now known about physical activity and pregnancy. Originally, the guidelines were established to restrict activity to no more than 15 minutes at a time, keep their heart rate below 140 beats per minute, and to not start an exercise program when pregnant if not active prior to becoming pregnant.[82] Emerging research at that time provided evidence to show there was no need to limit activity in otherwise healthy pregnant women.[83] In 1994, ACOG published new guidelines that encouraged rather than limited activity during pregnancy, including removing restrictions on heart rate and exercise duration from their guidelines.[84]

By 2002, recommendations encouraged moderate exercise for 30 minutes a day on most, if not all, days of the week for all women with a healthy pregnancy whether or not they were previously active or inactive.[85] In 2015, ACOG re-affirmed these guidelines in a new publication recommending that pregnant women participate in an exercise program with the goal of achieving 20-30 minutes of moderate-intensity activity on most if not all days of the week.[86] In the 2008 U.S Department of Health and Human Services Physical Activity Guidelines for Americans, specific recommendations were set for healthy pregnant and postpartum women. The 2008 Physical Activity Guidelines for Americans recommends at least 150 minutes of moderate-intensity aerobic activity spread throughout the week, the same guidelines for PA in the non-pregnant, healthy adult US population.[87]

Physical activity during pregnancy has a variety of benefits including management of blood glucose, maintenance of muscle mass, and greater control of

GWG.[85, 88] Insulin resistance is commonly exacerbated in pregnant women with a high BMI increasing their risk for gestational diabetes.[89] In order to avoid a decrease in muscle mass during pregnancy, regular physical activity is recommended. In addition to maintenance of muscle mass, Olson and Strawderman[90] showed a 1.7 times greater likelihood that women who are less active during pregnancy than before pregnancy will gain more than recommended as compared to women who maintain or increase their activity level during pregnancy regardless of pre-pregnancy BMI.[70]

Physical activity patterns during pregnancy. Despite the well-established recommendations and known benefits of physical activity, few pregnant women are meeting the recommendations for physical activity during pregnancy. A study using recent NHANES data found that pregnant women were on average spending 12.0 ± 0.86 minutes per day in moderate activity and less than 1 minute in vigorous activity. Using objectively measured Actigraph accelerometer data, total time spent in moderate or vigorous activity declined with progression of pregnancy, from the first trimester to the third (average moderate activity 7.6 ± 0.59 minutes per day). Furthermore, they reported that women spent 57.1% of their time in sedentary behavior (SB).[91] This was further demonstrated in a recent observational study reporting that women in their second trimester spent at least 70% of their day in SB.[92]

In a large population-based study, Evenson et al.[93] compared reported physical activity data collected from 1,979 pregnant women to 44,657 non-pregnant women and observed that 65.6% of pregnant women reported some physical activity in the last month, compared to 73.2% of non-pregnant women. Additionally, only 15.8% of

pregnant women reported that they met the recommendations of 150 minutes weekly of moderate activity compared to 26.1% of non-pregnant women.[93] Further research has examined the trends of women who were active prior to pregnancy. A review of activity patterns during pregnancy reported a relationship between pre-pregnancy exercise levels and exercise during pregnancy. Six of the seven studies reviewed found that women who were more active prior to pregnancy were significantly more likely to remain active during pregnancy compared to their more sedentary counterparts.[94]

Activity patterns and exercise not only change from pre-pregnancy to pregnancy but have been shown to shift from early to late gestation. A large cross-sectional study assessed the prevalence of physical activity during pregnancy in 1,279 women. The women were asked to complete a Pregnancy Physical Activity Questionnaire within 72 hours post-partum to assess self-reported physical activity during pregnancy. Women were then categorized as being active, defined as performing exercise twice or more per week, for at least 30 minutes per session, or sedentary.[95] Overall, the prevalence of exercise was lower during pregnancy compared to before pregnancy ($p=0.01$) and during the first trimester (13.6%) and the third trimester (13.4%) with a total of 20.1% of women reporting any type of exercise during some period of their pregnancy. Furthermore, only 7.2%, 7.6%, and 4.7% of women met the minimum of 150 minutes of aerobic exercise per week in the first, second, and third trimesters respectively.[95]

There is strong evidence to suggest that most women are not meeting the physical activity recommendations during pregnancy. Furthermore, research shows that, overall, women are decreasing time spent in physical activity and spending a substantial

portion of the day in sedentary behaviors thus exercising less and sitting more, a combination that is potentially harmful to both mother and fetus.

Interventions to Prevent GWG

With the research to show that there are modifiable behavioral factors that can significantly influence the risk of excessive weight gain it is important to utilize this knowledge to design a randomized controlled trial to identify the optimal approach to prevent EGWG to decrease the risk of future obesity.

Dietary Interventions A number of randomized control trials have been conducted focusing on dietary interventions during pregnancy.[23, 96-99] Dietary interventions typically aim to promote a healthy diet during pregnancy utilizing specific energy intake recommendations including percentage of energy from macronutrients and maintenance of a food diary.

In a randomized control trial of over 50 White obese pregnant Danish women, the intervention participants (n=23) were instructed to eat a healthy diet according to the official Danish dietary recommendations (less than or equal to 30% energy from fat, 15-20% protein, and 50-55% carbohydrate) and energy intake was recommended based on individual energy needs.[97] Use of dietary intervention proved to be successful in limiting energy intake (1773 kcal/day intervention versus 2282 kcal/day control, $p<0.005$) and limiting EGWG in the intervention group with a total GWG of 6.6 ± 5.5 kg compared to 13.3 ± 7.5 kg gain in the control group (mean difference of 6.7 kg, 95% CI 2.6-10.8 kg, $p=0.002$).

A meta-analysis of 7,278 women from 44 randomized controlled trials evaluated the effects of lifestyle interventions in pregnancy and identified diet-based interventions as a more effective treatment approach to reduce GWG (-3.84 ± -5.22 to -5.22 kg weight gain, $p<0.001$) compared to physical activity (-0.72 ± -1.20 to – 0.25 kg, $p<0.003$) or mixed approach (both diet and physical activity; -1.06 ± -1.67 to -0.46, $p<0.001$).[100] According to this meta-analysis, dietary interventions that recommend women eat a balanced diet of 1591-1776 kcal/day, a low-glycemic diet with whole grains, fruits, beans and vegetables, and a healthy diet with individualized energy intake are effective in reducing GWG.

A 2016 systematic review of 13 randomized controlled intervention studies in overweight and obese pregnant women concluded that there is variable success in reducing GWG with implementation of a dietary intervention.[101] Only 9 of the 13 were effective at significantly reducing GWG in the intervention group compared to the control; however, the 4 studies that did not find statistical significance between GWG did report a trend towards lower weight gain in the intervention group. In addition to GWG, the effect of intervention on diet changes was variable, with only five studies reporting an effect on dietary intake.

One tool used to assess diet quality is the Healthy Eating Index (HEI), a diet quality index aligned with recommendations form the Dietary Guidelines for Americans (DGA).[102] The 2010 version of this index, HEI-2010, was developed as a way to assess compliance with the 2010 DGA[103] and has been shown to be a valid and reliable measure of diet quality for all segments of the US population including women who are

pregnant or lactating .[104] The HEI-2010 reflects the updated Dietary Guidelines for 2010 to evaluate diet quality based on the consumption of the twelve different food categories noted previously, where nine categories scored based on adequacy of intake (total fruit, whole fruit, total vegetables, greens and beans, whole grains, dairy, protein foods, seafood and plant proteins, and fatty acids) and three categories based on moderation of intake (refined grains, sodium, and empty calories). Each component has a maximum point total of 5, 10, or 20 points with a maximum score of 100 for the overall index. Based on the total HEI score, a score of ≥ 80 is considered "good", a score between 50 to 80 "needs improvement", and ≤ 50 is "poor".[105] The current HEI-2015 was updated in the spring of 2017 and retained most of the components found in HEI-2010. HEI-2015 split the "empty calorie" component into two new components, "added sugars" and "saturated fats", to better reflect the DGA 2015 recommendation on limiting added sugars to less than 10% of total caloric intake.[106] Evaluation and validation of HEI-2015 are ongoing at this time.

The LIMIT randomized controlled trial used the 2005 Healthy Eating Index (HEI-2005), based on the 2005 Dietary Guidelines for Americans (DGA)[107], as a way to assess the effects of a dietary intervention on a group of overweight and obese women.[108] In the LIMIT intervention, 942 women were randomized to the Lifestyle Advice group between the 10th and 20th weeks of pregnancy and took part in the study until the end of their pregnancy. Each woman met once with a research dietitian who provided dietary advice based on the Australian standards and received individualized meal plans, healthy recipes, and other strategies for improving diet quality. Women in the Lifestyle

Advice groups made dietary goals and were asked to self-monitor progress with the assistance of a workbook provided by the researchers. The initial information was reinforced at 22, 24, and 32 weeks' gestation women with a trained research assistant via telephone, and in-person at week 28 and 36 of gestation with the research dietitian. This group of women also received physical activity education, were encouraged to set activity goals, and asked to self-monitor regular activity in the workbook provided by the research staff.

At study entry, 28 and 36 weeks' gestation, all participants completed the Harvard Semi-quantitative Food Frequency questionnaire. Based on the HEI-2005, women receiving the Lifestyle Advice significantly improved their diet quality based on HEI at both 28 and 36 weeks gestation compared to the standard care group (73.35 ± 6.62 vs. 71.86 ± 7.01, $p<0.0001$; 72.95 ± 6.82 vs. 71.17 ± 7.69, $p<0.0001$, respectively). Women in the Lifestyle Advice group also significantly increased their consumption of total fruit, whole fruit, and dark-green and orange vegetables and legumes compared with standard care.

HEI-2005 was used in a cross-sectional study to assess diet quality as it relates to pre-pregnancy and pregnancy weight in 100 pregnant women in Athens, Greece.[109] The mean adjusted HEI score for all women across pregnancy was 66.9 ± 0.6 but varied by pre-pregnancy BMI. HEI score during pregnancy was negatively associated with both pre-pregnancy BMI ($r= -0.298$, $p\leq 0.003$) and pregnancy BMI ($r= -0.345$, $p\leq 0.001$). Women with a normal BMI had a significantly higher HEI compared to overweight women (n=62, 67.1 ± 0.6 v n=19, 66.6 ± 0.6, respectively, $p <0.01$); however, there was

no difference between normal weight women and obese women (n=11, 67.1 ± 0.6 v 66.7 ± 0.4).

Based on this evidence, diet quality is an important factor to consider when designing an intervention to prevent excessive gestational weight gain. Special attention may be needed for overweight women based on diet quality prior to pregnancy.

Physical Activity Interventions Physical activity is a modifiable factor that has been studied to support its contribution in helping pregnant women minimize weight gain during pregnancy. The Project Viva cohort study (n= 1,388), a large prospective cohort study including Caucasian, non-Hispanic black, Hispanic, and Asian women, demonstrated an inverse relationship between EGWG with mid-pregnancy walking (OR 0.91; 95% CI: 0.82-1.00, per half-hour per day) and vigorous physical activity participation (OR 0.76; 95% CI: 0.60-0.97, per half-hour per day).[110]

A meta-analysis of nine supervised physical activity interventions and three home-based exercise interventions to prevent EGWG found that there was a significant mean difference in weight change during pregnancy between groups, suggesting a significant reduction in GWG in the intervention group on average (p = 0.03) overall.[111] However, only seven of the studies reported a reduction in GWG, and only one reported a significant difference when compared to the control group.[111] The other five studies did not observe any difference in GWG compared to the control groups.[111]

A recent physical activity intervention using a web-based behavioral intervention to increase physical activity and prevent EGWG in previously sedentary women was

successful at increasing activity but unsuccessful in preventing EGWG.[112] The group randomized to the behavioral intervention (BI) group used a web-based program designed to assist with goal setting, problem solving, and enabled pregnant women to self-monitor physical activity using a calendar to track exercise from enrollment to delivery. Women in the BI group were also instructed to gradually increase to 150 minutes of MVPA per week by gestational week 19 and maintain that level of activity until delivery. The BI was effective at increasing MVPA in bouts of at least 20- and 30-minutes from baseline data collection to mid-pregnancy and compared to the usual care group; MVPA in 20- and 30-minute bouts was significantly greater in the BI group (122 ± 106 minutes BI in 20-minute bouts vs. 46 ± 48 minutes usual care; 74 ± 70 minutes BI in 30-minute bouts vs. 14 ± 24 minutes usual care, $p<0.01$). However, there was no difference in the proportion of women who met the 2009 IOM weight gain recommendations (33.3% met in the usual care vs. 27.3% met in the BI group).[112]

The authors suggested that one possible explanation for the increased activity with no effect on weight gain was related to a significant increase in caloric intake in the BI group at mid-pregnancy compared to the usual care group (1,894 ± 594 calories usual care vs. 2,503 ± 703 calories BI group, $p=0.005$). Furthermore, repeated measures analysis found that the BI group significantly increased caloric intake from baseline to mid-pregnancy (336 ± 127 calories, $p=0.04$) possibly in response to the increase in prolonged walking within this group.[112] This study, unlike other PA interventions to prevent EGWG, found that when women increase intentional activity there is also a parallel increase in caloric intake.

There is little evidence to support that physical activity interventions alone are effective at preventing EGWG. However, there is strong evidence that interventions targeted at physical activity can increase intentional MVPA with or without a significant reduction in total GWG.

Mixed Approach (PA, diet, and counseling)

Effectiveness of previous mixed approach interventions Research on the feasibility of a theory-based behavioral lifestyle intervention during pregnancy to prevent EGWG is somewhat limited due to the lack of lifestyle interventions designed with a specific theoretical model. Few studies have looked at the comprehensive theory-based intervention, including physical activity and dietary interventions as well as behavioral or counseling strategies to prevent EGWG (Table 2).

As previously stated, recent systematic reviews of randomized controlled trials [100, 113, 114] suggest that dietary modification, in addition to physical activity are necessary to influence GWG. The use of a behavior change theory is an additional component that has the potential to promote adherence to the 2009 IOM weight gain recommendations. Using behavioral theories provides greater understanding on how interventions work by identifying underlying mechanisms that enable or undermine behavior change.

A systematic review published by the Cochrane library in 2012 and updated in 2015 evaluated the effectiveness of 49 randomized controlled trials with at least 11,444 participants. The review concluded that diet or exercise interventions, or both, reduced the risk of EGWG by an average of 20% (95% CI, 13 to 27%) overall.[115] The findings from

the Cochrane review are similar to findings from a recent IPD meta-analysis in which data for more than 12,000 women showed that pregnant women who receive any diet or physical activity intervention, or a combination of the two, during pregnancy had a significantly lower mean GWG (mean difference GWG -0.70 kg, 95% CI, -0.92 to -0.48, I^2 = 14.1%).[116]

A number of previous GWG interventions have also acknowledged the need to influence behavior through use of behavior change techniques and tools in order to optimize meeting gestational weight gain recommendations.[18, 111, 117-120] The combination of both diet and physical activity has also been shown to be effective in preventing EGWG. Mottola et al.[98] demonstrated positive results in a combined nutrition restriction and walking program intervention study in overweight Canadian pregnant women, the Nutrition and Exercise Lifestyle Intervention Program (NELIP).[98] Seventy-five overweight women (pre-pregnancy BMI 25.0 – 29.9 kg/m^2) were recruited between 16 – 20 weeks gestation to participate in the intervention until they delivered. The walking program was individualized based on target heart rate (30% of peak heart rate reserve) for each participant and was performed three to four times a week (40 minutes per session) under supervision of the researchers at least once per week.

The results of this intervention showed that 80% of the participants did not exceed 2009 IOM recommendations while on NELIP and average total weight gain on NELIP was only 6.8 ± 4.1 kg.[51] Unfortunately, many women had gained excessive weight before they joined the program, which lead to an average of 12.0 ± 5.7 kg total weight gain by the end of the intervention. Mottola and colleagues also observed a significant

increase in average daily step counts from the baseline value of 5,677.6 ± 1,738.0 steps to more than 10,000 steps per day.[98]

As demonstrated, there has been success with the use of dietary and physical activity interventions to prevent EGWG[98, 116] and recent work has examined the effectiveness of behavioral counseling and/or modification, with and without the use of a behavior change theory, in addition to diet and physical activity strategies.[18, 117, 118, 121-124] Some interventions have been successful while others have seen limited outcomes in relation to prevention of EGWG.[23, 99, 122]

The Fit for Delivery study is considered one of the more recent and somewhat successful behavioral interventions in the current literature.[23] A total of 400 racially diverse pregnant women of all body weights participated in the study from 10-16 weeks gestation until delivery and were randomly assigned to the intervention or standard care group.[125] The low-intensity behavioral intervention group included all aspects of standard care provided by their prenatal care providers in addition to: i) face-to-face visit with an interventionist at the beginning of treatment to discuss appropriate weight gain; ii) suggested physical activity goal of 30 minutes of walking most days of the week; and iii) dietary modifications through set calorie goals of 20 kcal/kg with an emphasis on decreasing high fat foods and daily self-monitoring of eating. All women in the intervention had contact with a registered dietitian (RD) three times during their participation through 10-15 minute supportive phone calls.

Furthermore, women were provided body-weight scales, food records, and pedometers along with weekly postcards encouraging healthy eating and exercise

habits. Weight gain was monitored throughout their pregnancy by personalized graphs of their gains and any woman who was gaining over or under the recommendations during any one month interval received additional brief phone calls with the RD.[125] The results from this study showed a significant difference between appropriate weight gain in the intervention and control groups in normal weight women (OR 0.38; 95% CI: 0.20, 0.87; p = 0.003) however, there was no difference in appropriate weight gain between groups for overweight and obese women.[125] A difference in all weight groups, normal and overweight, and obese, was observed for return to pre-pregnancy weight at 6 months post-partum, specifically normal-weight women had higher odds of returning to pre-pregnancy weight or below by 12 months compared to overweight and obese women (OR: 1.8, 95% CI 1.1 to 3.0, p = 0.03).[126] Postpartum characteristics including breastfeeding, age, parity, and delivery weeks were not found to significant predictors of return to pre-pregnancy weight at 12 months postpartum. Overall, 30.7% of the intervention group reached their preconception weight at 6 months compared to the 18.7% of standard care women.

A follow-up to the study published recently examined the 12-month outcomes of the intervention with particular interest in PPWR and behavioral changes.[126] In the women who completed the study and 12-month follow-up, those in the intervention arm had greater odds of returning to their pre-pregnancy weight at 12 months postpartum (OR: 0.35; 95% CI: 0.13, 0.98).

Table 2. Multi-component interventions in pregnancy

Author, year	Demographic information and design	Intervention start	Physical Activity	Diet Modification	Counseling component (theory or approach)	Success outcomes	Expected outcomes not met
Polley et al., 2002	N=120 All BMI Clinical RCT Pittsburgh, USA	<20 wks Controls: Usual care from medical provider and WIC	Biweekly newsletters prompting healthy exercise habits; encouraged to increase walking and develop more active lifestyle	Biweekly newsletters prompting healthy eating habits including decreasing high-fat foods and substituting healthier alternatives (fruit and vegetables)	GWG chart with each clinic visit weight sent with feedback after each visit; additional feedback & goal-setting if weight gain outside of recommended ranges Weekly phone calls from research staff to discuss progress towards goals 1990 IOM	**Decreased EGWG in normal weight women (33% vs. 58%)	No effect on GWG in OW women (59% vs. 32%)
Kinnunen et al., 2007	n= 105 6 maternity clinics All BMI, primiparas	8-9 wks Control: n=56 3 maternity	Individual LTPA (LTPA) plan; asked to achieve 800 METmin in	Four dietary recommendations: 1) regular meal patter with breakfast and	One primary dietary counseling session (20-30 min) and three booster sessions	Increased *vegetable & fruit intake (0.8 portions/day	No GWG difference between control and invention (14.3 kg v 14.6

Table 2. continued

Author, year	Demographic information and design	Intervention start	Physical Activity	Diet Modification	Counseling component (theory or approach)	Success outcomes	Expected outcomes not met
…Kinnunen et al.	Controlled trial Finland	clinics, 6 public health nurses (PHN); routine visit with PHN	LTPA per week	one hot meal every day, 2) five portion/day of vegetable & fruit, 3) intake of high fiber bread (>5 g/100 g), and 4) restrict intake of high-sugar snacks to <1 portion per day	(10 min) and one primary PA counseling session (20-30 min) with four booster sessions (10-15 min) with PHN Provided information on weight gain: 1990 IOM	more), **dietary fiber (3.6 g/day more) in intervention group	kg)
Wolff S, et al, 2008	n=50 OB RCT Copenhagen, Denmark	15 wks Control: No meetings with RD or restrictions on energy intake	None provided	Healthy eating according to the Danish dietary recommendations (Fat 30%, Protein 15-20%, carbohydrate 50-55%) EI restricted based on individually estimated ER and EE cost of fetal	10 consultations of 1 hour each with trained RD Goal 6-7 kg weight gain 1990 IOM	***Decreased GWG: (6.6 vs. 13.3) ***Decreased kcal and fat intake Intervention group retained 6.9 less weight than control	

Table 2. continued

Author, year	Demographic information and design	Intervention start	Physical Activity	Diet Modification	Counseling component (theory or approach)	Success outcomes	Expected outcomes not met
…Wolff et al.				growth (factor of 1.4- 1.2 AF +0.2 fetal growth)		4wk postpartum; attenuated increases in fasting insulin, leptin, and glucose	
Claesson et al, 2008∞	N=438, OB Clinical, perspective case control Sweden	Early pregnancy Control: (n=193) usual prenatal care	Aqua aerobics classes weekly (1-2x per week)	Midwife educated women on effects of poor diet and food intake (written material) and weight control	Weekly 30-min individual session with trained midwife to provide motivation and information on healthy GWG and behaviors during pregnancy Goal weight gain: <7 kg **Motivational Interview** 1990 IOM	*Decreased GWG (8.7 vs 11.3 kg); *Increased % gain <7kg (35.7 vs. 20.5)	No difference in neonatal outcomes

Table 2. continued

Author, year	Demographic information and design	Intervention start	Physical Activity	Diet Modification	Counseling component (theory or approach)	Success outcomes	Expected outcomes not met
Asbee SM, et al. 2009	N=100 RCT North Carolina, USA	<16 wks Control: n=43 Routine prenatal care	Instructed to engage in moderate-intensity exercise at least 3x/wk and preferable 5x/wk	Provided pregnancy-specific diet that consisted of 40% of calories from carbohydrates, 30% of calories from protein, and 30% of calories from fat	Initial visit: met with RD to receive a standardized counseling sessions with pregnancy-specific dietary and lifestyle, & weight gain recommendations Provided information on appropriate weight gain during pregnancy and weight from each prenatal appointment plotted on IOM weight gain grid	*Decreased GWG in intervention group (13.0 v 16.6 kg) No difference in percentage that met GWG recommendations (61.4% IG v 48.8% control)	Nulliparous women gained more weight than parous women (16.5 kg vs. 12.5 kg)
Shirazian T et al, 2010	N=21, OB	First trimester	Encourage walking as exercise	Six seminars focused on overcoming	Five one-on-one counseling sessions or phone	*Decreased GWG (17.86 vs 34 lbs)	No difference in % weight gain ≤15 lbs (p=0.159)

Table 2. continued

Author, year	Demographic information and design	Intervention start	Physical Activity	Diet Modification	Counseling component (theory or approach)	Success outcomes	Expected outcomes not met
…Shirazian et al.	Prospective historical matched control New York, USA	Control (n=20): matched to intervention group for BMI, parity, SES	during seminars ; pedometer	barriers to healthy living, nutrition during pregnancy, food label reading Provided food diary and written education materials	calls to monitor progress (at least 1/trimester) Goal weight gain: ≤15 lbs 1990 IOM		
Mottola et al., 2010	N=65 OW, OB Research center intervention, historical control Canada	16-20 wks Control: historical match for pre-preg BMI, age, parity (n=260)	Asked to walk 3-4x/wk at 30% heart rate reserve for 25 mins with goal of 40 mins; Attendance of ≥1 session/wk at research center; self-monitoring with pedometer & exercise log	Individualized meal plan ~2000 kcal/day, 40-55% total energy from CHO, 30% from fat, 20-30% protein, snacks and CHO distributed throughout day; log food at least 1 day/wk with feedback	Meet with RD to discuss individualized meal plan and weekly weigh-ins at research center; weight goal of 0.3-0.4 kg per wk in 2nd & 3rd trimester 1990 IOM criteria	Decreased EGWG during intervention **Decreased kcals and CHO intake, increased protein intake from baseline	

Table 2. continued

Author, year	Demographic information and design	Intervention start	Physical Activity	Diet Modification	Counseling component (theory or approach)	Success outcomes	Expected outcomes not met
Phelan et al, 2011∞	N=401, All BMI Randomized controlled trial Providence, Rhode Island, USA	10-16 weeks Control: (n=200) usual prenatal care + WIC nutrition counseling; pregnancy-related newsletters every 2 mo	Asked to walk 30 min most days + pedometers, Weekly postcards to prompt exercise	20kcal/kg/day + self monitoring of eating (provided body-weight scales, food diaries) Weekly postcards to prompt healthy eating	Individual counseling once + 3 brief (10-15 min) supportive phone calls by RD Personalized graphs of GWG (1990 IOM); additional meal & goal planning if gaining outside of recommendations **Social Learning Theory**	*Decreased EGWG in NW (40.2 vs 52.1%); Lower odds of **maternal gestational hypertension, *c-section, & ***macrosomia	No difference in OW/OB women for GWG or pregnancy complications
Althuizen et al., 2012	n= 219 Randomized controlled trial Eight midwifery practices in	15 weeks Control: n=113; Usual care provided by midwives	Encouraged to participate in 30 min of mod activity on 5 or all days of the week;	Provided education on energy balance, set nutrition related goals with focus on decreasing high fat foods.	Four, 15 min face-to-face counseling sessions with counselors; used principles of **Problem Solving Treatment for primary care (PST-**		*Higher mean birth weight in intervention group No intervention effect on EGWG (71% EGWG of

Table 2. continued

Author, year	Demographic information and design	Intervention start	Physical Activity	Diet Modification	Counseling component (theory or approach)	Success outcomes	Expected outcomes not met
…Althuizen et al.	Dutch towns with 23,000–735,000 inhabitants.		Personalized goals made at each counseling session for type, frequency, intensity, and duration of activity		**pc)** GWG goal: IOM 1990 recommendations by BMI-group; weight plotted on chart for each session		total), postpartum weight retention
Bogaerts et al, 2013	n= 197 OB (BMI ≥29) Randomized controlled longitudinal trial	<15 weeks Control: n=63; routine prenatal care Brochure group: n=58; routine care + brochure with nutrition and physical	Counseled by midwives on energy balance, reading food labels, and healthy food pyramid for pregnancy women. Energy recommendations given: 50-55%	Methods to increase physical activity discussed with midwives	Four 1.5-2 hour counseling sessions using **motivational interviewing** **Transtheoretical model** 2009 IOM	*Significantly lower GWG in intervention and Brochure group compared to control (10.6 and 9.5 kg, v 13.5 kg)	Women in Brochure group had lower % of EGWG and total GWG than intervention group (53.4% v 61.8%, 10.6 v 9.5 kg)

Table 2. continued

Author, year	Demographic information and design	Intervention start	Physical Activity	Diet Modification	Counseling component (theory or approach)	Success outcomes	Expected outcomes not met
…Bogaerts et al.		activity advice during pregnancy to reduce limit EGWG	carbohydrate, 30-35% fat intake, 9-11% protein energy intake.				
Ruah et al., 2013 FeLIPO	N=250 NW, OW, OB Clinical Cluster-RCT Germany	20 wks Control: routine prenatal care with handout with general healthy lifestyle information (no diet or weight gain advice)	Aim: substitute intake of energy-dense foods and high-fat foods with low-fat alternatives, & more fruits, vegetables, and whole grain food. Individual feedback at 20th and 30th week on nutrition habits.	Provided information on PA guidelines (ACOG) and asked women to follow the FITT criteria (frequency, intensity, time, type). Given list of local prenatal exercise programs and advised to participate.	Counseling modules at 20th & 30th week gestation with trained researcher. Counseled on nutrition, PA, and GWG monitoring: weekly self-monitoring of weight on individualized weight gain chart; goal-setting 2009 IOM	**Decreased GWG (14.1 vs 15.6 kg); **Decreased EGWG (38 vs. 60%)	No difference in GDM, birth weight, LGA, mode of delivery between groups

Table 2. continued

Author, year	Demographic information and design	Intervention start	Physical Activity	Diet Modification	Counseling component (theory or approach)	Success outcomes	Expected outcomes not met
Dodd et al., 2014 LIMIT RCT	n= 1,873 Multicentre, randomized trial South Australia	10-20 weeks Control: n= 928 Routine advice on diet, exercise, and GWG	Lifestyle advice (LA) group: Educated on benefits of exercise during pregnancy, provided tips to increase incidental activity and walking, and leisure time PA Walking group (n=40, nested group of LA): In addition to LA group components; participate in >3/wk	Diet advice given based on Australian standards. Individualized education with meal plan and healthy eating tips	Delivered by RD and trained research assistant Goal-setting, self-monitoring progress with workbook, &problem-solving 2009 IOM	*Significant improvement in HEI score for LA group compared to control at 28wks & 36wks **Significant improvement in total physical activity in LA group compared to control	No difference in GWG between groups (9.39 kg LA vs. 9.44 kg C) No significant difference between groups for infant born LGA, preterm birth, or birth complications Low participation in Walking group (only 14% of women attended at least one session)

Table 2. continued

Author, year	Demographic information and design	Intervention start	Physical Activity	Diet Modification	Counseling component (theory or approach)	Success outcomes	Expected outcomes not met
Dodd et al…			supervised walking sessions				
Skouteris et al, 2016 HIPP study	n=261 All BMI Randomized controlled trial Victoria, Australia	18 weeks Control: Education Alone (EA) n= 131 Attended two education session + usual prenatal care	Not specified	Not specified	Heath Coaching (HC) Individual counseling: 1-hr session (in-person or on phone) at baseline, ½ hr session at 27 weeks, 15-min follow-up at 30 wk, and optional 15-min call at 32 wk with Health Coach; promote healthy behaviors and address mood management/body image issues Group counseling: two 3-hr	*Higher readiness and importance to achieve healthy GWG & increased knowledge for appropriate GWG in HC group *Improved sleep quality in HC group	No difference in EGWG between groups (40% HC vs. 36% EA) or total GWG (12.82 kg HC vs. 12.07 kg EA)

Table 2. continued

Author, year	Demographic information and design	Intervention start	Physical Activity	Diet Modification	Counseling component (theory or approach)	Success outcomes	Expected outcomes not met
…Skouteris et al.					education group session; information on healthy behaviors, stress control & coping, and goal-setting 2009 IOM		

*P≤0.01; **P<0.05; ***P≤0.05≤P<0.06.

∞Used a behavior change theory or behavior change technique

IOM: Institute of Medicine; RD: Registered Dietitian; PA: physical activity; EI: energy intake; ER: energy restriction; EE: energy expenditure; USA: United States of America; RCT: randomized controlled trial; EGWG: excessive gestational weight gain; GWG: gestational weight gain; OB: obese; OW: overweight; LTPA: leisure time physical activity

Furthermore, of the women in the intervention arm that gained in excess of IOM guidelines, a greater percentage of them returned to pre-pregnancy weight at 12 months compared to the standard care group (29.5% intervention versus 15.5% usual care). Researchers also showed significant improvement in cognitive restraint scores in the intervention group compared to standard care (p=0.04 during pregnancy; p=0.051 6 months postpartum) and an increase in the proportion of women that participated in self-weighing practices in the intervention group at 30 weeks gestation (OR: 13.7, 95% CI: 5.8-43.6, p=0.0001) and 6 months postpartum (OR 2.7, 95% CI: 1.3-45.9, p=0.009). There was a small but insignificant increase in physical activity in the intervention group from early pregnancy to 6 months postpartum (F=2.5, p=0.06). A significant effect at 12 months was only observed in self-weighing practices (OR: 2.7, 95% CI 1.2-6.1, p=0.02) and physical activity variables.

Findings from the Fit for Delivery intervention are consistent with results from the preliminary study that was used to inform the Fit for Delivery design.[99] The Fit for Delivery preliminary study reported that the number of normal weight women who exceeded the IOM guidelines was significantly less for those participating in the intervention compared to those with usual care (33 versus 58%, respectively; p<0.05).[99] However, as seen with Fit for Delivery, there was no significant effect on overweight women participating in the intervention with 59% of the intervention and 32% of the control gaining more than recommended.[125] Both studies demonstrated that a low-intensity behavioral intervention significantly reduced the proportion of women who exceed the IOM weight gain recommendations in normal weight women; however,

further research is needed to determine how to effectively prevent EGWG among overweight and obese women.

A recent publication evaluating a failed counseling intervention proposed several recommendations to improve the outcomes for future randomized controlled trials aiming to promote appropriate weight gain during pregnancy.[127] Conclusions were drawn from the New Life(style) randomized trial in which the intervention arm of the study consisted of five individualized counseling modules discussing weight gain during and after pregnancy, physical activity and diet, and how to maintain or optimize healthy lifestyle throughout their pregnancy.[122] Counseling sessions were provided by two counselors with a background in physical activity or remedial education and were held face-to-face at 18, 22, 30 and 36 weeks of gestation with a telephone session at 8 weeks postpartum.[127]

There was no effect on the prevention of excessive weight gain (β= -0.05; 95% CI: -1.10, 1.00) or postpartum weight retention (B = 0.94; 95% CI -2.41, 0.53) between the control and intervention group. In total, 145 out of the 219 women regardless of group (71%) gained more than the recommended weight between 15 and 35 weeks of gestation. Results from the follow-up fidelity analysis revealed low attendance at all counseling session (<60.4%), moderate to low dose of intervention and behavioral theory components at the counseling sessions (17.3-60.5%), and better performance based on fidelity criteria by one of the two counselors ($p<0.001$).[127]

A large meta-analysis and a systematic review of interventions found mixed results on the effectiveness of prevention of weight gain during pregnancy.[100, 128] In the

Skouteris et al.[128] systematic review 6 of the 10 studies reported significantly less weight gain in women who participated in a theory-based intervention program, with a mix of weight reduction across all BMI groups. Two of the successful behavior change interventions utilized motivational interviewing, a behavior change technique, as part of the intervention. Of the interventions targeting healthy lifestyle behaviors (i.e., eating and physical activity habits) four of the six reported significant improvements in nutritional habits, however only one of the five studies measuring physical activity reported significant behavior change in relation to increased activity.[128]

Thangaratinam et al.[100] presented a more comprehensive meta-analysis with 44 relevant RCT evaluating three categories of interventions: diet, physical activity, and a mixed approach.[100] The mixed approach included at least one of the following: counseling sessions, education regarding the benefits of diet and physical activity, and feedback on weight gain. The results showed that there was a 1.42 kg reduction (95% CI: 0.95 – 1.89) in GWG with any intervention (diet, PA, and a mixed approach) compared with control; however, the largest reduction was found in dietary interventions (3.84 kg; 95% CI: 2.45 – 5.22, $p < 0.001$). Similar to Skouteris et al.[128], this meta-analysis showed that there was no significant difference between the groups in meeting the IOM weight gain recommendations (relative risk 0.85; 95% CI: 0.66 – 1.1). However, studies based on theory were more effective compared to non-theory based studies targeting EGWG.

Both reviews recommended further and more intensive use of targeted behavior change interventions including motivational interviewing and self-monitoring in order to provide the most benefit for the pregnant population. According to the researchers,

emphasis should be placed on previously successful diet-based interventions utilizing individualization of a healthy diet with a maximum of 30% fat, 15-20% protein, and 50-55% carbohydrates. The need for use of a combination of behavioral interventions in addition to patient education was also highlighted.

Although there is limited evidence to support the efficacy of lifestyle interventions to prevent EGWG, a recent publication from the American Heart Association (AHA) found strong evidence to support the use of a more intensive, comprehensive lifestyle intervention in overweight and obese adults. The AHA 2013 guidelines for the management of overweight and obesity in adults provided strong evidence that an in-person, high-intensity comprehensive lifestyle interventions provided in individual or group session by a trained interventionist is the most effective behavioral weight loss treatment intervention.[129] A comprehensive lifestyle intervention was defined as one that included diet modification, increased physical activity, and a structured behavior change program that includes regular self-monitoring of food intake, physical activity, and weight gain. There is a need for research on the use and effectiveness of a high-intensity, comprehensive lifestyle intervention during pregnancy to prevent EGWG.

Behavior Change Counseling Theory and Strategies

Need for behavior change theory Pregnancy is a teachable moment, which lends to it being an ideal point in time to promote behavioral change. The description of a "teachable moment" is defined as a naturally occurring life transition or health event that is thought to motivate individuals to spontaneously adopt risk-reducing health

behaviors.[18] Using the time during pregnancy to target behavioral change relating to diet and physical activity, as well as change psychological factors such as motivation and/or confidence to make behavior change, could make a difference in weight gain during pregnancy and long-term weight management. Use of a well-established theoretical framework and evidence-based counseling strategies are essential in yielding positive outcomes.[100, 130]

Providing a detailed theoretical framework is important for identifying what, if any, theory can impact behavior change within the pregnant population. A meta-analysis aimed at analyzing how behavior based interventions targeting dietary or physical activity modifications to reduce GWG found little evidence to support the effectiveness of behavioral change techniques in preventing EGWG.[131] A systematic review of behavior change interventions to prevent EGWG found that the theory-based interventions that were successful in preventing EGWG utilized motivational interviewing or another behavior change technique.[130] Only two out of the twelve RCTs used a behavior change theory within their study design. Use of the social learning theory or the transtheoretical model had no effect on weight outcomes.[132, 133] Gardner et al makes a point that limited effectiveness may not be a result of poor theory development due to the limited detail regarding how the theory was used in the design of the two interventions.[131]

Specific attention needs to be given to a few key modifiable aspects of behavior, particularly self-efficacy, motivation, and readiness to change, all of which are factors identified as having a significant contribution in preventing EWGW.[130]

Self-determination theory (SDT) is a motivation theory and a complementary theoretical framework to the use of motivational interviewing, a behavior change technique.[134, 135] SDT is defined as "the approach to human motivation that uses traditional empirical methods while highlighting the importance of humans' evolved inner resources for personality development and behavioral self-regulation."[134] SDT aims to explain how self-motivation can influence personal growth, integration, well-being, and self-regulation of behaviors. The theory posits a person's behavior is dependent on the satisfaction of three basic needs identified in SDT: competence, autonomy, and relatedness. Autonomous motivation and sustained behavior change are directly related to increased satisfaction of these three basic needs. SDT explores social, environmental, and internal processes that support or undermine motivation and the three psychological needs necessary for behavior change.

The theory suggests that all people have the ability to regulate their behavior through personal development and behavioral self-regulation. The foundation of SDT is based on the assumption that all people want to grow and engage in experiences that will foster self-development, also known as the organismic dialectical approach.[134] However, growth and development are not an automatic processes, they require social and environmental support.

The ability for growth is based on the support provided in the social context that will encourage or catalyze change through motivation. The desire to engage in self-development is aided by the regulation of behavioral components (e.g., values and beliefs) that influence different types of motivation (intrinsic and extrinsic motivation).

People choose to act autonomously for a variety of reasons. People may be motivated by money, personal commitments or inherent values. According to SDT, the type of regulation and level of self-determination determine the reason a person chooses to act on a behavior.

The self-determination continuum of extrinsic and intrinsic motivation demonstrates the different types and source of motivation. The continuum moves from "amotivation," a complete absence of motivation, to "intrinsic regulation" (Figure 2). Along the continuum lies a range of motivation from a "high" to "low" level of self-determination: intrinsic, integrated identified, introjected (three types of intrinsic motivation), external motivation, and amotivation. Motivation that stems from internal regulation is controlled less by external factors and is self-initiated, autonomous, and self-chosen. External motivation is controlled by external factors that in turn influence a person's ability to find inherent enjoyment and value in an activity.

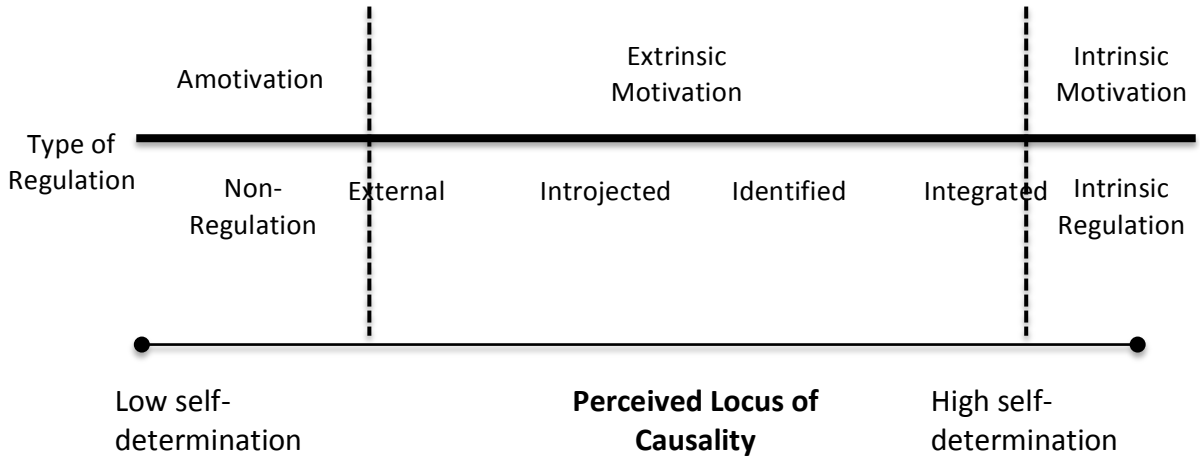

Figure 2: The self-determination continuum (Adapted from Ryan & Deci)[106]

External motivation is characterized as activities done to obtain an external reward, avoid punishment, or done because of social-pressure. Engagement in an activity is based only on external sources. For example, a man with heart disease who decides to follow a certain diet because his family is making him would be considered external motivation.

Introjected motivation is a type of extrinsic motivation but partially self-integrated. In other words, external pressures influence motivation along with some internal pressures such as feelings of guilt, shame, and anxiety. Even though introjected motivation is influenced by internal sources, it is still external because the action is not fully or freely chosen. Take the previous example of a man with heart disease, instead of his family making him follow a certain diet, he chooses to do it independently but it is done because he knows his family wants him to.[134]

Identified motivation is more autonomous than other types of external motivation in that the behavior is valued or important but not identified as enjoyable. For example, the man with heart disease chooses to change his diet because he knows it is important to his heart health.[134]

Integrated motivation is the most internally regulated type of extrinsic motivation. Integrated regulation is very similar to identified regulation in that a behavior is done because it has value. It differs from identified regulation in that the values are consistent with a person's other values and needs. In this case, the man with heart disease decides to change his diet because his greater life-goals and values include being physically healthy and living a long-life in order to see his family grow.[134]

Intrinsic motivation is based on a person's ability to feel satisfaction with a behavior "for its own sake".[134] People who are intrinsically motivated act from a place of inherent enjoyment, satisfaction, or challenge. The Cognitive Evaluation Theory (CET), a mini-theory within SDT proposes that social contexts, such as rewards, interpersonal controls, and ego-involvements, influence motivation. To support intrinsic motivation, satisfaction must come from the inherent enjoyment of engagement in the activity.

Key constructs: The SDT identifies autonomy, competence, and relatedness as the factors needed to facilitate intrinsic motivation or the ability to do an activity for the inherent satisfaction of the activity itself. Ryan and Deci define these basic needs as "an energizing state that, if satisfied, conduces toward health and well-being, but if not satisfied, contributes to pathology and ill-being".[134]

Autonomy is the desire to be in control of one's own life and a sense of free will towards a behavior. Autonomous motivation is tied to a self-regulation and self-determination (integrated or intrinsic motivation).

Competence is control of the outcome through mastery of environment. Lack of perceived competence contributes to amotivation because people feel they cannot change.

Relatedness is the need to connect, interact, and experience caring for others. Seeking relationships that build a sense of belonging and respect for feelings, thoughts, and beliefs help to satisfy this need.

SDT claims that by successfully promoting internalization or the "taking in" of values with little appeal, behavior is likely to change along with the source of

motivation. Adherence to internalized values of a specific behavior goal (e.g., exercise or diet) is thought to promote long-term behavior change as a result of regulating behavior change and motivation.

Use of Self-determination Theory in research and practice A systematic review of 66 physical activity interventions that assessed the relationship between SDT-constructs and outcomes adapted a general SDT process model to analyze the relationships between SDT variables and the predictors/outcomes of a SDT intervention. Teixeria et al.'s[136] SDT process model for exercise behavior suggests a relationship between SDT variables and their expected relationships resulting in success at both short- and long-term behavior change (Figure 3). According to their modal, a greater realization of identified motivation predicts short-term behavior change whereas, more intrinsic motivation predicts long-term change.[136]

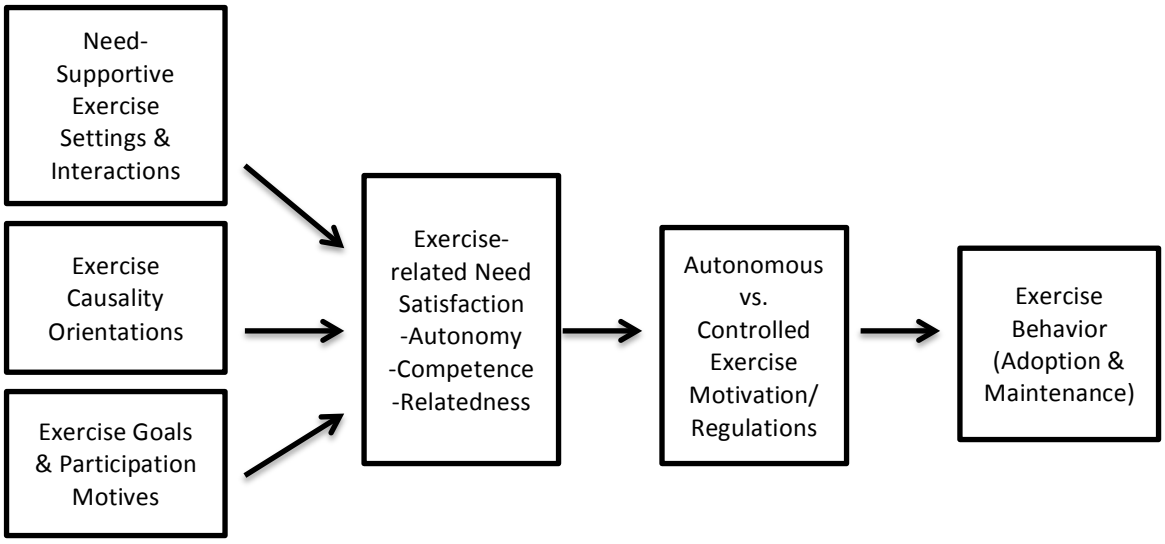

Figure 3: General SDT process model for exercise behavior (Adapted from Teixeira et

Research using SDT to test the effect on behavior change to promote weight control and physical activity has been done in a general population as well as during pregnancy.[137, 138] A randomized control trial in women to promote physical activity and weight control used an intervention designed to follow SDT principles. The aim was to create an autonomy-supportive environment in which counselors promoted each woman to have ownership over their own behavior in order to internalize their behavioral motivation.[137]

The intervention group identified six strategies to promote behavior change and internationalization of that behavior. First, the group established a sustainable knowledge base that supported informed choices through use of neutral language (e.g., "may" or "could", and not "should" or "must"). Second, extrinsic rewards were limited in order to encourage personal choice and self-initiation without extrinsic value being placed on action.

Third, a variety of options were provided for activity and dietary choices. Fourth, options and choices were advised that would lead to a specific outcomes (e.g., weight control) and value for behavior change and possible outcome were provided. Fifth, the intervention team promoted identification of shared values or goals and their lifestyles. Lastly, the intervention team provided informational and positive feedback.

The intervention included 30 group sessions and occurred weekly or bi-monthly, lasting about 120 minutes each. At 12 months, the intervention group showed increased weight loss (-7.29%) and higher levels of physical activity (+138 ± 26 min/day of moderate plus vigorous exercise; +2,049 ± 571 steps per day) compared to control

(P<0.001). Women in the intervention also reported more autonomous self-regulation, higher exercise intrinsic motivation and perceived competence, and more autonomous motives for exercise. The results from this study show that use of the SDT can have an effect on weight control and physical activity; however, time spent in intervention sessions was greater than what is seen in many interventions used to prevent excessive weight gain in pregnancy.

Use of Self-determination Theory during pregnancy. Gaston et al.[138] examined the link between exercise behaviors during pregnancy and the level of autonomous regulation observed at different stages of pregnancy.[138] Over the period of 93 women's pregnancies, exercise behaviors were observed in relation to different forms of motivation and behavioral regulation. Results showed that identified regulation, a conscious valuing of a behavioral goal that is personally important and the third form of extrinsic motivation, was found to be the single best predictor of exercise behavior. Identified regulation was strongly associated with fewer barriers to exercise as opposed to external regulation, or externally rewarded motivation not seen as personally important to the individual.

These finding highlight the need for the intervention counselors to incorporate strategies to enhance autonomous forms of motivation in order to improve exercise behaviors through identified regulated motivation. Furthermore, it is important to note that researchers observed that identified regulation for exercise was significantly greater in the first trimester compared to the second or third trimester. Use of

motivational strategies to promote internal regulation of activities is also important throughout the stages of pregnancy.

Results show that SDT is effective in regulating behavioral change with potential for long-term benefits. Effective use in a pregnant population needs to be evaluated and may be best done in an intensive, clinical setting which will offer the participant a greater amount of flexibility and ease of participation. The Institute of Medicine and the Academy of Nutrition and Dietetics both call for quality health- and theory-related research that can be used to support evidence-based health care.[139, 140] Combining the use of Motivational interviewing, a behavior change strategy, with SDT has potential to promote the internalization of positive behavior change within a pregnant population and should be examined further.

Motivational interviewing (MI). is defined as "a directive, client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence."[135] The purpose of MI is to change the direction of a conversation about behavior change. It is designed to enhance the patient's desire to change and instill the self-efficacy and confidence in the patient to make the changes necessary. The main difference between MI and other behavior change strategies is the client-centered emphasis. In motivational interviewing, the motivation for change must come from within the patient, and the principles of motivational interviewing are designed to facilitate this.

Instead of trying to give the patient reasons for change (e.g. avoiding disease, improving quality of life), the counselor must allow the patient to come up with their

own reasons for change. Tahan et al. describes the opportunity in each counseling session for the counselor to "establish collaborative, respectful, trusting and individualized relationships with their clients/support systems to design a comprehensive and effective case management plan of care."[141]

Spirit of MI: MI is fully conceptualized when both the principles and practices are fully utilized by the practitioner. The basic principles or the spirit of MI include:

Collaboration. The relationship between patient and practitioner is meant to be a partnership, where the work is done "for" and "with" a person in a collaborative manner. MI is defined by the guiding style of counseling, meant to foster an exploration opposed to prescriptive advice.

Evocation. It is the goal of both the patient and practitioner to evoke new ideas and solutions to the problem. In a collaborative manner, the practitioner is working to draw out ideas rather than impose their own ideas and opinions onto the patient. The patient is likely to be motivated to make a change when it is self-determined.

Autonomy. MI emphasizes that patients are responsible for making their own decisions. When a patient is in control of their own choices, there is a greater sense of self-determination and higher motivation to change.

Integrating Motivational Interviewing and Self-determination Theory

The principles of MI and SDT compliment each other and when used together, account for both an applied and theoretical framework for behavior change. Both MI and SDT are established in the theory that people possess the ability to change and that

change stems from an internal source, inherent in all people. The strategy of MI is to guide patients to behavior change by identifying the values and needs that are important to the client. SDT claims that greater identification of values and needs by a client leads to a greater sense of intrinsic motivation that is not controlled by external factors.

Motivational Interviewing is thought to be successful due to its support for each of the three psychological needs identified in SDT, competence, autonomy, and relatedness.[134] The principles of MI target the patient's need for competence through positive feedback and goal setting. The client-centered strategies used in motivational interviewing, such as "rolling with resistance" and letting the client make the decisions, support the patient's need to feel autonomous.

Finally, the patient's need for relatedness is addressed by the case manager's expression of empathy. When the patient feels that they are free from the judgment of the counselor, they can be more open with feedback as the relationship between patient and professional deepens. When the patient feels that their needs are being addressed, the likelihood of increased openness, increased adherence and successful behavior change are greater.[142]

Conclusion

In the last decade, there has been both a national and global call for reduction in obesity. Pregnancy is an ideal moment to intervene for multiple reasons. It is a rare moment in time that women are more inclined to modify behaviors to optimize the health of their unborn fetus. Frequent interactions with health care providers offer a

unique opportunity to facilitate behavior modification and interventions. Unfortunately, physical activity and diet recommendations are rarely discussed and gestational weight gain recommendations are either not shared or not appropriate for the patient's pre-pregnancy BMI status.

The substantial research conducted on GWG interventions provides much of the foundation necessary to design an intervention that will be successfully at promoting appropriate weight gain. Recent systematic reviews of GWG interventions designed to prevent EGWG discovered that modification of diet and exercise[115] are necessary to effect GWG however, interventions using both have largely been unsuccessful at increasing the proportion of women meeting weight gain guidelines.

It is the goal of the current study, the Behavioral Wellness in Pregnancy, to combine what is known to improve outcomes (diet and PA modification) and the demand for interventions to use a behavioral framework known to yield changes in healthy behaviors and increase intervention effectiveness.[100]

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CHAPTER 3: THE BEHAVIORAL WELLNESS IN PREGNANCY STUDY: A RANDOMIZED CONTROLLED TRIAL OF A MULTI-COMPONENT INTERVENTION TO PROMOTE APPROPRIATE GESTATIONAL WEIGHT GAIN

A paper to be submitted to American Journal of Clinical Nutrition

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Abstract

Objective: Adequate weight gain during pregnancy is important to both maternal and fetal outcomes. To date, a randomized controlled trial has yet to show efficacy for a gestational weight gain (GWG) intervention to increase the proportion of women meeting weight gain guidelines during pregnancy. **Objective:** To determine if a multi-component behavioral intervention with a Registered Dietitian Nutritionist (RDN) significantly improves the proportion of women that adhere to the 2009 IOM weight gain guidelines. **Design:** Participants were randomized to usual care (n = 24) or intervention (n = 23) between 8-14 weeks gestation. The intervention included a minimum of 6 one-on-one counseling sessions over approximately 30 weeks focusing on healthy diet and physical activity (PA) goals. In addition to the face-to-face visits, weekly communication via email supported healthy eating, PA, and appropriate weight gain. GWG, PA, and diet were assessed between 8-14 weeks, 26-28 weeks and 34-36 weeks gestation; weight retention was measured two-months postpartum. **Results:** The proportion of women meeting the guidelines was significantly greater in those receiving the intervention than usual care (60.8% vs. 25.0%, OR: 4.67 CI: 1.3-16.2; p = 0.019). Further, 36.4% of the intervention women were at or below pre-pregnancy weight at

two-months postpartum compared to 12.5% in usual care (p = 0.05). **Conclusions:** A multi-component behavioral intervention improved adherence to 2009 IOM weight gain guidelines. **Trial registration:** Clinical trial with clinicaltrial.gov: NCT02168647

Introduction

Gestational weight gain (GWG) is an important, modifiable risk factor during pregnancy to prevent maternal and fetal complications. Data from the Pregnancy Risk Assessment Monitoring System and the National Vital Statistics System reported that approximately 47% of women, regardless of pre-pregnancy BMI, are gaining in excess of the weight gain guidelines for pregnancy.[1, 2] Excessive gestational weight gain (EGWG) is an even greater concern for women who are categorized as overweight or obese prior to pregnancy, with 66% of overweight women and 55% of obese women gaining in excess.[1]

Regardless of pre-pregnancy BMI, the consequences of EGWG affect both mother and infant, with increased risk for post-pregnancy weight retention and in turn, cumulative weight-gain over several pregnancies leading to development of chronic disease such as type 2 diabetes, heart disease and cancer.[3-5] Excessive weight gain during pregnancy is also associated with obesity of offspring from infancy into adulthood.[6, 7] Thus, reducing the percentage of women gaining weight outside of current guidelines has long-term health implications for both mother and child. In a recent impact study, researchers compared the effect of GWG on obesity and found that eliminating EGWG during pregnancy significantly reduced prevalence of obesity at age 40.[8]

To date, results from existing interventions targeting weight gain during pregnancy are equivocal. Thus, it is unclear how to effectively prevent EGWG. [9-12] Utilizing behavioral theory and one-on-one counseling to elicit behavior change is effective for behavior change in other populations[13-17] and may be an effective approach to reduce the proportion of women who gain outside of the IOM guidelines.[9] One potentially useful theory is Self-Determination Theory (SDT), a theory that explores human motivation and the factors that encourage or undermine health-related behaviors.[18] In non-pregnant populations, the use of SDT as a theoretical framework for weight loss interventions has been effective at facilitating behavior change that was necessary for successful outcomes.[14, 19] In a pregnant population, targeting behaviors including diet and physical activity in combination with a Motivational Interviewing (MI) counseling approach may be more effective to reduce EGWG.

The primary aim of the study was to test the efficacy of a SDT-based lifestyle intervention to increase the proportion of women meeting the 2009 IOM weight gain guidelines compared to usual care (UC) using a randomized controlled design. A secondary aim was to determine the influence of the intervention on postpartum weight retention. This study, The Behavioral-Wellness in Pregnancy, is a continuation of previous research conducted as part of The Blossom Project. The mission of The Blossom Project is "to improve the lives of women and their children, one pregnancy at a time". Previous research conducted by The Blossom Project laboratory included evaluation of prenatal lifestyle, specifically diet and PA, and pregnancy interventions.[20, 21]

Subjects and Methods

Participant Selection. Fifty-six pregnant women between the ages 18-45 years old with a singleton pregnancy, and between the 8th and 14th week of gestation were enrolled from a Midwest town between April 2014 – March 2017. Women were recruited from the community with the assistance of two local OBGYN offices, via word of mouth, online postings, and fliers distributed to the community. Mass emails were also sent out to university faculty, staff, and students. Women were only eligible if they participated in exercise less than 3 sessions per week for less than 30 minutes per day for at least 6 months prior to conception. The criterion for "inactive" was established based on the cut-off for defining "regular exercise" during pregnancy.[22-24] Additional inclusion criteria included a body mass index (BMI) between 18.5-45.5 kg/m^2, receiving regular prenatal care, and physician documented approval to participate in the study. Exclusion criteria were a history of chronic disease (e.g., Type 1 diabetes, cardiovascular disease, thyroid disease), and previous diagnosis of gestational diabetes or pre-eclampsia, Additionally, to be eligible, all participants had to be willing, if asked, to walk 10,000 steps per day, meet with a RDN on a monthly basis, and follow nutrition recommendations provided by the RDN. Each participant's medical provider confirmed qualification for participation and provided medical consent to participate.

Ethics approval was obtained from the Institutional Review Board at Iowa State University (Ames, Iowa) and all participants signed informed consent documents prior to participation. The trial was registered as a clinical trial with clinicaltrial.gov, identifier code NCT02168647.

Study Procedures.

At the initial study visit, participants self-reported demographics including age, education level, race, marital status, number of previous pregnancies, parity, average weekly minutes of moderate-vigorous physical activity (MVPA) prior to pregnancy, and weekly MVPA since becoming pregnant (prior to enrollment). At this time, women also self-reported their pre-pregnancy weight and provided consent to obtain the weight from all prenatal appointments. Height and weight were measured (without shoes, coats, or heavy clothing items) to the nearest 0.1 cm and 0.1 kg, respectively (Ayrton 226 Hite-Rite Precision Mechanical Stadiometer, Quick Medical GS, Snoqualmie, WA, and Detecto Model 6855 Cardinal Scale, Manufacturing Co., Webb City, MO).

Data collection. Data was collected for all participants during three, 7-day data collection periods between week 8-14 (baseline), week 26-28 (visit 2), and week 34-36 (visit 3) of pregnancy. Each data collection period was identical except for the addition of an oral glucose tolerance test at visit 2. Trained members of the Blossom Project collected and analyzed all research data. These included the project principle investigator, lead graduate student, and undergraduate dietetic students.

Usual care. Women randomized to the UC group attended their routinely scheduled visits with their prenatal providers. At each prenatal visit, nurses weighed participants and the recorded weight was faxed to Blossom Project staff. The weight from each prenatal appointment was plotted on an IOM weight gain chart specific to each participants pre-pregnancy BMI and emailed to the participant within a week of the appointment.[25] Appropriate weight gain was determined based on pre-pregnancy

BMI using self-reported pre-pregnancy weight and height measured by researchers at the enrollment appointment. Weight gain was calculated as weight measured at each prenatal appointment or data collection visit minus self-reported pre-pregnancy weight. The researchers provided no additional lifestyle counseling to this group

Intervention. Participants in the intervention received a multi-component (PA and diet) behavioral lifestyle intervention that included counseling and a wearable fitness tracker including dietary software (Fitbit® Flex Activity Monitor; Fitbit Inc., San Francisco, CA) and was targeted towards increasing physical activity and modifying carbohydrate intake, with the primary goal of increasing the proportion of women that met the 2009 IOM GWG weight gain guidelines. Participants in this group took part in a minimum of six, 15-30 minute one-on-one visits with a Registered Dietitian Nutritionist (RDN)/Licensed Dietitian from no later than week 14 gestation to childbirth. One-on-one sessions took place at a research facility or the OBGYN clinic where the participant received their routine prenatal care. Participants were weighed by the RDN at each face-to-face session. Weight gain was plotted on an IOM weight gain chart and feedback on weight gain was provided.

The counseling sessions focused on appropriate weight gain during pregnancy through the use of an individualized meal plan, PA goals, and behavioral modification. Participants were able to view steps taken per day and log food intake on the Fitbit® website. Additionally, participants had weekly email contact with the RDN to discuss nutrition and physical activity goals, weight gain, and address any questions or concerns.

Physical Activity intervention. Following randomization, women assigned to this group received their Fitbit Flex and were instructed on its care and use including both PA and diet-related features on the app. Each participant was provided a Fitbit® website account set up with a Blossom Project username code to ensure privacy of the participant's identity. The monitor tracks daily steps taken, distance traveled, and active minutes. Use of a Fitbit® product included access to the product website that allowed participants to log activities and dietary intake. Participants were encouraged to use their Fitbit to motivate and track adherence towards the recommendation of ≥10,000 steps per day. The first three weeks of the program allowed for a gradual increase in walking time with participants increasing step counts by 10% each week following baseline data collection.

Dietary intervention. The dietary intervention included a 225-gram carbohydrate diet emphasizing a lower percentage of total calories from carbohydrates to achieve appropriate weight gain. Based on a 2000-calorie diet, women were asked to consume approximately 45% calories from carbohydrate, 25% protein, and 30% fat with an emphasis on whole grains, lean proteins, and mono- and polyunsaturated fats. A personalized meal plan was developed to outline appropriate intake throughout the day. Additional documents including a flexible three-day meal plan example, a "quick tips" reference sheet, and a daily food group checklist, were created and provided to participants to encourage use and compliance of the meal plan. Participants were also asked to keep a food journal on the Fitbit® website on one or two days per week to be reviewed with the RDN during the monthly counseling sessions.

Behavior-counseling sessions. Women randomized to the intervention group also participated in monthly one-on-one counseling sessions with the RDN. The counseling sessions were used to promote behavior change and were based on the theoretical framework of self-determination theory (SDT) and Motivational Interviewing (MI). To promote behavior change, researchers used the MI counseling approach to facilitate a sense of ownership over participant's behavior, with the goal to internalize the locus of control and motivation. Strategies used by the researchers included: creating an automony-supportive environment by increasing physical activity and dietary knowledge, supporting change talk from participants, providing positive feedback and ideas for behavior change when advice was asked, aiding participants in the exploration of their values, goals, and the discrepancies between current behaviors and desired outcomes, and encouraging choice and self-initiation.

All sessions followed the four phases of process change used in MI.[26] Behavior change techniques specific to MI used at each session included: open-ended questions, affirmation, reflective statements, summary statements (OARS), questions to elicit change talk (DARN questions- Desire, Ability, Reason, Need), double-sided reflection, hypothetical thinking, support for change, emotional support, and a summary of the plan. Session structure and broad goals were designed to model a successful weight loss SDT-based intervention.[14]

Outcomes. *Gestational Weight Gain.* The primary outcome was the proportion of women that met the 2009 IOM weight gain guidelines. Weight gain from each data collection visit was used to examine the rate of GWG by subtracting self-reported pre-

pregnancy weight from the measured weight at each visit. Total weight gain was calculated as measured weight by research staff at the final data collection visit minus self-reported pre-pregnancy weight. Recommended GWG was calculated as expected first trimester total GWG + ([gestational age at time of weight measurement] – 13 weeks 0 days] * weekly recommended weight gain for 2nd and 3rd trimesters based on pre-pregnancy BMI). Participants total GWG was categorized as inadequate, adequate, or excessive using the minimum and maximum values of the weekly-recommended weight gain range.[25]

Pregnancy complications and fetal outcomes. Data on birth outcomes was collected from delivering hospitals with the consent of each participant. At two-months post-partum, participants returned to the research center for weight measurement and a post-partum survey to provide additional birth information.

Physical Activity. Prior to the start of each data collection visit, all participants were instructed how to wear a SenseWear® Mini armband (SenseWear® armband by BodyMedia, Inc., Pittsburgh, PA), an activity monitor, to objectively record quantitative data on daily PA including energy expenditure and PA intensity. Previous research has shown this monitor is a good predictor of energy expenditure compared to indirect calorimetry in mid-pregnancy.[27] Participants were asked to wear the monitor for a full 7-consecutive, 24-hours per days except when submerged in water. Additionally, women were asked to record their daily PA in a log. Participants were also instructed on how to wear an activPAL™ activity monitor (PAL Technologies Ltd., Glasgow, UK) that is worn on the upper thigh over the quadriceps muscle and attached to the leg using an adhesive

pad. Previous research has shown the activPAL™ to effectively detect change in posture (sitting/lying, standing/stepping), time spent in different positions (upright, sitting, lying), and step count.[28-32] Instructions on how to use the monitors were given verbally and in writing.

Dietary intake. A weighed 3-day diet record was used to assess dietary intake. During each data collection visit, participants were asked to weigh their food on two weekdays and one weekend day using a food scale provided by the research team. Nutritionist Pro™ (Axxya Systems, Stafford, TX), dietary analysis software was used to analyze the intake data (e.g., total energy intake, macronutrients [absolute and relative amounts]). The Healthy Eating Index 2010 (HEI-2010) was used to assess diet quality. HEI is a diet quality assessment tool that aligns with the Dietary Guidelines for Americans 2010.[33] It is validated as a reliable measure of diet quality for the general population as well as for pregnant and lactating women.[34]

Statistical analysis. A sample size of 40 women, 20 women per study arm, was estimated as necessary to have 80% statistical power with statistical significant set at $p < 0.05$ to detect a 40% difference between the proportion of intervention and usual care participants that gained outside of the 2009 IOM weight gain guidelines for pregnancy. A sample size of over 50 women was randomized to allow for 20% participant attrition.

Demographic group differences were analyzed using chi-square test for categorical variables and student's t test for continuous variables. Weight gain, the primary outcome, was assessed as both a continuous (kg) and a nominal variable (under, normal, over). Chi-square tests were used to assess group differences for the

following analysis: 1) the proportion of women who met or did not meet the IOM guidelines; 2) the difference in the proportion of those who gained weight below, within and exceeded the recommended ranges; and 3) the proportion of women who were above or at/below pre-pregnancy weight at two months postpartum. Independent sample t-tests were used to compare the difference in postpartum weight retention, infant birth weight, birth length, gestational length at delivery, and APGAR scores between groups. To assess rate of GWG, the weight and exact gestational date from each prenatal appointment and data collection visit were used to calculate a slope for each participant's weight gain. Independent sample t-tests were used to compare the difference in slope between groups.

Multiple logistic regression analysis was used to examine the effects of treatment group and BMI category and their interaction on the proportion of women who exceeded the 2009 IOM recommended weight gain. The groups of women with weight gain below or within the recommendation were combined in this analysis.

Mixed-model repeated-measures analysis was used to assess the effects of treatment group over time (gestational length) on changes in physical activity and dietary variables. Participants were treated as a random effect in the model. Post hoc pair-wise comparisons of least-squares means were performed on significant differences between factors among levels. Significance was set at p of < 0.05.

Results

Participant enrollment and baseline characteristics. Seven women withdrew from the study for the following reasons: miscarriage (n=4; 2 intervention; 2 UC) and

lack of time (n=3; 2 intervention, 1 UC). A total of 48 women completed all data collections periods. One additional woman was excluded from the analysis due to weight loss related to additional health issues during the study (Figure 1). Thus, 47 women were included in analyses. Participants were predominately White (82.9%), married (97.9%), and had at least a 4-year secondary degree (89.3%). There were no significant differences in baseline characteristics between groups (Table 1, n = 47). Among women in the intervention group, 100% received ≥6 one-on-one counseling sessions (average session attendance = 6.8 ± 0.7).

Gestational weight gain. Regardless of pre-pregnancy BMI, there was a significant difference between intervention and UC women who adhered to the IOM guidelines at week 34-36 of pregnancy (60.9% versus 25.0%, respectively; $p = 0.015$). Furthermore, in the intervention group, 30.4% of women gained excessively compared to 62.5% of women in the UC group (Table 2). Net weight retention at two-months post partum was lower in the intervention group, though not significantly different between groups (4.4 ± 4.5 kg UC versus 2.3 ± 3.5 kg intervention; $p = 0.08$).

Total GWG (12.5 ± 4.8 kg UC versus 11.0 ± 3.6 kg intervention; $p = 0.11$) and rate of GWG (0.50 ± 0.17 UC versus 0.42 ± 0.12 intervention; $p = 0.06$) did not significantly differ between groups.

BMI group and gestational weight gain. There was no interaction between treatment group and BMI category for weight gain outside of the IOM guidelines but there was a main effect of treatment group ($p<0.003$). Interactions between treatment group, GWG category, and pre-pregnancy BMI category were explored. A significant

treatment effect on adherence to the IOM categories of total weight gain was observed in women categorized as overweight (0% UC women within range versus 57.1% of intervention women within range; $p = 0.03$).

Pregnancy complications and fetal outcomes. With the exception of one-minute APGAR score, there were no significant differences in pregnancy complications or birth outcomes between groups (Table 5).

Lifestyle components. We examined the effect of the intervention on diet and PA behaviors including average daily step count, MPVA in 30-minute bouts of length or more, total energy intake, and percent of energy from carbohydrates. There was a significant interaction between treatment group and time for average daily step count ($F = 6.75$, $p = 0.0019$) (Table 4). Average daily step count increased from baseline to weeks 26-28 in the intervention group ($p = 0.0002$) and was significantly greater in the intervention group compared to UC at weeks 26-28 ($p = 0.0062$). MVPA in bouts of 30-minute or more significantly increased from baseline to weeks 26-28 in the intervention group ($p = 0.008$). The intervention group spent significantly greater amount of time in bouts of MVPA in 30-minutes or more compared to the UC group at weeks 26-28 ($p = 0.014$).

There was a significant main effect of group for percent total energy from carbohydrates ($F = 3.72$, $p = 0.028$). The intervention group reported intake of significantly less carbohydrates (measured as percent of total energy from carbohydrates) at week 26-28 ($p = 0.0085$) and week 34-36 ($p = 0.0057$) compared to

the UC group. There was a significant increase in intervention HEI from baseline to week 26-28 (p<0.01) but no change in HEI scores across time for UC.

Discussion

Promotion of appropriate weight gain during pregnancy is a challenge. The findings from this study suggest that a SDT-based, multi-component intervention using MI significantly may be an effective tool for helping women achieve healthy weight gain throughout pregnancy and positively change behaviors related to better health outcomes including improved diet quality and increased physical activity.

In the last decade, a number of meta-analysis and systematic reviews have assessed the impact of lifestyle interventions using physical activity, and dietary modifications alone or in combination with the intent to limit EGWG.[10, 11, 35-37] Although there is sufficient evidence to suggest that lifestyle interventions have a modest effect on total weight gain (kg), there has not been a significant effect on increasing the proportion of women gaining within GWG guidelines.[9] When significance has been found, reductions are mainly observed for the participants with a normal pre-pregnancy BMI (≤24.9 kg/m^2), while those in higher BMI categories do not improve. Results from the present study demonstrate that this intervention was effective at increasing the proportion of women that met the current weight gain guidelines, regardless of BMI category, with greater than 50% of women categorized as overweight or obese successfully meeting the current guidelines.

There are several components implemented in this study that may have contributed to positive outcomes compared to previous lifestyle interventions. These

include the use of an individually tailored, multi-component, and higher intensity intervention grounded in behavior change theory**.** Using a "one-size-fits-all" approach has not been an effective strategy in previous GWG interventions, even when diet and PA-related behavior modifications were used together.(13, 14) For example, The Fit for Delivery study, a low-intensity behavioral-theory based intervention, included education on appropriate weight gain, diet modification, and PA goals.[38] Their standardized approach for all women regardless of pre-pregnancy BMI resulted in a significant difference in GWG for normal weight women (45.7% intervention group met vs. 35.1% standard care group) but was not successful among overweight and obese women (20.7% intervention group met vs. 24.4% standard care group).[38] Although some success was reported from Fit for Delivery study, the current study stands apart due to several key components that were implemented throughout the intervention. We believe these key components led to the high proportion of success among all women, specifically the individually tailored, one-on-one intensive care.

This study tailored the intervention to each woman's targeted diet and PA needs and goals, which may have improved its overall effectiveness. It is well established in prenatal intervention research that using both diet and PA can effectively minimize EGWG.(34) For example, the Nutrition and Exercise Lifestyle Intervention Program (NELIP) employed both diet and PA modification and demonstrated significant success in preventing EGWG while enrolled in the program compared to a historical control. However, although there was a decrease in the amount of weight women gained during the intervention, many of the women had already gained in excess prior to enrollment,

which led to overall excess in gain at the end of the study highlighting the need for early intervention.[39] Other studies have reported success at improving PA or diet behaviors, yet were unable to prevent EGWG.[21, 39-41] A previous study published by the Blossom Project found that targeting PA behaviors during pregnancy is effective at improving overall PA but found no difference in weight gain outcomes between groups.[21] Consequentially, intervention group participants increased PA but also significantly increased caloric intake. Using the results from both the NELIP and previous Blossom Project study, we designed the current study to intervene early in pregnancy and provide both PA and diet goals, which may have contributed to the positive change observed in diet quality and increased PA, leading to the overall success of the current intervention.

In addition to early intervention and modification of both PA and diet behaviors, the use of a higher intensity (≥six counseling sessions during intervention plus weekly contact) is a likely contributor to the significant effect of adherence to GWG guidelines. A recent systematic review for MI-based weight loss interventions in non-pregnant populations found that interventions that provide individual counseling, in addition to having a treatment duration of six months or more, were more likely to report a significant effect of intervention on weight loss.[13] The Health in Pregnancy and Post Birth study (HIPP), a comprehensive lifestyle intervention that utilized health coaching to prevent EGWG, reported no difference in EGWG between groups. [41] The authors attributed the lack of effect to the length of their intervention and a single one-on-one counseling session with a health coach. Unlike previous studies, a high percentage of

overweight and obese women in the current study's intervention group that met the current weight gain guidelines. This further highlights the need for higher intensity and individualization of care for these populations, the groups that are also the highest risk of gaining in excess.[2]

Looking beyond weight gain, the intervention had no consequential effects, negative or positive, on pregnancy or birth complications. Although there was a significant difference in one-minute APGAR scores between groups, with a higher score reported in the intervention group, these scores are relatively subjective and a one-point difference is not likely a meaningful outcome. Previous GWG intervention studies also found no positive effect of intervention on maternal and fetal outcomes.[38, 42-45] However, larger prospective studies suggest that both timing and amount of weight gain influence infant outcomes including birth weight, body composition, and long-term health.[46-48] In the current study, we were adequately powered to detect a difference in our primary outcome but not secondary outcomes like these. As such, larger studies are necessary to determine the effect of this intervention on fetal outcomes.

Strengths of this study included its randomized design, enrolling individuals of all BMI groups, and high-intensity and frequent contact with the research staff. Researchers also provided women with feedback on weight gain that was adjusted according to the IOM recommended weight specific to each woman's gestational length at the time it was measured. This provided woman a tailored view of their weight gain throughout pregnancy and an opportunity to discuss how to adjust if they were gaining too much or not enough weight with the RDN. Additionally, all women randomized to

the intervention group received tailored care and counseling from early pregnancy until childbirth. Lastly, the study used an established behavior change theory and MI approach to facilitate behavior change.

The study did have some limitations. The sample was relatively homogenous with respect to education, marital status, and ethnicity, which is reflective of the region in which the study was conducted. Nonetheless, the lack of diversity limits the generalizability of findings. Further, women that enrolled and participated in this study were aware of the intervention expectations, which included asking women to modify their diet and PA behaviors and as such, may have been more motivated to change than the general pregnant population. Lastly, though the high intensity and frequent contact with participant is a significant strength of this study, it also potentially limits the translatability of this intervention as time and financial constraints may preclude providing this level of support throughout pregnancy in a non-research setting. While the current design may not be readily translatable to a clinical setting, it is important to note that the current study was an efficacy trial to determine whether or not this intervention would be effective.

Conclusions

In conclusion, the use of a multi-component, behaviorally-based intervention designed using a theoretical framework (SDT) and utilizing a behavior change counseling approach (MI) significantly increased the proportion of women in the intervention group that met current weight gain guidelines for pregnancy compared to women receiving usual care. The potential impact that gaining the appropriate amount of weight during

pregnancy has on long-term health outcomes highlights the importance of continued work to substantially reduce the occurrence of EGWG. The current study was an efficacy trial and as such, it is important to further determine whether this RCT can be translated to a larger, more diverse pregnant population in a clinical setting. In addition, before this intervention can be translated to a clinical care setting, further analysis will need to identify key components, such as individualized one-on-one contact with a trained health professional, intervention components, length, and intensity of intervention, contributed to the success of this study. Based on the results of this study, lifestyle behavior modification can work in increasing the proportion of women that gain the appropriate amount of weight during pregnancy. However, it is important to create a delivery method using the components of the current study that is more likely to be adapted and translated in our current health care setting.

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Authors' Contributions

All authors contributed to the study design. LMBS conducted the intervention under the direction of CGC and drafted the manuscript.

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TABLES

Table 1. Descriptive characteristics of study participants at baseline

	All Mean ± SD (n= 47)	Usual Care Mean ± SD (n= 24)	Intervention Mean ± SD (n= 23)	P-value
Pre-pregnancy BMI (kg/m^2)	25. 0 ± 4.5	24.3 ± 4.1	25.7 ± 5.0	0.26
Pre-pregnancy weight (kg)	69.4 ± 15.1	67.3 ± 15.0	71.7 ± 15.3	0.32
Age (years)	31.4 ± 4.1	31.2 ± 3.6	31.6 ± 4.6	0.73
No. of pregnancies	2.3 ± 1.4	2.5 ± 1.3	2.2 ± 1.4	0.37
Parity	1.0 ± 1.0	1.0 ± 0.9	1.0 ± 1.1	0.78
Pre-pregnancy volume of exercise[1]	47 ± 41	54 ± 44	40 ± 36	0.23
Volume of exercise prior to enroll[1]	33 ± 43	29 ± 37	38 ± 50	0.47

[1]Volume of exercise was self-reported in minutes per week.

Table 2: Gestational weight gain (GWG) adequacy during pregnancy by treatment group[1]

			Intervention effect		
	UC (n= 24)	Intervention (n= 23)	OR	95 % CI	P[3]
Met IOM (34-36 weeks gestation), n (%)	6 (25%)	14 (60.8%)	4.7	1.3, 16.2	0.0155
IOM categories of total weight gain					
Exceed IOM, n (%)	15 (62.5%)	7 (30.4%)	5.0	1.3, 18.6	0.0294
Mean gain (kg)	15.0 ± 4.0	15.3 ± 1.9			
Within IOM, n (%)	6 (25.0%)	14 (60.8%)	1.0		
Mean gain (kg)	9.5 ± 1.4	9.7 ± 1.6			
Below IOM, n (%)	3 (12.5%)	2 (8.7%)	3.5	0.5, 26.6	0.31
Mean gain (kg)	5.9 ± 1.5	5.3 ± 1.8			
2 months postpartum					
Subjects at or below pre-pregnancy weight (%)	12.5%	36.4%	4.0	0.9, 1.7.7	0.05

Table 3. Gestational weight gain (GWG) during pregnancy by treatment group and BMI category[1]

	Normal- weight		Overweight		Obese	
	UC (n= 16)	Intervention (n=12)	UC (n= 6)	Intervention (n= 7)	UC (n= 2)	Intervention (n= 4)
Prepregnancy BMI (kg/m^2)	21.8 ± 1.5	22.1 ± 2.5	28.3 ± 1.3	27.6 ± 1.6	32.6 ± 0.1	33.6 ± 3.4
Prepregnancy weight (kg)	58.3 ± 7.0	60.3 ± 7.9	81.8 ± 8.1	78.9 ± 8.3	95.0 ± 2.3	93.6 ± 7.3
Met IOM (34-36 weeks gestation), n (%)	6 (37.5%)	8 (66.6%)	0 (0.0%)	4 (57.1%)[a]	0 (0.0%)	2 (50%)
Total weight gain (kg) (range, kg)	12.7 ± 4.8 (7.2-23.1)	11.8 ± 3.3 (6.6-18.1)	10.9 ± 4.8 (3-17.9)	9.3 ± 3.1 (4.1-13.6)	16.1 ± 3.8 (13.4-18.8)	11.7 ± 4.7 (7.5-16.4)
IOM categories of total weight gain						
Exceed IOM, n (%) Mean gain (kg)	8 (50.0%) (16.4)	3 (25.0%) (16.5)	5 (83.4%) (12.5)	2 (28.6%) (12.9)	2 (50%) (16.1)	2 (50%) (15.8)
Within IOM, n (%) Mean gain (kg)	6 (37.5%) (9.5)	8 (66.6%) (10.7)	0 (0.0%) --	4 (57.1%)[a] (8.8)	0 (0.0%) --	2 (50%) (7.7)
Below IOM, n (%) Mean gain (kg)	2 (12.5%) (7.4)	1 (8.3%) (6.6)	1 (16.6%) (3.0)	1 (14.2%) (4.1)	0 (0.0%) --	0 (0.0%) --

[1]IOM recommendation: 2009 Institute of Medicine GWG recommendations.
[a]Indicates significant treatment effect within each BMI group ($p < 0.05$).

Table 4: Behavioral component changes during pregnancy[1]

	Usual Care (n = 24)	Intervention (n = 23)	Time	Treatment x time
Steps per day			F = 5.36, p = 0.0063	F = 6.75, p = 0.0019
Baseline	6808 ± 2165	6661 ± 1737[b]		
Week 26-28[a]	6629 ± 2322	8603 ± 3062[b]		
Week 34-36	6283 ± 2322	7410 ± 2767		
≥30 min bouts MVPA			NS	F = 4.98, p = 0.0088
Baseline	38.8 ± 56.6	41.4 ± 88.6[b]		
Week 26-28[a]	28.4 ± 55.8	81.3 ± 73.7[b]		
Week 34-36	52.5 ± 94.7	45.6 ± 60.4		
Total energy intake			F = 3.72, p = 0.028	NS
Baseline	1734 ± 563	1908 ± 360		
Week 26-28	1889 ± 533	2095 ± 455		
Week 34-36	1974 ± 523	1978 ± 422		
% of energy from carbohydrates			NS	NS
Baseline	53.1 ± 10.9	49.0 ± 8.5		
Week 26-28[a]	51.8 ± 7.4	45.6 ± 9.6		
Week 34-36[a]	54.0 ± 8.0	49.1 ± 7.1		
HEI score			F = 3.97, p = 0.0221	F = 2.84, p = 0.0633
Baseline	63.1 ± 16.4	61.2 ± 10.5[b]		
Week 26-28	63.9 ± 15.8	70.6 ± 12.8[b]		
Week 34-36	65.9 ± 14.8	66.0 ± 10.4		

[1]Values are reported as means ± SD

[a]Post hoc pair-wise comparison between groups at timepoint significant p<0.01.

[b]Post hoc pair-wise comparison for change in score across pregnancy significant, p<0.01

Table 5. Effect of treatment on pregnancy outcomes

	Usual Care	Intervention	*p*-value
Birth weight (kg)	3.59 ± 0.6	3.58 ± 0.4	0.98
Birth length (cm)	52.4 ± 3.7	52.1 ± 2.3	0.79
Gestational age at delivery (days)	277 ± 12	274 ± 15	0.41
APGAR score			
1 minute	7.6 ± 1.8	8.4 ± 0.5	0.05
5 minute	8.8 ± 0.7	9.0 ± 0.0	0.29
Pre-term delivery (<37 wk) (n)	1	0	0.33
Low birth weight (<2500 g) (n)	1	0	0.52
Macrosomia (>4000 g) (n)	6	4	0.72
Cesarean delivery (n)			
Planned	0	3	0.10
Unplanned	2	3	0.66
Gestational diabetes (n)	1	0	0.52
Preeclampsia (n)	1	0	0.52
Pregnancy induced hypertension (n)	0	2	0.22

Figure

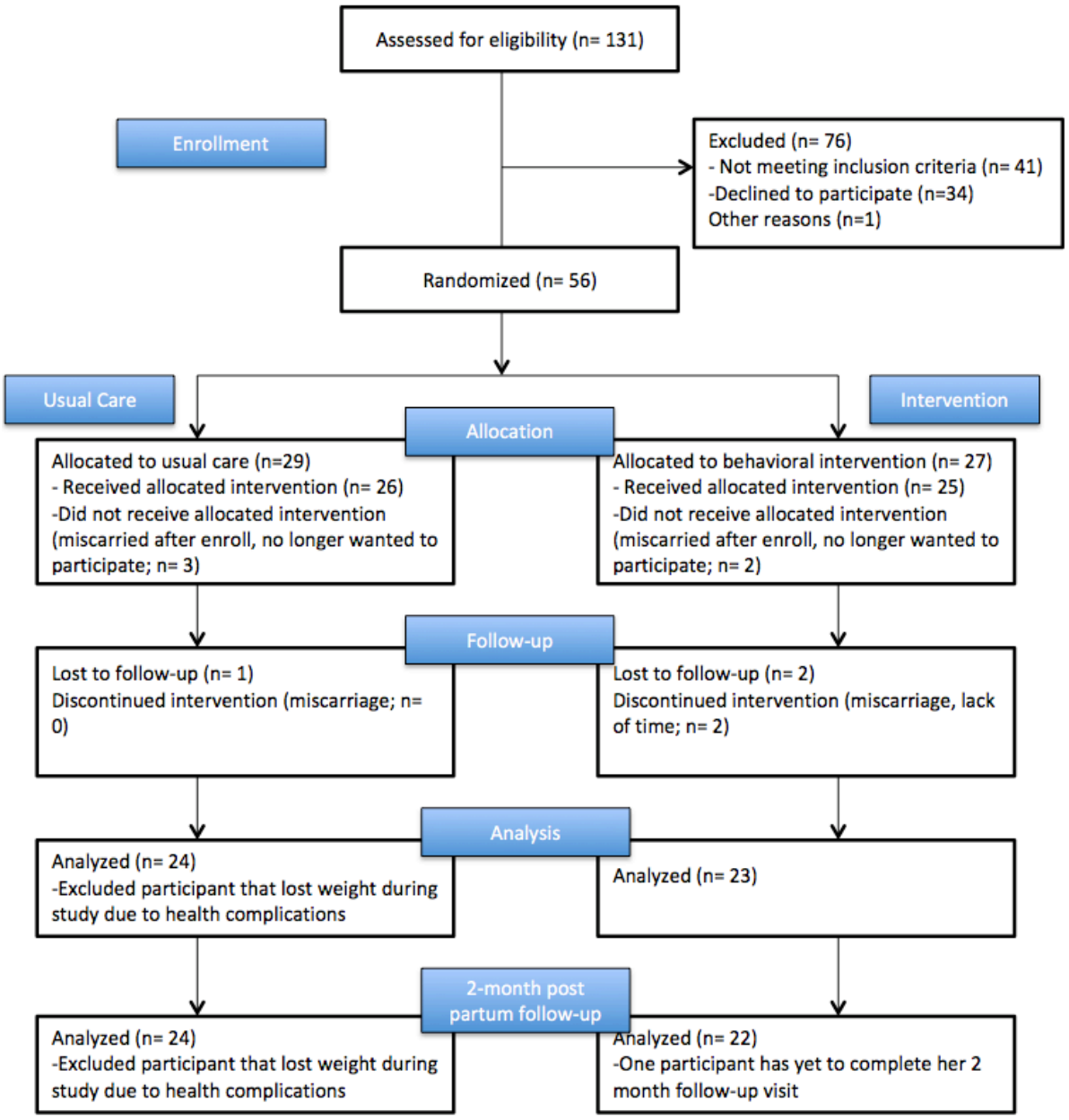

Figure 1. CONSORT diagram of recruitment and enrollment

CHAPTER 5. IMPACT OF A BEHAVIORALLY-BASED RANDOMIZED CONTROLLED TRIAL ON MATERNAL HEALTHY LIFESTYLE THROUGHOUT PRENGNACY

A paper to be submitted to the journal of the International Society of Behavioral Nutrition and Physical Activity

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Abstract

Objective: Although regular physical activity (PA) and intake of a healthy diet are recommended during pregnancy, few women are meeting the requirements. The purpose of this study is to evaluate the efficacy of a multi-component lifestyle intervention to change PA and dietary behaviors in previously sedentary pregnant women. **Methods**: A total of forty-eight inactive pregnant women were included in the analysis (usual care, n = 25; intervention group, n = 23). To promote appropriate weight gain during pregnancy, the women in the intervention group received behavior counseling with a Registered Dietitian Nutritionist, a Fitbit® Flex to monitor daily PA, and an individualized meal plan. Women were encouraged to set a daily step goal (≥10000 steps per day) and eat 45% of total calories from carbohydrates. A combined lifestyle score (LS) was calculated for each participant using data from objective PA assessment and weighed diet records collected at early-, mid-, and late-pregnancy. **Results:** Participants in the intervention group significantly improved total LS (p<0.0001) and had significantly higher total (p<0.05) and PA LSs (p<0.05) at mid-pregnancy compared to

usual care. Empty calorie and total step count score were the only significant behavioral predictors of gestational weight gain at weeks 34-36 gestation (r^2 = 0.86, F = 46.12, p< 0.0001). **Conclusion:** The use of a multi-component lifestyle intervention significantly improved the composite healthy lifestyle scores in previously inactive pregnant women.

Introduction

In the United States and around the world, it is recognized that health behaviors play an important role in the prevention and management of chronic disorders including obesity[1, 2], type 2 diabetes mellitus[3], and cardiovascular disease[4]. There is strong evidence that shows a large proportion of our society does not participate in positive health behaviors including regular physical activity (PA) and a healthy diet.[5-8] This fact holds true during pregnancy [9] despite the fact it is an opportune moment to make healthy choices that benefit both mother and baby.[10]

Physical activity is an important behavior in pregnancy necessary to counteract the normal state of insulin resistance present in late gestation and promote appropriate weight gain.[11] Olson and Strawderman[12] showed that there is a 1.7 times greater likelihood of excessive weight gain in woman who are less physically active during pregnancy than prior to pregnancy compared to women who maintain or increase their PA level during pregnancy.[13]

As with the general population, there are specific guidelines and recommendations for PA during pregnancy. The American College of Obstetricians and Gynecologists (ACOG) recommends that pregnant women without contraindications should engage in at least 20-30 minutes of moderate to vigorous PA on most if not all

days of the week. Recommendations by the United States Department of Health and Human Services recommend pregnant women participate in at least 150 minutes of moderate-intensity physical activity (MVPA) per week.[14, 15]

Unfortunately, few pregnant women are meeting the recommendations for PA during pregnancy. A study using recent National Health and Nutrition Examination Survey data found that pregnant women were, on average, spending 12 ± 0.86 minutes per day in moderate activity.[9] Furthermore, total time spent in moderate or vigorous PA declined with progression of pregnancy, from the first to the third trimester (moderate activity 7.6 ± 0.59 minutes per day in third trimester).[9] In addition to declines in PA, many women spend greater than 50% of their day engaging in sedentary behaviors (SB) such as sitting or lying down.[9] A recent observational study found that women in their 2nd trimester spent 70% of their day in SB.[16]

Dietary intake during pregnancy is also an important factor influencing infant outcomes including fetal development and growth.[17-19] Diet quality during pregnancy also plays a role in maternal outcomes including post-partum diet quality and weight retention.[20] Compliance with recommended nutritional guidelines during pregnancy is known to be less than ideal. Previous research has shown a decrease in fruit intake and an increase in meat intake and energy from solid fats and added sugars from early to late pregnancy.[21, 22] Furthermore, women of childbearing age have low diet quality, which could continue into the early weeks of pregnancy, a critical time for fetal development.[23]

Recognizing the importance of diet and PA during pregnancy has led to an increase in interventions that evaluate strategies to improve these lifestyle factors in pregnant women. Exploration of the impact of an intervention during pregnancy on lifestyle factors is often examined as it relates to behavior change and in turn, the changes effect on gestational weight gain (GWG). To better understand the effect of the intervention on behavior modification, we created a pregnancy lifestyle score that includes diet and PA variables that are shown to affect GWG. We believe a composite score will help us to better assess a number of diet and PA variables and eliminate some error related to multiple comparisons of numerous factors.

The primary purpose of the current study was to analyze the impact of a multi-component theory-based intervention on GWG (results can be found in Chapter 3). The purpose of this analysis is to evaluate the efficacy of a multi-component lifestyle intervention to change PA and dietary behaviors in previously sedentary pregnant women. It was hypothesized that women receiving this intervention would increase overall PA and improve dietary behaviors compared to women who did not receive the intervention.

Methods

Study eligibility, participants, and randomization. Fifty-six women between 8-14 weeks gestation were enrolled into a RCT (Clinical trial # NCT02168647) over a three-year period. Participants were recruited with the use of fliers posted online, in the community, and given in the local prenatal clinics. Mass recruiting emails were also sent on campus to staff, faculty, and students. Eligibility criteria included a singleton

pregnancy, gestational age between 8 and 14 weeks, a BMI between 18.5-45.5 kg/m^2, age 18-45 years, receiving regular prenatal care, physician documented approval to participate in the study, no history of chronic disease (e.g. Type 1 diabetes mellitus, cardiovascular disease, thyroid disease), no previous diagnosis of gestational diabetes or pre-eclampsia, no use of medication known to influence overall metabolism, and ability to effectively communicate with research staff.

Women were also required to be low active prior to enrollment in the study. We defined "low active" as less than there, 30-minute sessions per week based on previously reported cut-offs to determine "regular exercises" during pregnancy.[24-26] To determine eligibility, women were asked to answer two questions prior to enrollment: 1) *Do you currently participate in any PA outside of normal daily activity?* and 2) *Did you participate in any PA outside of your normal daily activity during the last six months?* If the answer was "yes" to either one of the two questions, the woman was asked to describe the type of PA, frequency, and duration.

A computer-generated random allocation was used to randomize women into one of two groups, usual care (UC) or lifestyle intervention one week of baseline data collection. Both the researchers and participants were blinded to group assignment until baseline data was completed. Participants collected data at study entry (baseline), 26-28 weeks gestation, and 34-46 weeks gestational for one full week (24-hour, 7 days) at each timepoint. All participants returned at two months postpartum for a follow-up visit. Participation in the intervention group began immediately after randomization.

Eight women withdrew from the study prior to completion for the following reasons: medical complications (n= 4), lost to follow-up (n= 1), and lack of time (n= 3).

Usual Care. Women randomized to the UC group attended their routinely scheduled visits with their prenatal providers. At each prenatal visit, nurses weighed participants and the recorded weight was faxed to the Blossom Project staff. Appropriate weight gain was calculated based on pre-pregnancy BMI using self-reported pre-pregnancy weight and height measured by researchers at the enrollment appointment. The weight from each prenatal appointment was plotted on the appropriate IOM weight gain chart (see appendix O) and emailed to the participant. Weight gained was calculated using self-reported pre-pregnancy weight. The researchers provided no additional lifestyle counseling to the usual care participants.

Intervention. Participants in the intervention received a behavioral lifestyle intervention designed to increase PA, modify carbohydrate intake, and prevent excessive gestational weight gain (EGWG). Immediately post-randomization, women in this group were instructed on how to use the Fitbit® (Fitbit Inc., San Francisco, CA) activity monitor and log food on the Fitbit® website.

Participants in the intervention group took part in one-on-one visits with a Registered Dietitian Nutritionist (RDN)/Licensed Dietitian (LD) from no later than week 14 gestation to childbirth. One-on-one sessions took place at an off campus research center or OBGYN clinic where the participant received their routine prenatal care. The RDN met with intervention participants once a month, with a minimum of six face-to-face meetings during the intervention period. Participants were weighed at each face-

to-face session by the RDN. Weight gain was plotted on an IOM weight gain chart and feedback on weight gain was provided.

The counseling sessions focused on appropriate weight gain during pregnancy through the use of an individualized meal plan, PA goals, and behavioral modification. Participants were able to view steps taken per day and log food intake on the Fitbit® website. Additionally, participants had weekly contact with the RDN by email to discuss nutrition and PA goals, weight gain, and address any questions or concerns.

Dietary intervention. Dietary intervention began at randomization to the intervention group with use of a 225-gram carbohydrate diet emphasizing a lower percentage of total calories from carbohydrates to achieve appropriate weight gain. Based on a 2000-calorie diet, women were asked to consume approximately 45% calories from carbohydrate, 25% protein, and 30% fat with an emphasis on whole grains, lean proteins, and mono- and polyunsaturated fats. A meal plan was developed to outline intake throughout the day (see appendix N). Additional documents were created and provided to participants to encourage use and compliance of the meal plan (appendix N). Participants were asked to keep a weekly food journal on the Fitbit® website to be reviewed with the RDN.

Physical Activity intervention. Each participant in the intervention group was provided with a Fitbit® Flex activity monitor to encourage adherence with the PA recommendations, ≥10,000 steps per day. Each participant was provided a Fitbit® website account set up with a Blossom Project username code to ensure privacy of the participant's identity. The monitor tracks daily steps taken, distance traveled, and active

minutes. Use of a Fitbit® product included access to the product website that allowed participants to log activities. The first three weeks of the program allowed for a gradual increase in walking time with participants increasing step counts by 10% each week following baseline data collection.

Behavior-counseling sessions. Women randomized to the intervention group participated in the monthly one-on-one counseling sessions with the RDN/LD. The counseling sessions were used to promote behavior change and based on the theoretical framework of self-determination theory (SDT) and Motivational Interviewing (MI) principles. These principles were used to highlight the importance of inner resources for personality development and behavioral self-regulation in a supportive atmosphere. SDT identifies three needs that are required to achieve behavioral growth: competence, relatedness, and autonomy.[27] MI strategies were used during the one-on-one visits to facilitate behavior change and goal setting with participants. MI utilizes a client-centered counseling style to elicit behavior change.[28]

Dietary intake assessment. A weighed three-day diet record was used to assess dietary intake. Participants were asked to weigh their food on two weekdays and one weekend day using a food scale provided by the research team. Nutritionist Pro™ (Axxya Systems, Stafford, TX) dietary analysis software was used to analyze the intake data (e.g. total energy intake, macronutrients [absolute and relative amounts]). The average intake of total fruit (including 100% juice), whole fruit, vegetables, greens and beans, whole grains, dairy, protein foods, seafood and plant proteins, refined grains, ratio of polyunsaturated and monounsaturated to saturated fatty acids, sodium, and empty

calories (calories from solid fats, alcoholic beverages, and added sugars) were used to determine diet quality using the Healthy Eating Index (HEI) 2010.

The Healthy Eating Index (HEI) was developed as a way to assess compliance with the Dietary Guidelines for Americans (DGA)[29] and has been shown to be a valid and reliable measure of diet quality for all segments of the United States (U.S.) population including women who are pregnant or lactating.[30] The HEI-2010 (HEI-2010) reflects the updated Dietary Guidelines for 2010 to evaluate diet quality based on the consumption of the 12 different food categories noted previously. Nine categories are scored based on adequacy of intake (total fruit, whole fruit, total vegetables, greens and beans, whole grains, dairy, protein foods, seafood and plant proteins, and fatty acids) and three categories are scored based on moderation of intake (refined grains, sodium, and empty calories). Each component has a maximum of 5, 10, or 20 points with a maximum total score of 100 for the overall index. An excel spreadsheet was created to calculate the 12 component scores and overall HEI score.

Physical Activity assessment. Prior to the start of each data collection visit, all participants were instructed how to wear a SenseWear® Mini armband (SWA; SenseWear® armband by BodyMedia, Inc., Pittsburgh, PA), an activity monitor, to objectively record quantitative data on daily PA including energy expenditure and PA intensity. Previous research has shown the monitor to be a good predictor of energy expenditure compared to indirect calorimetry in mid-pregnancy.[31] The monitor requires direct skin contact and is worn on the posterior upper left arm over the triceps muscle.

Participants were asked to wear the monitor for 7-consecutive days, 24-hours per day except when submerged in water (e.g., swimming, water aerobics, showering). Additionally, women were asked to record their daily PA in a log to confirm unusual activity, document aquatic exercise, and sleep time. Six participants reported swim time during at least one of the data collection visits. The swim time was accounted for during data analysis for each participant based on the intensity of the activity and categorized with a corresponding MET value from the 2011 Compendium of Physical Activity.[32]

Participants were also asked and instructed on how to wear an activPAL™ activity monitor (AP; PAL Technologies Ltd., Glasgow, UK) that was worn on the upper leg over the quadriceps muscle and attached to the leg using an adhesive pad. Information gathered from this monitor was used to assess the start and stop time spent sitting/lying, standing, and stepping. The activPAL™ was also used to determine step counts, and postural transitions. Previous research has shown the monitor to effectively detect change in posture (sitting/lying, standing/stepping), time spent in different positions (upright, sitting, lying), stepping speed, and step count.[33-37] Instructions on how to use the monitors were given verbally and in writing.

Data analysis. Data from the SWA was analyzed for each participant's three time points (baseline between weeks 8-14, between weeks 26-28, and between weeks 34-36 of gestation). All SWA data was analyzed in minute-by-minute increments starting at 12:00 am on day 1 of data collection and ending at 11:59 pm on day 7 of data collection. The minute-by-minute data from the SWA were downloaded into the manufacturer's software version 8.0 (algorithm 5.2h). All SWA data was exported into Microsoft Office

Excel 2007 (Microsoft, Redmond, WA, USA). An excel code was written to analyze time spent in bouts of MVPA. The following data were analyzed: moderate (3-5.9 METs)-vigorous (> 6.0 METs) PA minutes sustained for at least 10-minutes, 20-minutes, and 30-minutes. MVPA in 10-minute bouts was defined as at least 8 minutes of MVPA within 10-consecutive minutes.[38, 39] Twenty- and 30-minute bouts were defined as MVPA for at least 16 and 24 minutes respectively, with only 2 minutes below the moderate intensity threshold within any 10-minute period.

Monitor wear time was assessed using the SWA records that detected when the monitor is not worn (e.g., off-body time). If off-body time exceeded more than 500 minutes for the week, the files were further evaluated using the PA record to determine what activity was done during that time. Each participant was allotted at least 90 minutes per day of nonwear time to account for self-care (e.g., shower, bath, etc.).

Data from the AP accelerometer monitor (software 7.1.18) was analyzed at all three time points to assess postural positioning and patterns of daily activity such as standing, stepping, and lying down. Activity was recorded in second-by-second, 15-second and one-minute epochs starting at 12:00 am on day 1 of data collection and ending at 11:59 pm on day 7 of data collection. Recorded data was exported to an excel file using an excel code written to analyze steps per day. An in-house software was used to parse the data into time spent sitting, standing, and stepping and analyze sedentary time. Sedentary time was only assessed during waking hours. In order to assess sedentary time during waking hours, physical activity logs and SWA files were used to confirm valid awake ranges for each participant at all data collection periods. Based on

standards in the field, a valid day is defined as 10 or more hours of monitor wear during waking hours.[38] Using the output from the processing script, an excel file was used to determine average minutes per day spent sedentary, standing and stepping in increments of 0-10, 10-20, 20-30, 30-40, 40-50 and 60+ minutes.

Lifestyle score. Several maternal lifestyle behaviors during pregnancy have been associated with maternal and fetal health outcomes. Lifestyle behaviors, specifically diet and exercise, are important factors in maternal health during pregnancy, fetal outcomes, and health in the postpartum period. In order to assess a number of diet and PA variables and avoid potential statistical error related to multiple testing. The research staff developed a lifestyle score that encompasses four diet and four PA variables that influence maternal and fetal health during pregnancy. Each of the 8 components was worth a maximum of 10 points with a combined maximum score of 80 points for the total Lifestyle Score (LS). The following are the components of the LS:

Physical activity components

Average sedentary time duration in bouts of 60 minutes or more. In a cross-sectional observational study, increased number of breaks from sedentary time was associated with significantly lower waist circumference, BMI, triglycerides, and 2- hour glucose levels independent of total sedentary time.[40] In pregnancy, increasing sedentary time is positively associated with LDL cholesterol, glucose levels, and C-reactive protein (CRP).[41] Furthermore, more time spent in total daily PA is associated with the prevention of EGWG.[42] Based on recently collected data, a positive association was

observed between glucose intolerance and prolonged, uninterrupted sedentary time in bouts of 60 minutes or more.[43]

A maximum score of 10 was given to participants whose average sedentary time in bouts of 60 minutes or more was ≤150.9 minutes and minimum score of 0 was given to participants with ≥333 minutes. This number was determined using the regression analysis to find the mean average duration of sedentary time in bouts of 60 minutes or more associated with irregular fasting glucose values.[43] Sedentary time was derived from the AP monitor and actiparse.rb processing.

Step Count. Step count is a factor dependent on walking, an accessible and achievable form of exercise to increase PA during pregnancy.[44] The women randomized to the intervention group were asked to work up to a goal of an average of 10,000 steps per day each week. Previous research found that sedentary women (defined as <5,000 steps per day) had higher odds ratio of increased GWG compared to low active (5000 to 7500 daily steps), somewhat active (7500 to 1000 daily steps), active (≥ 10000 steps daily) in 2nd and 3rd trimester.[45] The Active group had 1.1 kg ($p = 0.04$) and 1.4 kg ($p = 0.02$) less GWG, than the sedentary group in the 2nd and 3rd trimester, respectively. In the last two trimesters, the active group had 1.1 kg ($p = 0.06$) less GWG, than the sedentary group.

The maximum score of 10 was given to women who achieved an average of ≥10,000 steps per day and a minimum score of 0 was given to women with an average ≤4,000 steps per day. Average steps per day were calculated using data from the AP monitor.

MVPA in 20-minute bouts or more. In 2002, the American Congress of Obstetricians and Gynecologists (ACOG) encouraged moderate exercise for 30 minutes a day on most, if not all, days of the week for all women with a healthy pregnancy.[46] As of 2015, ACOG re-affirmed these guidelines in a new publication recommending that pregnant women participate in an exercise program with the goal of achieving 20-30 minutes of moderate-intensity activity on most, if not all days of the week.[14] In the 2008 U.S Department of Health and Human Services Physical Activity Guidelines for Americans, specific recommendations were set for healthy pregnant and postpartum women. The 2008 Physical Activity Guidelines for Americans recommend at least 150 minutes of moderate-intensity aerobic activity spread throughout the week, the same guidelines for PA in the non-pregnant, healthy adult U.S. population.[15]

Using previously described data processing methods, data from the SWA monitors was used to find MVPA in bouts of 20 minutes or more. Women received a maximum of 10 points for ≥150 minutes of MVPA in 20-minute bouts of more per week and a minimum score of 0 for no time spent in MVPA per week.

Total Metabolic Equivalent of Task (MET) minutes per day. Previous multiple regression analysis of total daily MET-minutes was used to explain potential predictors of GWG. This analysis found that total MET-minutes per day was a significant predictor of GWG at week 18 of gestation ($p = 0.038$) and week 35 of gestation ($p = 0.038$).[47] Data from this analysis was used to stratify total MET-minutes per day at week 18 and week 34 and determine the mean MET-minutes in women who met the 2009 IOM GWG recommendations and the women who exceeded the recommendations. Based on this

data, women who had an average total of ≥1,965 minutes or more MET-minute per day at baseline and week 26-28 gestation were given the maximum 10 points. Women who had an average total MET-minute per day of ≥1,807 minutes or more at week 34-36 of data collection were given a maximum of 10 points.

Dietary components

Percent of total calories from carbohydrates. The meal plan component of this intervention was designed to provide 45% of total calories from carbohydrates. The meal plan was based on findings from a previous GWG intervention that found women gained significantly less weight when following a similar carbohydrate specific diet.[48] Furthermore, data from an unpublished prospective, longitudinal study during the 2nd and 3rd trimester of pregnancy showed that there was a positive correlation between carbohydrate intake and GWG at week 35 ($p=0.098$).[47] The 10 point score was given based on percent of total calories from carbohydrates. If women were within a range of 42.5% to 47.5% of total calories from carbohydrates they were given the full ten points. Minimum scores were given if women ate ≥60% or ≤30% of total calories from carbohydrates.

Percent of total calories from protein. Protein requirements increase during pregnancy to support expansion of blood volume, uterus, and fetal and placental protein accretion.[49] The additional protein requirements for pregnancy are based on the amount of protein present in the fetus, placenta, and maternal tissues, with a calculated 925 grams of protein deposited during pregnancy including 12.5 kg of maternal weight gain and an infant weighing 3.3 kg at term. To ensure protein needs are met during

pregnancy, the current recommended dietary allowance (RDA) is 1.1 grams of protein per 1 kg of body weight per day or an additional 25 grams of protein per day.[50] The current acceptable macronutrient distribution range (AMDR) for pregnant women is 10-35% of total calories from protein. A maximum score of 10 points for protein was given to those within the AMDR range.

Healthy Eating Index. As noted previously, HEI is a tool used to assess diet quality based on compliance with the Dietary Guidelines for Americans. A higher score on the HEI is an indicator of good diet quality. Improved diet quality and higher intake of specific components within HEI have previously been associated with improved maternal health.[51-53] The maximum 10 points for HEI was given to women with a total HEI-2010 score of 100. HEI score is typically out of 100 but 20 points was subtracted from the LS HEI to account for the 20 points awarded for the empty calorie component.

Empty Calories Empty calorie points are derived from the HEI-2010 and are one of the 12 components of the HEI score.[30] The highest possible point value given for empty calories within the HEI is 20. The empty calorie component includes the following dietary components: added sugars, solid fats, and alcohol. This component was included with the overall LS based on the evidence demonstrating a relationship between the foods that contribute to the empty calorie score and EGWG. In early pregnancy, diets high in sweets have a positive relationship with EGWG (OR = 2.52, 95% CI = 1.10-5.77, p=0.029).[51] Furthermore, intake of added sugar was positively associated with GWG (+2.8 kg, 95% CI 0.8-4.9, p= 0.02) and sweets, snacks, cakes and ice cream, all dietary items high in added sugars, are predictors of GWG (RR = 1.84, 95% CI 1.14-2.96,

p<0.0006).[54] A maximum of 10 points was given to women with an HEI empty calories score of 20 and a minimum score of 0 was given to women with an HEI empty calories score of 0.

Statistical analyses

Data is reported as mean ± standard deviation (SD). Repeated-measures ANOVA assessed the effects of treatment group on the change in the overall LS across pregnancy. Mixed model repeated measures analyzed the sum score of both the diet and PA components individually. When the treatment x time interaction was significant, post hoc tests assessed the effect of treatment group at each point in time. Effect sizes, as measured with Cohen's *d*, were used to quantify the magnitude of diet, PA, and total LS changes between groups at baseline, week 26-28, and week 34-36 of gestation. A *d* = 0.2 is considered a 'small' effect size, *d* = 0.5 represents a 'medium' effect size and *d* = 0.8 a 'large' effect size.[55] To assess whether there was an effect of treatment across BMI category, interaction between treatment group, time and BMI category was explored in relation to total LS, PA LS, and diet LS.

Evaluation of predictors of GWG was done using stepwise and multiple regressions. Group was included in the models to explore if group allocation explained any variation in GWG. Statistical analyses were conducted in JMP Pro 13.1.0 (SAS Institute Inc., Cary, NC).

Results

Descriptive characteristics. There were no differences between groups in demographic characteristics (Table 1). The majority of participants were married (97.9%), White (82.9%), and had at least a 4-year post-secondary degree (89.3%)

Lifestyle score Total LS, diet and PA LS comparisons and effect sizes are reported in Table 2. For total LS, there was a significant interaction between group and time ($F = 6.4$, $p = 0.0024$) and a significant main effect of time ($F = 6.9$, $p = 0.0015$). Women in the intervention group had a significant increase in total LS from baseline to week 26-28 gestation (51.6 ± 8.3 baseline LS versus 60.1 ± 10.9 week 26-28 LS, $p<0.0001$) and had significantly higher LS at week 26-28 of gestation (53.6 ± 9.5 LS usual care versus 60.1 ± 10.9 LS intervention, $p = 0.0164$). No significant difference was found between groups at week 34-36 of gestation.

There was no evidence of interaction between treatment group, BMI category, and time however there was a main effect of BMI category ($F = 6.6$, $p = 0.0033$). Post hoc all-pair comparisons found that women categorized as normal weight and overweight had significantly higher total LS compared to obese women (56.8 ± 9.2 LS normal weight and 55.5 ± 7.5 LS overweight women versus 46.1 ± 9.6 LS obese women, $p<0.001$ and $p = 0.005$, respectively). The intervention had a large and significant effect on total LS in mid-pregnancy. A significant effect was not observed in late-pregnancy (see Table 2).

Diet scores. There were no significant differences between groups for the sum of dietary components. There was a significant main effect of time for diet LS ($F = 4.5$, $p =$

0.0128). Regardless of group, there was a significant increase in LS diet score from baseline to week 26-28 gestation (26.6 ± 5.1 baseline versus 28.7 ± 5.4 week 26-28, *p* = 0.0167). There was no main effect of or interaction between treatment group, BMI category, and time for diet LS. The intervention had a small effect on diet LS in mid-pregnancy and a non-significant small effect in late-pregnancy (see Table 2).

PA scores. There was a significant interaction of group and time (F = 6.67, *p* = 0.002) and a moderately significant main effect of time (F = 3.16, p = 0.0471) for the sum of PA components. The intervention group had a significantly higher sum PA score of 30.8 ± 6.6 compared to the usual group score of 25.8 ± 7.0 (*p* = 0.007). A significant increase in sum PA score was observed in women in the intervention group from baseline to mid-pregnancy (25.0 ± 7.6 baseline PA score versus 30.8 ± 6.6 week 26-28 PA score, *p* = 0.0246). There was a large significant effect of intervention on PA score in mid-pregnancy (see Table 2).

There was a statistically significant main effect of time BMI category (F = 4.9, p = 0.0118) but no interaction between treatment group, time, and BMI category for PA LS. Women in the obese category had a significantly lower PA LS compared to normal weight women (28.4 ± 7.5 normal weight versus 20.9 ± 6.6 obese women, *p* = 0.0084). There was no significant difference in PA LS between women categorized as overweight (27.0 ± 6.1 LS score) and women in the normal (*p* = 0.55) and obese BMI categories of women (p = 0.07).

Predictors of GWG. After forcing group randomization into the stepwise regression model (p = 0.54), significant predictors of percentage of 2009 IOM GWG at

weeks 34-36 were GWG at weeks 26-28 ($p<0.0001$), pre-pregnancy BMI ($p<0.0001$), empty calorie score at week 34-36 ($p = 0.003$) and step score at weeks 34-36 ($p = 0.005$). When all LS constructs were entered together into a standard multiple regression and accounted for 86% of the variation ($F = 46.12$, $p< 0.0001$).

Discussion

Results from this study demonstrate that a multi-component, theory-based lifestyle intervention significantly increases healthy lifestyle factors, including PA and dietary behaviors in previously sedentary pregnant women. The finding that a lifestyle intervention was effective at improving overall lifestyle factors is important to better understanding how to prevent inappropriate GWG.

To our knowledge, this is the first study to use a pregnancy lifestyle score to assess the effects of a pregnancy intervention developed to modify diet intake and PA to promote maternal health during and after pregnancy. This novel approach to analyzing diet and PA variables with a composite measure allowed us to examine the cumulative effect of lifestyle on maternal health during pregnancy in response to a multi-component theory-based intervention.

The improvement in PA behavior between groups and over time in the intervention group is meaningful especially for a group of previously inactive pregnant women. An improvement in PA LS demonstrates the potential to affect not only one specific PA variable (e.g., intentional exercise), but the multiple factors that impact a healthy PA pattern (e.g., sedentary behaviors).

Many pregnancy intervention studies have targeted modification of PA through increasing intentional exercise[56], as is recommended by ACOG[14] and the Physical Activity Guidelines for Americans.[15] It has only been in the last decade that research has increasingly focused on the effect of intentional activity as well as sedentary behaviors.[57] Unlike exercise, there are no specific recommendations for SB or the amount of time spent sedentary. It is only in the latest publication of the American Diabetes Association (ADA) 2017 *Standards of Care*, that sedentary behaviors were addressed with the new recommendation that all individuals, including those with diabetes, should interrupt prolonged sitting every 30 minutes by standing, walking or participating in some light activities. [58] Sedentary time (ST), or the time spent in sedentary behaviors, is associated with poor pregnancy outcomes including increased risk of gestational Diabetes Mellitus (GDM)[59], elevated LDL cholesterol, and C-reactive protein.[41]

Intervening to encourage women to move more and sit less is a strategy not currently used in any known GWG intervention. However, knowing that lack of time, childcare, and energy are often cited as barriers to PA during pregnancy[60] and the increasing need to ask women to spend less time sedentary, highlights the need to find an approach that will encourage women to participate in more intentional PA and spend less time sedentary. The use of non-specific exercise goals but rather, step goals, in the current intervention, was meant to encourage women to not only move more than they had previously, but move more often.

The findings that LS differ significantly across BMI category, regardless of time or treatment group is meaningful for the future care of pregnant women. It is interesting to note that there was no significant difference in diet LS between women categorized as normal, overweight, or obese in either group. The results were surprising considering the negative association between diet quality and increasing BMI. A cross-sectional study used HEI to assess the relationship between diet quality and pre-gravid and gravid weight status and found that women categorized as overweight or obese have significantly poorer diet quality compared with women of normal BMI. [53] HEI score is also negatively correlated with pre-pregnancy BMI status. Moran et al.[20] reported similar findings demonstrating that over pregnancy there is a decrease in HEI-2005 in overweight and obese women that persists into the post-partum period.[61] Despite what has previously been shown, we found that the dietary composite score, diet LS, was not significantly different between BMI categories.

The lack of intervention effect on diet LS alone, regardless of BMI, might be explained by the lack of concrete evidence to show what specific dietary factors influence overall health and weight gain during pregnancy. Although research supports the benefit of reduced carbohydrate intake during pregnancy in relation to pregnancy outcomes[48], there is a need for additional high quality pregnancy dietary assessment research that properly identifies strong predictors of GWG. In the present study, only empty calorie intake in late-pregnancy was a significant predictor of percentage of IOM GWG at weeks 34-36 of gestation. However, the large intervention effect on the total LS speaks to the benefit of using combined lifestyle score that takes both diet and PA into

account. As previously stated, the combination of diet and exercise interventions in GWG interventions is more proven to be more effective than the isolated use of just one component.[62]

The combined design of the current study, in addition to the individual counseling component, provide important implications for clinical obstetric care. The importance of a combined approach has already been established in GWG intervention research. A 2017 individual participant data meta-analysis that included data from more than 12,000 women showed that dietary, PA, or a combination of the two was associated with lower GWG when compared to standard care.[63] Although it is known that a combined approach has a positive effect, the researchers encourage the further evaluation of individual components of the intervention to determine specific, detailed clinical recommendations and care. Based on our findings, additional efforts should focus on identifying what components of the dietary intervention impacted pregnancy outcomes.

Strengths to this study include the analysis of multiple aspects of healthy maternal lifestyle during pregnancy including PA, SB, and dietary behaviors that have shown to affect GWG. Additional strengths include: use of a randomized controlled trial design, objective measures of PA and diet data, and recruitment of low-active or sedentary women. By enrolling women who were sedentary prior to pregnancy minimized the variability within the control group allowing us to control for pre-pregnancy PA levels assuming a low likelihood that these participants would increase their activity level on their own without an intervention.

This study was powered to detect a difference in appropriate gestational weight gain and was not powered to find results specific to changes in physical activity and diet variables. Another limitation of the study was lack of demographic diversity. The majority of participants were Caucasian, highly educated, and married.

Conclusion

In conclusion, the use of a multi-component lifestyle intervention significantly improved healthy lifestyle factors in previously sedentary pregnant women. Additionally, improvements in the PA LS provide important evidence to suggest that targeting overall activity, as opposed to increases in intentional exercise, is beneficial to multiple components of PA that influence overall maternal health. Future research aiming to address positive behavior, specifically healthy dietary components, may want to consider additional factors in the analysis of overall quality. Regardless, a multi-component intervention is an effective tool to improve overall healthy lifestyle behaviors during pregnancy.

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TABLES

Table 1. Demographic characteristics of participants at baseline[1]

Characteristic	All n = 48	Usual Care n = 25	Intervention n = 23	P - value
Age (years)	31.4 ± 4.1	31.2 ± 3.6	31.6 ± 4.6	0.32
Pre-pregnancy BMI ($kg \bullet m^2$)	25.0 ± 4.5	24.3 ± 4.1	25.7 ± 5.0	0.26
No. of pregnancies (including current	2.3 ± 1.4	2.6 ± 1.5	1.9 ± 1.3	0.07
Parity	1.0 ± 1.0	1.0 ± 0.9	1.0 ± 1.1	0.78

[1]Values are reported as means ± SD.

Table 2: Comparison and effect sizes for total, diet, and physical activity Lifestyle Scores between treatment group and across pregnancy[a]

Outcome	Time point	Usual Care	Intervention	Time x treatment interaction[b]	Treatment effect Cohen's *d*[c]	
					d (95% CI)	P
Diet LS score	Baseline	26.5 ± 5.2	26.7 ± 5.0	F = 0.47 p = 0.62	0.05 (-2.6 to 3.2)	0.86
	Week 26-28	27.9 ± 5.4	29.6 ± 1.1		0.34 (-1.2 to 4.6)	0.24
	Week 34-36	28.1 ± 5.3	28.7 ± 3.9		0.14 (-2.2 to 3.7)	0.61
PA LS score	Baseline	26.9 ± 7.4	25.0 ± 7.6	F = 6.67 p = 0.002	0.25 (-2.2 to 6.1)	0.37
	Week 26-28	25.8 ± 7.0	30.8 ± 6.6		0.68 (0.8 to 9.2)	0.02
	Week 34-36	25.9 ± 7.7	27.1 ± 7.6		0.16 (-3.0 to 5.4)	0.57
Sum LS score	Baseline	53.4 ± 8.9	51.8 ± 8.3	F = 6.43 p = 0.0024	0.17 (-3.6 to 6.9)	0.538
	Week 26-28	53.6 ± 9.5	60.4 ± 10.7		0.71 (1.4 to 12.1)	0.01
	Week 34-36	54.6 ± 9.7	56.0 ± 8.6		0.14 (-4.1 to 6.8)	0.6

[a]Values are mean ± SD.
[b]Mixed model repeated measures analysis including treatment, time, and treatment x time. P-value reported for time x treatment interaction.
[c]Effect size calculated with Cohen's d with associated p-value and 95% CI.

Table 3. Multiple regression lifestyle score predictors of gestational weight gain

	Stepwise regression sequence				ANOVA for final model				
	Predictor	P-value	R^2	AIC	Source	DF	Sum of Squares	Mean Square	F-ratio
Outcome	**Percent of IOM GWG at weeks 34-36**				Model	5	74121.4	14824.3	46.12
	Group assignment*	0.54	0.009	474.2	Error	39	12536.0	321.4	Prob > F
	GWG at weeks 26-28	<0.0001	0.59	437.4	C. Total	44	86657		<0.0001
	Pre-pregnancy BMI	<0.0001	0.78	412.2					
	Empty calories week 34-36	0.003	0.82	404.6					
	Steps week 34-36	0.005	0.86	398.1					

Values are presented as mean ± SD, P-values and R^2 values are cumulative and include outcomes previously listed in the model. $P < 0.1$ was used as the inclusion criterion for stepwise regression.

CHAPTER 5. EFFICACY OF A THEORY-BASED INTERVENTION TO MODIFY PSYCHOSOCIAL VARIABLES RELATED TO HEALTHY BEHAVIOR CHANGE DURING PREGNANCY

A paper to be submitted to the journal of the International Society of Behavioral Nutrition and Physical Activity

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Abstract:

Objective: Behavior change interventions may explain the underlying mechanisms that influence the adoption of healthy behaviors to promote appropriate weight gain during pregnancy. Therefore, the primary goal of this study was to analyze the impact of an intervention based on self-determination theory (SDT) and motivational interviewing (MI) on psychosocial mediators, healthy behaviors (i.e., physical activity [PA] and diet), and gestational weight gain (GWG). **Methods:** Forty-eight previously inactive pregnant women completed a randomized-controlled theory-based GWG intervention. Women were randomized to usual care (n=25) or intervention (n=23) in early pregnancy (week 8-14 gestation). Usual care participants were asked to continue their standard prenatal care and routine while women in the intervention group participated in monthly one-on-one counseling sessions with a Registered Dietitian Nutritionist (RDN) trained in MI. The intervention group was encouraged to increase daily activity (≥10000 steps per day) and follow an individualized diet plan designed to help achieve adequate GWG. Psychosocial mediators, weighed diet records, and objective PA were measured at three points throughout pregnancy with follow-up

at two-months postpartum. **Results:** Intervention participants reported higher levels of perceived competence for diet in mid-pregnancy (p<0.01), and exercise in mid- (p<0.01) and late-pregnancy (p<0.001) compared to usual care. Self-efficacy for diet improved from baseline to late pregnancy (p<0.01) in the intervention group. Additionally, self-efficacy for exercise increased in the intervention group from baseline to mid-pregnancy (p<0.01). Only barriers to exercise and perceived competence for diet in late pregnancy were significant predictors of total GWG (p<0.05). **Conclusion:** In conclusion, the behavior-theory based GWG intervention using a randomized controlled design positively changed mediators of behavior in the intervention group.

Introduction

Sustainable long-term health requires the implementation of strategies to change lifestyle behaviors that in turn lead to prevention of chronic disease. Lifestyle interventions rooted in theory-based approaches are key to ensuring these behaviors are adopted and sustained. These approaches are thought to be more effective than non theory-based strategies for changing behavior during an important transitional period in women's life, pregnancy.[1]

There is clear evidence to demonstrate that maintaining or participating in regular physical activity (PA) and eating a healthy diet during pregnancy is beneficial. Maintaining or adopting the recommended exercise intensity and duration during pregnancy reduces the risk of gestational diabetes and pre-eclampsia, and positively effects mental-health.[2, 3] Furthermore, interventions aimed at limiting excessive gestational weight gain (EGWG) are known to be most effective if dietary behaviors are

targeted as part of the intervention.[4] Unfortunately, many women are not adhering to healthy behavior recommendations or making healthy lifestyle choices during pregnancy.[5]

The impact of unhealthy behaviors during pregnancy is clearly demonstrated by the impact of unhealthy behaviors on increased incidence of chronic diseases such as obesity, cardiovascular disease, and type 2 Diabetes Mellitus in the United States today.[6-10] Pregnancy is a powerful time to influence behavior because that behavior not only impacts the well being of the mother, but also that of the fetus.[1] Specifically, EGWG plays a crucial role in future generations risk of chronic disease and obesity. Women who gain in excess during pregnancy have children that are 30-45% more likely to be obese.[11, 12]

Theoretical frameworks are important to include in gestational weight gain (GWG) interventions because they can inform and may explain the underlying mechanisms that influence behavior change and maintenance. Understanding the basic factors that lead to change helps interventions target the intervening variables and better understand the path necessary for change to occur. Furthermore, the most effective interventions at limiting EGWG are those that include behavior change strategies or are designed with a theory in mind.[13, 14]

Previous GWG intervention studies have been informed by or grounded in theories and approaches such as social cognitive theory, theory of planned behavior, the health belief model, motivational interviewing (MI) and the transtheoretial model.[15-19] None to date have significantly prevented women from gaining in excess of the 2009

IOM weight gain guidelines, however studies have demonstrated the ability to influence behavior change (e.g., PA).[20] No GWG intervention study has yet to examine the influence of an intervention grounded in self-determination theory (SDT).

An intervention based on the principles of SDT has the potential to address specific constructs that other behavior-theories have not used to predict behavior change, specifically type of motivation, both in quantity and quality. SDT is based on human motivation.[21] SDT posits that behavior can be determined by motivation and the type of motivation is determined by a persons values, beliefs, and personal development. According to SDT, the extent to which a person is motivated to perform a certain behavior depends on the degree to which they internalize and integrate the behavior with one self.[22] More autonomous motivation, also known as intrinsic motivation, is characterized by a greater integration of the behavior to one self (participating in the behavior for enjoyment or satisfaction). On the other end of the spectrum there is controlled motivation, also defined as amotivation or extrinsic motivation, in which a behavior is done because of external pressure (acting to avoid punishment or receive a reward).

Along this continuum of motivation lies various levels of motivation, ranging from more autonomous motivation to more controlled motivation. Both autonomous and controlled motivations are hypothesized to direct behavior, although it is autonomous motivation that leads to greater commitment and long-term maintenance.[21, 23] SDT identifies three basic psychological needs that are necessary for a person to move from a less controlled to more autonomous sense of motivation:

autonomy (feeling choice to engage in a behavior), competence (the need to feel competent and confident), and relatedness (feeling understood by and connected to others).[21, 24, 25]

Motivational interviewing (MI) is a counseling approach that compliments the concept and constructs of SDT. MI is defined as "a collaborative conversation style for strengthening a person's own motivation and commitment to change."[26] The use of MI techniques facilitates more autonomous actions through change in the SDT mediators of autonomous self-regulation and perceived competence. MI focuses on helping to elicit behavior change by guiding a person to self-identify why they want to change and then allowing them to direct how they can make that change.

SDT and MI interventions, alone and together, have been effective at improving health-related behavior outcomes such as increased PA, weight loss, and self-regulation in non-pregnant populations.[27-30] It is our hypothesis that the implementation of an intervention based on the principles of SDT and MI in a group of previously sedentary pregnant women will positively change psychosocial mediating variables (i.e., perceived competence and self-efficacy) that support positive behavior change (i.e., PA and diet quality). The purpose of this study was to explore the influence of a SDT and MI intervention on mediators of behavior change and the relationship between behavior change mediators and the primary outcome of the intervention, GWG.

Methods

Study design. "Be-Well" (the **Be**havioral **Well**ness in pregnancy study) was a randomized controlled trial, consisting of a comprehensive theory-based intervention to

reduce EGWG. A secondary outcome was to promote well-being during pregnancy. Participants were enrolled in the study and randomized to one of two groups using the random generator function for Microsoft Excel 2007 for Windows. Both the research staff and participants were blinded to group allocation during baseline data collection. Women in the intervention group received a minimum of six one-on-one counseling sessions with a Registered Dietitian Nutritionist (RDN)/Licensed Dietitian trained in MI throughout the intervention. The usual care group received the standard prenatal care provided by their OBGYN.

Participants. A total of 56 women were enrolled in this study. Recruitment for the study took place over a three-year period. Women were recruited from the local metropolitan community using fliers, online postings, word of mouth, and mass recruitment emails sent out to the local university. Two local OBGYN offices also assisted in the recruitment of women from the area.

To be included in the study, women had to have a BMI between 18.5-45.5 kg/m^2, age 18-45 years, between 8 and 14 weeks gestation, receiving regular prenatal care, obtain physician-documented approval to participate in the study, no prior history of chronic disease (e.g., Type 1 diabetes mellitus, cardiovascular disease, thyroid disease), or previous diagnosis of gestational diabetes or pre-eclampsia. Only inactive women were eligible to participate in the study. Sedentary was defined as participation in exercise ≤3 sessions per week for less than 30 minutes per day for the last 6 months prior to conception.[31-33] Prior to enrollment, women gave written informed consent to

participate. The study was approved by the university IRB committee and was registered as a clinical trial with clinicaltrial.gov (NCT02168647).

Intervention

Behavior-counseling sessions. Women randomized to the intervention group participated in monthly one-on-one counseling sessions with a RDN/licensed dietitian with training in MI. The minimum of six counseling sessions occurred throughout participation in the study. The sessions were used to promote behavior change based on the theoretical framework of SDT and Motivational Interviewing (MI) principles.

The sessions followed SDT constructs of autonomy, competence, and relatedness, and included both a PA and dietary component. To promote behavior change, researchers used the MI counseling approach to facilitate a sense of ownership over participant's behavior, with the goal to internalize the locus of control and motivation. Strategies used by the researchers included: creating an automony-supportive environment by increasing physical activity and dietary knowledge, supporting change talk from participants, providing positive feedback and ideas for behavior change when advice was asked, aiding participants in the exploration of their values, goals, and the discrepancies between current behaviors and desired outcomes, and encouraging choice and self-initiation. Specific examples are detailed below.

All sessions followed the four phases of process change used in MI.[26] Behavior change techniques specific to MI were used at each session and include: open-ended questions, affirmation, reflective statements, summary statements (OARS), questions to elicit change talk (DARN questions- Desire, Ability, Reason, Need), double-sided

reflection, hypothetical thinking, support for change, emotional support, and a summary of the plan. Session structure and broad goals were designed to model a successful weight loss SDT-based intervention.[28]

The initial intervention session (immediately post-randomization) included exploration of participant's motivation for behavior change using a readiness ruler modeled from Mason and Butler.[34] The readiness ruler assessed the importance to change, confidence to change, and readiness to change in relation to the question "*On a scale from 0 to 10, with 10 being very blank (important, confident, interested)… how important is it to you to make the changes necessary to have a healthy pregnancy and gain the appropriate amount of weight during your pregnancy?; how confident are you that you can make the necessary changes to have a healthy pregnancy and gain the appropriate amount of weight during your pregnancy?; how interested are you in making the changes necessary to have a healthy pregnancy and gain the appropriate amount of weight during your pregnancy?".*

The ruler provided guidance on future conversations between the RDN and the participants regarding their readiness to make PA and/or diet-related lifestyle changes. A lower score (0 to 3) required expression of concern, offering of support and information. A medium score (4 to 7) resulted in increased exploration of the positive and negative aspects of the participant's reasons and desires to change. A high score (8 to 10) or for those with greater readiness to change, more immediate action planning and offering of information was provided.

Each subsequent session focused on development of PA and diet goals specific to the individual participant. Each session was approximately 30 minutes and each participant was asked to reflect on behavior change over the last month. At each session, participants identified one PA and diet goal that was in-line with the overall goal of having a healthy pregnancy. The initial sessions goals included increasing knowledge as it related to PA and diet behaviors and the presentation of the Blossom Project Meal Plan as a tool to facilitate dietary behavior change. The first three sessions focused on exploring inconsistencies between participant's values/goals and their current behavior. MI behavior change techniques (BCTs) were used to facilitate behavior change and support the three basic psychological needs identified in SDT as necessary to encourage autonomous regulated motivation (Table 1).[35, 36]

In addition to the monthly counseling sessions, an email was sent from the RDN to each participant on a weekly basis. The emails were used to provide regular communication and support to the intervention women.

Usual Care. Women randomized to the usual care group did not participate in the behavior-counseling intervention. They received the standard care provided by their medical provider. Additionally, women in the usual care group were asked to provide consent for the weight at each of their prenatal appointments to be faxed to the research staff. The research staff plotted their weight gain (measured $weight_{prenatal\ appointment}$ minus pre-pregnancy $weight_{self\text{-}report}$) on an Institute of Medicine growth chart for pregnancy specific to their pre-pregnancy BMI category. The plot was emailed to the

usual care subject within one week of the appointment and no feedback on GWG was provided.

Measures. GWG was the primary study outcome. While PA and diet were our secondary behavioral outcomes.

Anthropometrics All participants were weighed within 0.1 kg on an electronic scale by the research staff at three data collections points during the pregnancy: baseline (week 8-14 of gestation), visit 2 (week 26-28 of gestation), visit 3 (week 34-36 gestation), and at 2 months post-partum. Height to the 0.1 cm was measured at enrollment. Self-reported pre-pregnancy weight and measured height were used to calculate pre-pregnancy BMI (kg/m^2). A recent study that included a cohort of 5,092 women reported high validity between self-reported pre-pregnancy weight and clinically measured weight within a year of conception (Spearman correlation coefficient = 0.97) and 86.7% correctly classifying pre-pregnancy BMI category.[37] Gestational weight gain (GWG) was measured as: measured $weight_{data\ collection\ visit}$ minus pre-pregnancy $weight_{self\text{-}report}$. Post-partum weight retention was measured as: pre-pregnancy $weight_{self\text{-}reported}$ minus measured $weight_{2\text{-}months\ post\text{-}partum}$.

Physical activity. An activity monitor was used to measure PA variables at the three data collection points in pregnancy. The SenseWear® Mini armband (SenseWear® armband by BodyMedia, Inc., Pittsburgh, PA) was worn on the upper left arm and used to measure energy expenditure and moderate-vigorous physical activity in bouts of 20-minutes or more, in line with American College of Obestetricians and Gynecologists PA recommendations.[38] See chapter 4 for detailed explanation of PA analysis.

Dietary intake At each data collection point, women completed a three day weighed food log during each data collection point (one weekend day and two weekdays). Women were visually and verbally shown by the RDN how to weigh and record the food and asked to provide detailed information on all food items recorded in the log. Food logs were analyzed using Nutritionist Pro™ (Axxya Systems, Stafford, TX). Refer to Chapter 4 for detailed explanation of diet analysis.

Psychosocial measures All participants completed a series of self-administered validated questionnaires at each data collection point throughout the study. Our primary psychosocial outcome was perceived competence and self-efficacy, depression, and the health care climate support questionnaire were all secondary outcomes.

The *Edinburg Depression Scale (EDS)*[39] is a 10-item questionnaire developed for postpartum women. It has been validated in a group of non-childbearing mothers[40] and during pregnancy.[41] The questions are scored on a scale of 0 to 3, with 3 indicating higher seriousness of symptoms. The total score ranges between 0 and 30. A score of 10-12 indicates presence of depressive symptoms and a score above 13 indicates need for further assessment and management of potential depression.[39] Estimated internal reliability and consistency for EDS items in this sample was $\alpha = 0.82$.

Barriers to exercise were assessed using a 10-item scale adapted to pregnancy.[42] Each item or barrier to exercise was preceded by the stem "I do not exercise because…" with a 10-item response (e.g., "I do not exercise because I am feeling tired"). Questions were scored on a Likert scale ranging from 1 = minor barrier to 6 = major barrier.

Reliability and internal consistency of barriers to exercise items in this sample were tested using Cronbach's α (α = 0.83).

The *Perceived competence scale (PC)* is a 4-item questionnaire to assess the degree in which participants felt confident in their ability to make, maintain, or a change behavior. The scale was created by William and Deci and meant to be adapted for different targeted behaviors.[43, 44] Participant's responded to a PCS specific to exercise and a PCS for diet. Participants were asked to indicate the extent to which each statement in the PCS was true. An example of a PCS for diet is "I now feel capable of maintaining a healthy diet" and a PCS example for exercise is "I am able to meet the challenge of being physically active during all trimesters of my pregnancy". Answers on the 4-item scales were rated on a 7-point Likert scale ranging from 1 = not true at all to 7 = very true. The internal consistency and reliability for PCS diet and PCS exercise in this sample were α = 0.81 and α = 0.70, respectively.

Self-efficacy (SE) to regulate exercise and diet was measured using a scale that was created based on recommendations by Bandura[45, 46] and McAuley and Mihalko[47]. The exercise scale included 18 items to assess the participants' degree of confidence in their ability to perform regular exercise three or more times per week when provided with a specific situation (e.g., "I can regularly exercise when I'm feeling tired."). The diet scale included 29 items to assess participants' degree of confidence in their ability to maintain a healthy diet on a regular basis provided with a certain situation (e.g., "I can maintain a healthy diet while watching television"). Scores were summed and averaged

to a single mean score. The sample Chronbach's was α = 0.70 for SE exercise and α = 0.87 for SE diet.

The *health care climate questionnaire (HCCQ)*[48] was used to as a check to assess participants perceived feelings of support provided by health-care practitioners (doctors, nurses, counselors, etc.) throughout pregnancy. Women enrolled in the study did not come from a single care provider and this scale was used as a manipulation check for difference in health-care practitioners support. Answers to the 15 item scale were rated on a 7-point Likert scale ranging from 1 = strongly disagree to 7 = strongly agree.

A *Needs satisfaction in individualized lifestyle counseling program* included domain-specific responses to the individualized counseling questions needed to assess the three basic needs identified by SDT as necessary for self-regulation of motivation. The needs satisfaction scale was only given at the last time point and only to the intervention group. The three domains included autonomy, relatedness, and competence. Women were asked to consider the experience with the research counselor and respond to "how the individualized lifestyle counseling made me feel…" responses on a Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). Four of the responses represented feelings of autonomy (e.g., "…made me feel free to decide for myself what to do"), four represented relatedness (e.g., "…made me feel that I belong and the people here care about me"), and three represented competence (e.g., "…made me feel that I am capable of controlling my weight gain during my pregnancy").

Scores are presented as an average of each domain. Overall reliability and internal consistency were high for this sample ($\alpha = 0.83$).

Statistical analysis

Descriptive characteristics were assessed with independent t-tests and chi-square analyses to compare differences between groups.

Mixed-model repeated measure analysis was used to test intervention effects and compare differences between and within groups over time. The interaction term of treatment x time was used to assess difference over time and between groups and post hoc pairwise comparisons were done on any significant differences.

To assess changes in diet and physical activity behavior, mixed-model repeated measure analysis was used with subject included as a random effect. The analysis included a comparison over time, across group, and the interaction of time x group.

Pearson correlations were used to assess if the mediators (psychosocial variables) were related to the studies primary outcome (GWG). Significant correlations between mediators and GWG were further examined using partial correlation controlling for group assignment. Significant correlations between psychosocial variables and GWG were further analyzed using stepwise multiple regression analysis to identify significant predictors of weight gain. Two multiple regression models were used to test diet-related predictors and activity-related predictors. One participant was excluded from the correlation and regression analyses due to unexpected weight loss related to non-study related health complication after enrolling in the study.

Significance was set at $p<0.05$. Statistical analyses were conduced in JMP Pro 13.1.0 (SAS Institute Inc., Cary, NC).

Results

Out of the 56 enrolled, 8 did not complete all data collection visits in the study. Expect when otherwise specified, a total of 48 women were included in the final analysis. There was no difference in descriptive characteristics between groups (Table 2). Therefore, descriptive variables were not included as covariates in subsequent analyses.

Treatment effects. Changes in psychosocial variables during the intervention are described in Table 3. Mixed-model repeated measures analyses showed no significant difference on barriers to exercise or EDS between or within groups. Except for barriers to exercise, all variables changed in the expected direction in the intervention group and the opposite direction in the usual care group (Table 3).

When groups were compared, all differences favored the intervention group (Table 3). Perceived competence (PC) for diet and PA both had a significant interaction between treatment x time. Post hoc pairwise comparison showed that PC for diet was significantly higher for the intervention group compared to the control at week 34-36 of gestation ($p = 0.018$) and PC for PA was significantly higher in the intervention group at weeks 26-28 gestation ($p = 0.0033$) and at weeks 34-36 of gestation ($p = 0.0019$) compared to usual care. In the usual care group, PC for PA significantly decreased from baseline to week 34-36 of gestation ($p = 0.0059$).

Self-efficacy (SE) for diet and SE for exercise both had a significant interaction for treatment x time. Post hoc pairwise comparison analysis of SE diet variables showed that scores significantly increased in the intervention group from baseline to week 34-36 gestation (p = 0.014). Scores for SE diet were significantly greater in the intervention group at 2-months post-partum compared to the usual care group (p = 0.0041). SE exercise significantly increased in the intervention group from baseline to week 26-28 gestation (p = 0.036) and significantly decreased in the usual care group from baseline to week 34-36 gestation (p = 0.017). SE exercise was also significantly different between groups at both week 26-28 gestation (p = 0.0042), week 34-36 (p = 0.0006), and 2-months post-partum (p = 0.0091).

Participants in the intervention group reported high scores for competence (6.0 ± 0.9), relatedness (6.0 ± 0.7), and autonomy (5.8 ± 0.8) on the needs satisfaction for a lifestyle intervention counseling program inventory given at weeks 34-36 gestation. There was no difference in HCCQ score between groups (5.1 ± 1.2 usual care versus 5.0 ± 1.7 intervention, p = 0.67).

Behavioral measures. Physical activity, as measured in MVPA in bouts of 20-minutes or more, increased in the intervention group from baseline to mid-pregnancy compared to a decline in MVPA in the usual care group. Figure 1a and 1b show a graphic relationship between PA and exercise-related psychosocial variables change over time by group. In figure 1a both psychosocial and MVPA variables increase in the intervention group from baseline to mid-pregnancy. MVPA decreases in late pregnancy in the intervention group along with a slight decrease in SE for exercise. Figure 1b shows the

increase in average steps per day in the intervention group from baseline to mid-pregnancy parallel to the increase in SE for exercise. Average steps per day decreases in the usual care group from baseline to mid- and late-pregnancy in line with the decrease in SE for exercise.

Diet quality, as measured using the Healthy Eating Index (HEI), significantly increased from baseline to mid-pregnancy in the intervention group (p = 0.0065) compared to a decrease in the usual care group. Figure 1c compares the change in perceived competence for diet and HEI over time and between groups. HEI and perceived competence for diet both increase from baseline to mid-pregnancy in the intervention group and HEI score and perceived competence for diet decrease in the usual care group.

Associations between predictors and weight gain. For all variables except barriers to exercise, negative correlations represent relationships between increases in the predictor and decreases in GWG. At the mid-point of the intervention (week 26-28 gestation), the strongest correlates of GWG were decreases in perceived diet competence, exercise self-efficacy, and diet self-efficacy (Table 4). At the end of the intervention (weeks 34-36 gestation) the strongest correlates of GWG were decreases in perceived diet competence, exercise self-efficacy, diet self-efficacy and an increase in barriers to exercise. Perceived diet competence was the only significant predictor of 2-month post partum weight retention.

Two multiple regression models with GWG as the dependent variable and group assignment as a forced covariate were used to analyze predictors of GWG. Using the

significant correlates of GWG (found in table 4), a stepwise multiple regression was run for significant diet-related correlates and activity-related correlates. Only perceived competence for diet at the end of the intervention was a significant predictor of GWG (r^2 = -0.14, p = 0.0257) in the diet-related regression model. In the exercise-related model, barriers to exercise at the end of the intervention was the only significant predictor of GWG (r^2 = 0.20, p = 0.0051).

The same two models, with the inclusion of postpartum perceived competence for diet in the diet-related correlate model, were used to predict two-month postpartum weight retention. Only postpartum perceived competence for diet was a significant predictor of weight retention (r^2 = -0.12, p = 0.02). None of the activity correlates were a significant predictor of weight retention.

Discussion

In this study, we explored the change in motivation, self-regulation, and behavioral components in pregnant women enrolled in a theory based GWG intervention. The hypothesis that women in the intervention group would improve self-regulatory psychosocial variables including perceived competence for diet and PA and self-efficacy for diet and exercise was supported. Furthermore, the positive changes in psychosocial variables continued into the postpartum period in the intervention group. We also found evidence that participating in the intervention modified healthy behaviors such as diet quality and PA in previously sedentary pregnant women. Overall, the results of this study support the benefits of a theory-based intervention to address self-regulation and behavior change.

In accordance with SDT and MI, participants were encouraged to explore their own path to behavior change facilitated by the research staff. During pregnancy, when women may be more motivated to change, there are additional barriers, both perceived and inherent to pregnancy, that minimize the likelihood that healthy behaviors, specifically PA, will improve.

Understanding and enhancing pregnant women's perceptions of the value of PA during pregnancy is an important component in changing PA behavior. Gaston et al demonstrated that pregnant women who identified themselves as being farther along the SDT motivation continuum were less likely to identify perceived exercise barriers.[49] This study, as well as other studies that have explored the relationship between exercise beliefs, barriers and frequency of exercise behaviors, support that there is an inverse relationship between participation in PA and perceived barriers[50], perceived competence, and self-efficacy for exercise.[51]

Findings from this study, the first lifestyle intervention study in pregnancy to use SDT, support the empirical use of the theory to direct and facilitate internalization of perceived behavioral regulation. Over time, women in the intervention group reported increases in SDT-related variables that paralleled positive changes in behavior and weight gain. Research studies in the non-pregnant population have clearly shown that greater forms of self-regulation are associated with positive heath outcomes such as weight loss[28], improved glycemic control in diabetic patients[44], smoking cessation[52], and greater adherence to long-term PA[53].

In this study, women were guided towards behavior change rather than told how to change their behavior. Autonomy was supported with the use of behavioral goals created by the participant rather than provided as instruction from the research staff. Women were able to feel a sense of choice and with the guidance of the research staff, understand how to plan and achieve realistic achievable goals. In accordance with the principles of SDT, when supportive conditions are in place (competence, relatedness, autonomy), people can feel confident in themselves to make a behavior change that they initiated willingly.

It is important that women in this study reported high agreement with SDT intervention constructs as this provides evidence to support previous research demonstrating that when the intervention staff supports the basic needs of self-determination, participants feel less controlled.[54, 55] Increased autonomy-support allowed women in the intervention to feel more autonomous to make their own decisions, in-line with a more self-determined motivational regulation.

Utilization of the MI counseling approach likely fostered self-motivated behavior change by helping the participant's self-identify reasons to change, supporting the choice to change, and development of appropriate goals. The strategies MI utilized provide support in promoting the internalization and integration of new behaviors. We are only aware of one previous GWG intervention that used the MI approach in an obese Belgian population.[17] Although the intervention was effective at lowering total GWG compared to the control (10.6 kg ± 7 vs. 13.7 ± 7.3), 61.8% of the intervention group still gained more than 9 kg, the high end of the 2009 IOM recommendation for

weight gain in obese pregnant women (range 5-9.1 kg).[17] The study also failed to measure change in motivation or the constructs related to the stages of change model, the behavior change theory used to inform the intervention program.[17] Unlike the current study, the authors failed to describe how they used specific elements of MI to support the basic needs of competence, autonomy, and relatedness to promote more autonomous motivation.

Few theory-based GWG intervention studies have reported on the intervention effects of measured changes in theory constructs that could be used to predict behavior.[16-19] One study that did report on measured psychosocial changes during the intervention was the HIPP study (Health in Pregnancy and Post Birth Study).[15] This GWG intervention based on a number of theoretical health behavior change constructs and behavior change techniques, reported on psychosocial measures including motivation, knowledge, expectations, and body attitudes. The study was unsuccessful at preventing EGWG however, women in the health-coaching group reported higher levels of readiness and importance to achieve healthy GWG, improved sleep quality, and increased knowledge regarding GWG and fetal health.

Although the HIPP study found the intervention group improved motivation to engage in healthy lifestyle behaviors during pregnancy, the researchers failed to define healthy lifestyle behaviors in pregnancy or collect behavioral data.[15] Furthermore, the study authors did not identify how theory-based constructs were used in the implementation of the intervention. It is critical that theory-based interventions properly identify how theories inform interventions and in turn, collect data that will

help to determine which components of the intervention worked to produce expected outcomes.

It is important to note that in this current study, women in the intervention reported an increase in self-regulatory variables related to behavior. When compared to usual care, in which all psychosocial variables decreased, the intervention group significantly increased perceived competence and self-efficacy as they relate to both diet and activity. In addition to increasing levels of perceived competence and self-efficacy, women in the intervention group reported high satisfaction with the three basic needs necessary to facilitate internalization of motivation (competence, relatedness, autonomy).

The change in MVPA behavior at the end of the intervention was somewhat unexpected, specifically the increase above baseline MVPA in the usual care group. We did anticipate there would be an increase in overall activity in the intervention group and a decrease from mid-pregnancy to late-pregnancy was expected. Even with the intervention, it is typical to see a decrease in intentional activity towards the end of pregnancy, in both the general population and in previous behavioral intervention studies.

The FeLIPO study (Feasibility of a Lifestyle-Intervention in Pregnancy to Optimize maternal weight development) a randomized controlled trial in Germany, assessed the effectiveness of a lifestyle intervention to prevent EGWG and specifically targeted changes in physical activity behaviors.[56] The intervention included individual counseling on PA recommendations, instruction on how to achieve the recommendations, and self-

reported weekly PA logs monitored by the research staff. Self-reported PA data demonstrated that women in the intervention group maintained baseline PA into mid-pregnancy compared to a decrease in PA in the control group. However, similar to our findings, the intervention group PA level decreased from mid-pregnancy to late-pregnancy. Other behavior change intervention studies have reported an increase in baseline PA measures to mid-pregnancy but many published studies have not reported PA behavior changes or only report findings from mid-pregnancy.[18, 57]

It was not surprising to observe a decline in PA in late pregnancy, regardless of psychosocial PA variable improvements. It is well known that demographic characteristics play a role in behavior patterns during pregnancy[50] but unlike psychosocial variables, demographic characteristics are harder to modify. Pregnant women frequently report feeling too tired, physical limitations, concerns about safety or being too busy as barriers to PA during pregnancy, especially towards the end of pregnancy[58, 59]. Although MVPA variables did decrease in the intervention group in late pregnancy, SE for exercise remained high in late-pregnancy and the postpartum period. It is important to note, that although MVPA increased in the usual care group in late-pregnancy, average steps per day declined from baseline to the end of pregnancy. For future studies, it might be beneficial to collect post-partum PA measures to assess what impact the psychosocial changes during pregnancy have in the long-term, during the postpartum period when sustained high amounts of PA are more physical feasible.

Overall, the results of this study support that a theory-based lifestyle intervention in pregnancy can lead to a positive change in both psychosocial variables

and healthy behaviors. The fact that pregnancy in and of itself is a barrier to behavior change highlights the importance of finding an effective intervention that can positively impact healthy behaviors, self-regulation and promote appropriate gestational weight gain.

There were a number of strengths to this study, such as a theoretically integrated intervention paired with an evidence-based counseling approach. Because the sample population willingly enrolled in the study with the understanding they would be participating in a behavior change intervention, it was possible that this sample of women had an underlying motivation to make positive behavior modifications during pregnancy. Inclusion of baseline assessment prior to group randomization helped to control for changes observed across pregnancy.

The study was not without limitation. The majority of participants enrolled were white, married, and had some form of post-secondary degree; however, the sample population was reflective of the enrollment community's general population. The primary purpose of the study was powered to detect a difference in adherence to IOM weight gain recommendations. The small sample size limited the ability to conduct a mediation analysis to further understand how the changes in psychosocial variables facilitated behavior change and subsequently influenced GWG. In the future, studies should consider including assessments of environmental support (e.g., structure and involvement) and behavioral regulation (e.g., external vs. intrinsic motivation) to better understand the process of motivational change in the structure of a lifestyle intervention.

Conclusion

In conclusion, the theory based GWG intervention using a randomized controlled design positively changed mediators of behavior in the intervention group. Furthermore, there was a correlation between increases in the measured psychosocial mediators and total GWG, both before and after controlling for group randomization. The success of the intervention to change both healthy behavior and mediators of behavior change provides foundation for further use of behavior-theory in GWG interventions.

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TABLES

Table 1. Summary of intervention session strategies and relation to SDT constructs and MI techniques

	Strategy	SDT constructs	Behavior change tools
Month 1 (Session 1-2)	Assessment Value Exploration◆ Increase Knowledge PA	Relatedness Autonomy Competence	Importance & confidence ruler∞ Develop a change plan∞ Self-monitoring of behavior (weight gain, PA monitor, & diet log)⊙ Participant-driven SMART goal-setting∞
	Increase Knowledge (Diet) Value Exploration◆ Review of typical day/behavior◆	Competence Autonomy Relatedness & Competence	Review of outcome goal∞ Self-monitoring of behavior (weight gain, PA monitor, & diet log)⊙ Participant-driven SMART goal-setting∞
Month 2 (Session 3)	Address Barriers & social support⊙ Emphasize autonomy◆ Agenda mapping◆ Review of typical day/behavior◆	Competence Autonomy Autonomy Relatedness & Competence	Troubleshooting∞ Review of outcome goal∞⊙ Looking back∞ Self-monitoring of behavior (weight gain, PA monitor, & diet log)⊙ Participant-driven SMART goal-setting∞
Month 3-4 (Session 4-5)	Promoting self acceptance Adopting behavior change Review of typical day/behavior◆	Autonomy Competence Relatedness & Competence	Identify past successes/strengths∞⊙ Review of outcome goal∞⊙ Self-monitoring of behavior (weight gain, PA monitor, & diet log)⊙ Participant-driven SMART goal-setting∞
Month 5-6 (Session 6-7)	Values Exploration (post-pregnancy) ∞ Review of typical day/behavior◆ Address questions related to post-pregnancy barriers	Autonomy Relatedness & Competence Competence	Importance & confidence ruler∞ Develop a plan post-pregnancy (looking forward)∞ Review of outcome goal∞⊙ Self-monitoring of behavior (weight gain, PA monitor, & diet log)⊙ Participant-driven SMART goal-setting∞

∞MI content BCT, ◆MI relational BCT[35];⊙BCCTv1 coding[36]; *SDT: Self-determination theory; MI: Motivational interviewing; PA: physical activity; SMART: Specific, Measurable, Achievable, Results-focused, Time-bound goals.*

Table 2. Descriptive characteristics of study participants at baseline[1]

	All (n = 48)	Usual care n = 25	Intervention n = 23	p-value
Age (years)	31.4 ± 4.1	31.2 ± 3.6	31.6 ± 4.6	0.32
Gestational age at baseline (weeks)	11.9 ± 1.8	12.2 ± 1.8	11.5 ± 1.8	0.19
Pre-pregnancy BMI (kg/m^2)	25. 0 ± 4.5	24.3 ± 4.1	25.7 ± 5.0	0.26
Normal (%)	58.4	64.0	52.2	
Overweight (%)	27.0	24.0	30.4	
Obese (%)	14.6	12.0	17.3	
Parity	1.0 ± 1.0	1.0 ± 0.9	1.0 ± 1.1	0.78
Ethnicity (%)				0.84
Caucasian	83.3	84	82.6	
Other (African American or Asian)	16.7	16	17.4	
Marital Status (%)				0.33
Married	97.9	96	100	
Single	2.1	4	0	

[1]Values are reported as means ± SD.

Table 3. Change in psychosocial and behavioral variables during pregnancy by group[1]

	Usual Care (n = 25)	Intervention (n = 23)	Mean difference between groups[2]	Time	Treatment x time
Barriers to exercise				NS	NS
Baseline	2.92 ± 0.56	2.78 ± 0.81	-0.14		
Week 26-28	2.96 ± 0.57	2.78 ± 0.89	-0.18		
Week 34-36	3.12 ± 0.64	2.84 ± 0.79	-0.28		
Postpartum	2.79 ± 0.61	2.70 ± 0.58	-0.09		
Perceived competence: Diet				F = 3.9 p = 0.01	F = 5.1, p = 0.0018
Baseline	5.29 ± 1.13	5.08 ± 0.99	-0.21		
Week 26-28	4.91 ± 1.27	5.43 ± 0.85	0.53		
Week 34-36[b**]	4.78 ± 1.26	5.54 ± 0.86	0.75		
Postpartum	5.33 ± 1.06	5.77 ± 0.81	0.44		
Perceived competence: Physical activity				F = 4.6, p = 0.0043	F = 3.7, p = 0.0133
Baseline	4.62 ± 1.12[c**]	4.83 ± 0.88	0.21	[a]F = 12.9,	
Week 26-28[b**]	4.22 ± 1.14	5.41 ± 1.00	1.19	P = 0.0008	
Week 34-36[b***]	3.74 ± 1.19[c**]	4.99 ± 1.05	1.25		
Postpartum	4.81 ± 1.09	5.33 ± 1.15	0.52		
Self-efficacy: Diet				NS	F = 4.5, p = 0.0049
Baseline	62.9 ± 14.0	64.0 ± 16.3[c**]	1.1		
Week 26-28	61.6 ± 18.7	69.9 ± 13.4	8.3		
Week 34-36	61.8 ± 15.9	72.8 ± 14.4[c**]	11.0		
Postpartum[b*]	59.7 ± 15.3	73.8 ± 13.3	14.1		
Self-efficacy: Exercise				[a]F = 16.7, p<0.0002	F = 6.6, p<0.0003
Baseline	56.9 ± 15.9[c**]	61.3 ± 19.4[c*]	4.3		
Week 26-28[b**]	51.8 ± 17.1	69.6 ± 15.0[c*]	17.9		
Week 34-36[b***]	48.2 ± 18.7[c**]	68.8 ± 18.7	20.6		
Postpartum[b**]	49.6 ± 13.9	67.5 ± 14.8	17.9		
Edinburgh depression scale				F = 5.1, p = 0.0023	NS
Baseline	4.92 ± 3.2	3.91 ± 2.7	-1.01		
Week 26-28	4.84 ± 4.3	3.74 ± 3.4	-1.1		
Week 34-36	6.33 ± 4.6	4.56 ± 3.7	-1.77		
Postpartum	3.95 ± 4.1	2.91 ± 2.9	-1.04		
Physical Activity: ≥20 min bouts MVPA				NS	F = 3.62, p = 0.0306
Baseline	68.6 ± 79.3	77.7 ± 125.6	9.1		
Week 26-28	56.3 ± 86.6	120.4 ± 105.0	64.1		
Week 34-36	94.8 ± 158.7	75.6 ± 77.5	-19.2		
Diet Quality: HEI score				F = 3.97, p = 0.0221	F = 2.84, p = 0.0633
Baseline	63.1 ± 16.4	61.2 ± 10.5[b]	-1.9		
Week 26-28	63.9 ± 15.8	70.6 ± 12.8[b]	6.7		
Week 34-36	65.9 ± 14.8	66.0 ± 10.4	0.1		

[1]Values are reported as means ± SD. [2]Calculated as mean intervention minus usual care.
[a]Main effect of group.
[b]Pairwise comparison significant difference between groups.
[c]Pairwise comparison difference within group over time.
*p<0.05, **p<0.01, ***p<0.001

Table 4. Correlation between psychosocial, GWG, and post partum weight retention

	Total GWG		Post partum weight retention	
Psychosocial variables	***r***	**Partial *r*[a]**	***r***	**Partial *r*[a]**
Barriers to exercise (late pregnancy)	0.43***	0.41	0.14	0.15
Perceived diet competence (mid-pregnancy)	-0.36*	-0.33*	-0.18	-0.20
Perceived diet competence (late pregnancy)	-0.36*	-0.32*	-0.12	-0.14
Exercise self-efficacy (mid-pregnancy)	-0.35**	-0.30**	-0.11	-0.15
Exercise self-efficacy (late-pregnancy)	-0.30*	-0.23*	-0.17	-0.22
Diet self-efficacy (late-pregnancy)	-0.35**	-0.31**	-0.25	-0.28
Perceived diet competence (postpartum)	--	--	-0.33*	-0.27*

*p<0.05, **p<0.01, ***p<0.001; partial r^a adjusted by intervention group.

Figures

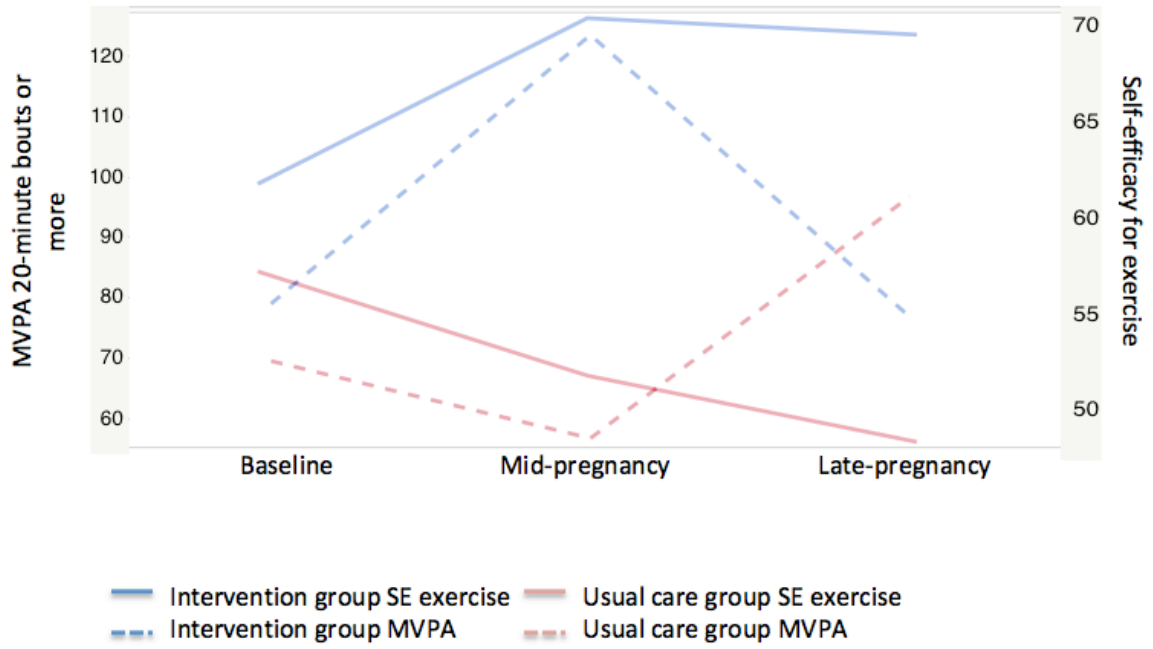

Figure 1a. Changes in MVPA in 20-minute bouts or more and self-efficacy for exercise over time by group

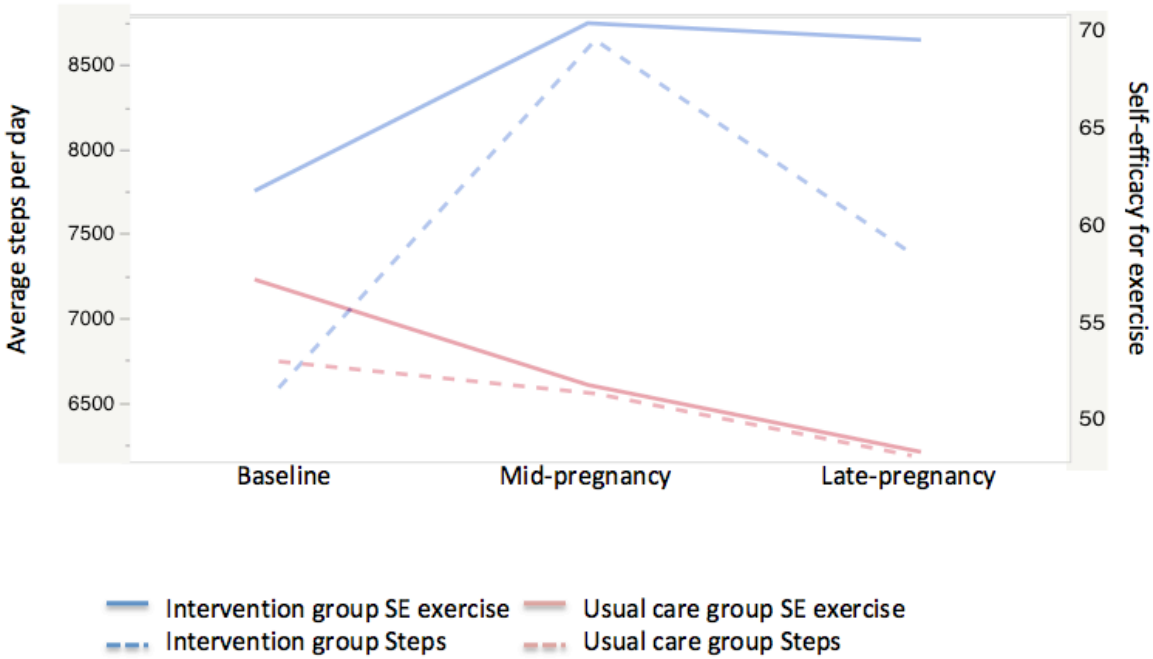

Figure 1b. Changes in average steps per day and self-efficacy for exercise over time by group

m

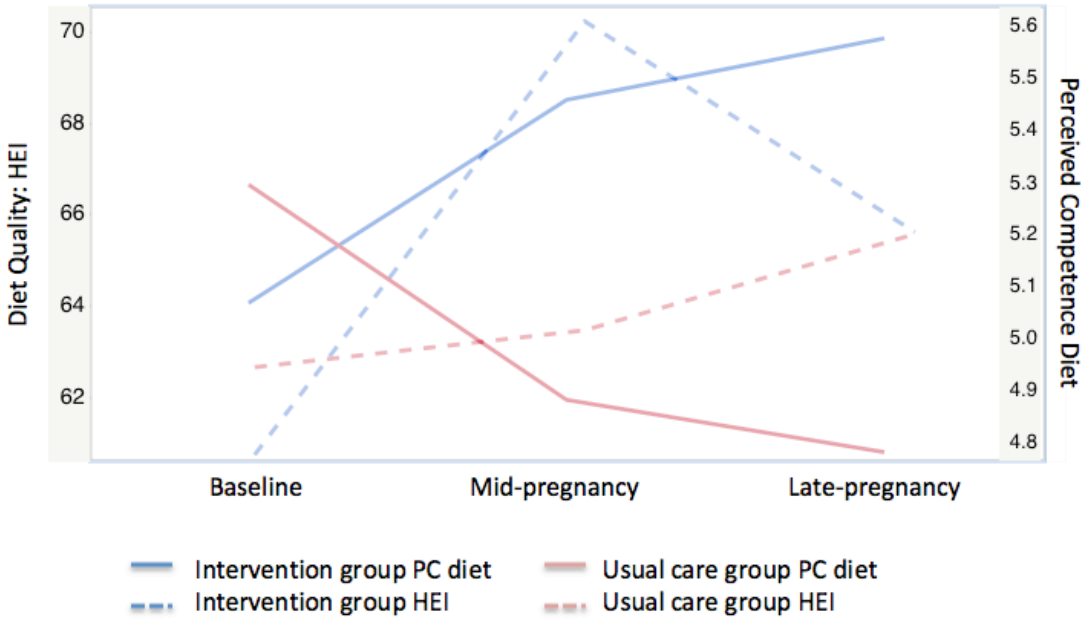

Figure 1c. Changes in diet quality and perceived competence for diet over time by group

CHAPTER 6: GENERAL CONCLUSIONS

It has been said that pregnancy is the opportune moment to make positive changes that directly affect the health of two people, mother and infant. In Healthy People 2020, a report published every decade with specific objectives for improving the health of all Americans, objective 9 out of 10 calls for a 10% decrease in obesity prevalence in US adults by 2020.[1] A recent hypothetical impact study demonstrated that prevention of excessive gestational weight gain (EGWG) yields meaningful reductions in long-term obesity. Based on the study analysis, elimination of EGWG results in a 10.7% reduction of midlife obesity in first time pregnancies and a 9.3% reduction in second pregnancies.[2] The results of the impact study provide promise for the efforts put towards eliminating obesity and also highlight the need to intervene before the cumulative effects of EGWG counteract the prevention of mid-life obesity.

The randomized controlled trial presented in this dissertation, the Behavioral-Wellness in Pregnancy study, provides an important foundation on which to build future GWG interventions and in turn, promote appropriate weight gain in pregnancy. The intervention was successful at significantly increasing the proportion of women that met the 2009 IOM weight gain recommendations. Objective physical activity and weighed diet data demonstrated significant improvements in average daily step count, 20- and 30- minute bouts of moderate-vigorous physical activity, and diet quality. Overall lifestyle behaviors associated with healthy pregnancy improved and were significantly greater in the intervention group compared to the control. Similarly, participation in the intervention improved psychosocial variables including self-efficacy for diet and

exercise. Women in the intervention group reported significantly greater competence for diet and physical activity in mid- and late-pregnancy compared to the usual care group as well. Lastly, the intervention had an overall positive effect on the three basic needs identified as critical to enhance self-determined motivation.

Key components of the current intervention included a multi-component behavior change approach, use of a behavior change theory to inform the intervention design, one-on-one monthly counseling sessions in addition to weekly contact with a RDN trained in MI, and early initiation of intervention. Given the benefits of participation in the study, clinicians should consider the inclusion of intervention components in regular prenatal care.

Considering the current national trends in GWG, the findings from this study demonstrate the ability of an intervention to successfully and significantly impact the high proportion of women gaining above the guidelines. More so, improvements in physical activity and diet quality provide strong evidence that an intervention that is theory-based can impact healthy behaviors during pregnancy.

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APPENDIX A. INSTITUTTIONAL REVIEW BOARD APPROVAL FOR THE BEHAVIORAL WELLNESS IN PREGNANCY STUDY

IOWA STATE UNIVERSITY
OF SCIENCE AND TECHNOLOGY

Institutional Review Board
Office for Responsible Research
Vice President for Research
1138 Pearson Hall
Ames, Iowa 50011-2207
515 294-4566
FAX 515 294-4267

Date: 4/25/2014

To: Dr. Christina Campbell
220 MacKay Hall

From: Office for Responsible Research

Title: The Blossom Project: "Be Well" Behavioral Wellness Study in Pregnancy

IRB ID: 14-199

Approval Date:	4/25/2014	**Date for Continuing Review:**	4/14/2016
Submission Type:	New	**Review Type:**	Full Committee

The project referenced above has received approval from the Institutional Review Board (IRB) at Iowa State University according to the dates shown above. Please refer to the IRB ID number shown above in all correspondence regarding this study.

To ensure compliance with federal regulations (45 CFR 46 & 21 CFR 56), please be sure to:

- **Use only the approved study materials** in your research, **including the recruitment materials and informed consent documents that have the IRB approval stamp.**
- **Retain signed informed consent documents for 3 years after the close of the study**, when documented consent is required.
- **Obtain IRB approval prior to implementing any changes** to the study by submitting a Modification Form for Non-Exempt Research or Amendment for Personnel Changes form, as necessary.
- **Immediately inform the IRB of** (1) **all serious and/or unexpected adverse experiences** involving risks to subjects or others; and (2) **any other unanticipated problems involving risks** to subjects or others.
- **Stop all research activity if IRB approval lapses**, unless continuation is necessary to prevent harm to research participants. Research activity can resume once IRB approval is reestablished.
- **Complete a new continuing review form** at least three to four weeks prior to the **date for continuing review** as noted above to provide sufficient time for the IRB to review and approve continuation of the study. We will send a courtesy reminder as this date approaches.

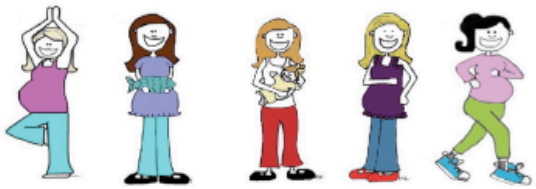
Please be aware that IRB approval means that you have met the requirements of federal regulations and ISU policies governing human subjects research. **Approval from other entities may also be needed.** For example, access to data from private records (e.g. student, medical, or employment records, etc.) that are protected by FERPA, HIPAA, or other confidentiality policies requires permission from the holders of those records. Similarly, for research conducted in institutions other than ISU (e.g., schools, other colleges or universities, medical facilities, companies, etc.), investigators must obtain permission from the institution(s) as required by their policies. **IRB approval in no way implies or guarantees that permission from these other entities will be granted.**

Upon completion of the project, please submit a Project Closure Form to the Office for Responsible Research, 1138 Pearson Hall, to officially close the project.

Please don't hesitate to contact us if you have questions or concerns at 515-294-4566 or IRB@iastate.edu.

APPENDIX B. RECRUITMENT MATERIALS

ISU IRB # 1 14-199
Approved Date: 22 March 2016
Expiration Date: 14 April 2018



The Blossom Project

"Be Well"

A program to promote improved health outcomes in pregnant women

WHAT YOU MAY RECEIVE:

- Free nutrition and physical activity counseling by a registered dietitian
- Eligible participants may be compensated a maximum of $245.00.

WHAT YOU WILL BE ASKED TO DO:

- Complete questionnaires at four time points
- Speak with a registered dietitian weekly
- Meet with a registered dietitian monthly
- Follow nutrition recommendations made by a registered dietitian
- Walk 10,000 steps daily

FOR FURTHER INFORMATION:

Contact the Recruitment Team at blossomproject@iastate.edu or at 515-294-8673

ISU IRB # 1 14-199
Approved Date: 22 March 2016
Expiration Date: 14 April 2018

Are you or is someone you know PREGNANT?

The Blossom Project

"Be Well"

A program to promote improved health outcomes in pregnant women

WHAT YOU MAY RECEIVE:

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FOR FURTHER INFORMATION:

Contact the Recruitment Team at blossomproject@iastate.edu or at 515-294-8673

IOWA STATE UNIVERSITY
OF SCIENCE AND TECHNOLOGY

The Blossom Project
515- 294-8673
blossomproject@iastate.edu

PREGNANT WOMEN NEEDED!

We are conducting a research study using physical activity and nutrition counseling to promote improved health outcomes in pregnant women.

QUALIFICATION CRITERIA INCLUDES:

- Must be pregnant (before week 14) and between the ages of 18-45
- Not a smoker
- Not pregnant with multiple babies (e.g. twins)
- No history of chronic disease (e.g. Type 1 diabetes, Type 2 diabetes, heart disease, renal disease, untreated thyroid condition; not previously diagnosed with gestational diabetes or pre eclampsia)
- Low-active or sedentary lifestyle prior to pregnancy (<3 30-minute intentional exercise sessions)
- Able to comprehend the information shared during the informed consent process
- Approval from your medical provider confirming you meet the qualification criteria will be required

A maximum of 4 data collection periods required. If asked, participant willing to walk 10,000 steps daily, meet with a registered dietitian on a monthly basis, have weekly communication with registered dietitian, and follow diet recommendations provided by the registered dietitian

Eligible participants will be compensated. Participation is voluntary.

For further information:
Contact the Recruitment Team at blossomproject@iastate.edu or 515-294-8673

ISU IRB #1 14-199
Approved Date: 26 March 2015
Expiration Date: 14 April 2018

The Blossom Project "Be Well" Recruiting Email

Thank you for your reply! You do indeed qualify for a study that we are currently conducting.

Here is more information about this study:

The purpose of this study is to provide a behavioral-lifestyle intervention to promote physical activity, prevent excessive gestational weight gain, minimize postpartum weight retention, and enhance mental well-being in pregnant women. If you agree to participate in this study you will be randomized to one of two groups; Individuals in Group 1 will have your weight at each prenatal visit plotted on an Institute of Medicine prenatal weight gain growth chart and provided to you. If randomized to group 2 you will have the opportunity to receive one-on-one counseling with a registered dietitian throughout pregnancy to promote healthy nutrition and physical activity behaviors. During your time in the study you will also be given a Fitbit Flex® activity monitor to help you keep track of your activity and diet during your pregnancy. All of this is provided at no cost to you.

Individuals in both groups will fill out various questionnaires related to your medical history and/or pregnancy. At any time you are invited to discuss concerns that you have about the study protocol.

You will visit the research center at ISU for 4 data collection periods at weeks 8-14, 26-28, and 34-36 of your pregnancy; as well as 2-month postpartum.

During the first three data collection periods the following measurements will be taken or collected:

- Weight,
- Physical activity assessment via 2 activity monitors worn on your arm and thigh for 8-days,
- Dietary assessment by recording the food and beverage that you consume for 3-days,
- Body composition, and
- Various questionnaires regarding self-efficacy, competence, motivation and barriers to control weight gain and exercise beliefs during pregnancy, and questionnaires to assess your physical health, psychological health, and social relationships.
- Between weeks 8-14 postpartum your body composition (percent body fat) will be measured using the BodPod, a means of assessing body composition by means of air displacement plethysmography.
- Between weeks 26-28 you will complete a 2-hour oral glucose tolerance test at our research facility

Additionally, the following data will be collected to assess birth outcomes:

- APGAR scores
- Birth weight
- Birth length
- Head circumference
- Gestational length at delivery

- Gender

At two-month postpartum the following data will be collected:

- Maternal weight
- Maternal body composition (BodPod)
- Questionnaires regarding physical activity and the intervention
- Length, weight, and body composition of the infant

To qualify for our study you must be:

- Between 18-45 years of age;
- Pregnant prior to 14 weeks gestation;
- Not pregnant with multiple babies (e.g. twins);
- Not a smoker;
- No history of chronic disease (e.g. Type 1 diabetes, Type 2 diabetes heart disease, renal disease, untreated thyroid condition; or previous diagnosis of gestational diabetes or pre-eclampsia);
- Low-active or sedentary lifestyle prior to pregnancy (< 3 30-minute intentional exercise sessions per week);
- BMI between 18.5 and 35.0 kg/m^2;
- Able to comprehend the information shared during the informed consent process.

For your participation, you will receive $200 following completion of the two-month follow-up visit and return of all equipment. An additional $15 for each of the first three data collection periods can be earned if the activity monitors are not off of the body for more than 90 minutes per day. Therefore, a maximum total of $245 compensation is possible.

I am attaching the consent form which provides more detailed information. I'll be happy to answer any more questions that you may have.

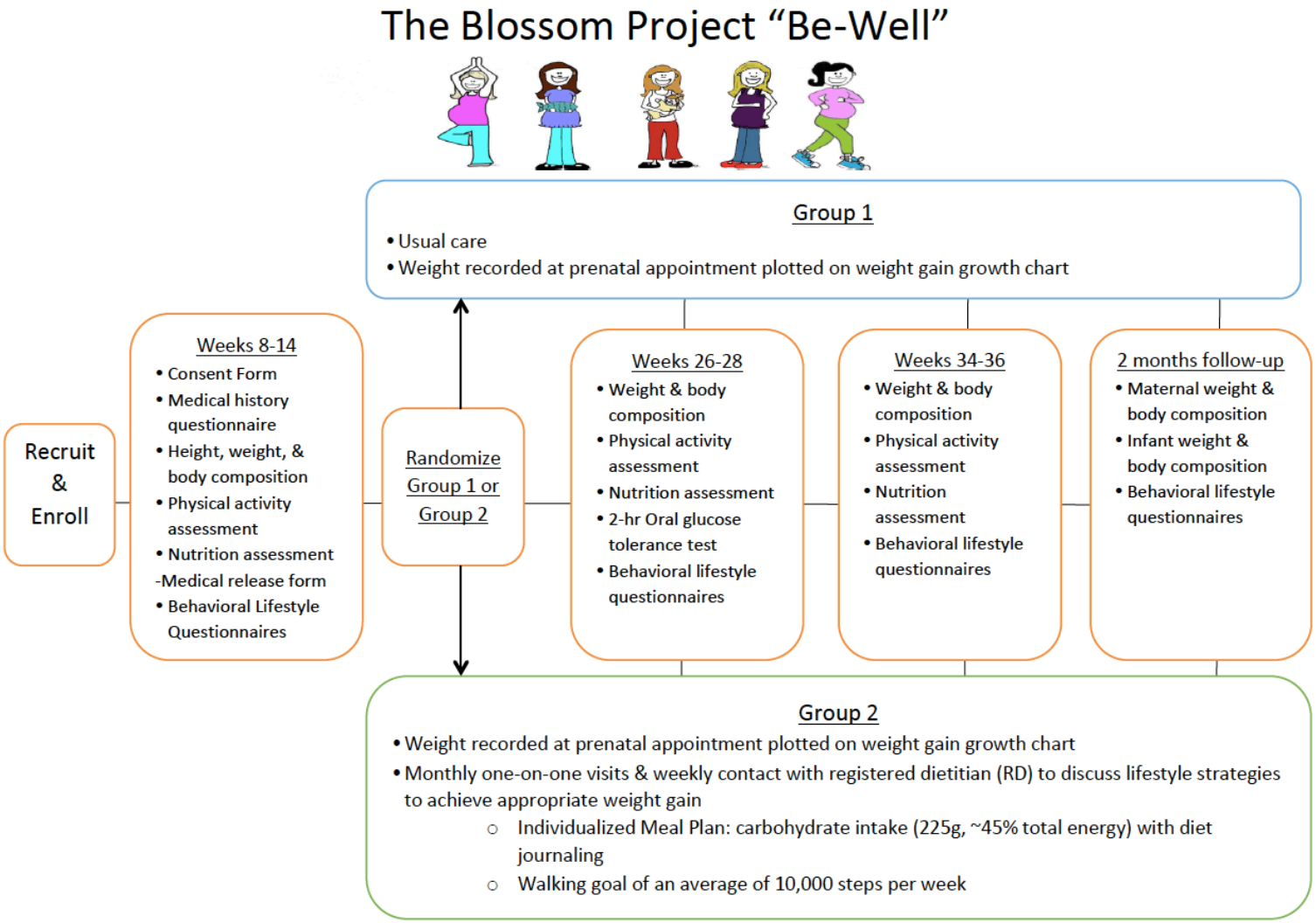
Please email me at buckingh@gmail.com if you have further questions. **Also, let me know whether you are or are not interested in participating. If you are interested, please provide me with your availability for a 30-45 minute appointment in the next [*time period to be specified depending upon what is applicable to the specific participant's current gestational length]*.**

I look forward to hearing from you soon!

Thanks!

Lyndi Buckingham
Blossom Project Online Study Coordinator
Iowa State University
515-294-8673
buckingh@gmail.com
blossomproject@iastate.edu

APPENDIX C. THE BEHAVIORAL WELLNESS IN PREGNANCY TIMELINE



APPENDIX D. CONSENT FORM

ISU IRB # 1 14-199
Approved Date: 22 March 2016
Expiration Date: 14 April 2018

CONSENT FORM FOR:
THE BLOSSOM PROJECT- "BE WELL"
BEHAVIORAL WELLNESS STUDY IN PREGNANCY

This form describes a research project. It has information to help you decide whether or not you wish to participate. Research studies include only people who choose to take part—your participation is completely voluntary. Please discuss any questions you have about the study or about this form with the project staff before deciding to participate.

Who is conducting this study?

Christina Gayer Campbell, PhD, RD
Associate Professor, Nutrition
Department of Food Science and Nutrition
Mailing Address: 220 MacKay Hall
Physical Address: 1105 Human Nutrition Science Building
Iowa State University
Ames, IA 50011-1123
515-294-4260; ccampbel@iastate.edu.

What is the purpose of this study?
The aim of our study is to evaluate the effectiveness of a behavioral-lifestyle intervention during pregnancy on the following: physical activity participation, how much weight is gained during pregnancy and remains after the baby is born, and overall well-being. To determine if the intervention works, if you agree to participate you will be randomized to one of two groups after you have completed the first "baseline" data collection (described below). Group 1 will continue with their daily routine. Group 2 will participate in the lifestyle intervention.

Why am I invited to participate in this study?
You are being asked to take part in this study because you are a healthy woman living in the communities in and around Ames, IA who has shown interest in our study by responding to our recruiting efforts. You have been selected to participate based on several criteria including:

- Between 18-45 years of age;
- Pregnant prior to 14 weeks gestation;
- Not pregnant with multiple babies (e.g. twins);
- Not a smoker;
- No history of chronic disease (e.g. Type 1 diabetes, Type 2 diabetes heart disease, renal disease, untreated thyroid condition; or previous diagnosis of gestational diabetes or pre-eclampsia);
- Low-active or sedentary lifestyle prior to pregnancy (< 3 30-minute intentional exercise sessions per week);
- BMI between 18.5 and 35.0 kg/m^2;
- Able to comprehend the information shared during the informed consent process.

Regardless of group assignment, what will I be asked to do?

If you agree to participate, you will be asked to do the following:

You will be required to receive confirmation that you are healthy enough to participate in this study from your medical provider. At your first visit, you will need to provide contact information (including name and phone number) for your medical provider. The attached consent letter will

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be sent by the principal investigator to your medical provider and returned via fax to a member of the project staff before you begin any participation in the study.

If you are diagnosed with multiple fetuses, or miscarry after enrolling in the study, you will no longer be able to participate in the study. If you have any known metal allergies or implanted electromagnetic devices you will not be able to participate in this study due to possible adverse effects when using the Sensewear® armband monitor.

Between weeks 8-14, 26-28, & 34-36 of your pregnancy

Your participation in this study may last up to 11 months (e.g. 8th week of pregnancy to 2 months post-partum). There will be 3 data collection periods; each requiring 2 visits (data initiation [described below] and return of equipment). A data collection period is for 8 days (see details below). For each data collection period, you will be asked to meet with a member of the project staff at the Nutrition and Wellness Research Center (2325 N. Loop Drive #6146, Ames, Iowa) or the facility located on campus in the Human Nutritional Sciences Building (HNSB) rooms 2021, 2022, and 2023. For your convenience, please provide us with a contact number to facilitate scheduling. The initial meeting to receive instructions regarding the physical activity and diet data collection will last 60-75 minutes; subsequent data initiation meetings will last approximately 30 minutes.

During each data initiation visit (between weeks 8-14, 26-28, 34-36 of pregnancy) you will be given two activity monitors and the equipment needed to collect a weighed 3-day diet record. Your height and weight will be measured, body composition will be assessed (first data collection period), and you will be asked to complete questionnaires. It should take approximately 15 minutes to complete these surveys.

You will be provided with a **SenseWear® Mini physical activity armband** that is worn on the upper left arm over the triceps muscle. The activity monitor will be worn for 8 days, 24 hours a day to ensure the best possible data collection. The monitor is not water resistant and needs to be removed when showering and swimming. This activity monitor has been used in many studies at ISU, including studies with pregnant women, with minimal complaints.

You will be provided with an **activPAL™ activity monitor** that is worn on the upper leg over the quadriceps muscle and will be attached to your leg using an adhesive pad. The activPAL will be worn for 8 days, 24 hours a day except when showering and swimming since it is not waterproof. We have previously used this activity monitor in Blossom Project studies with minimal complaints.

The 8-day **physical activity record** requires you to record all of your daily activities for 24 hours into a log that will be provided for the same 8- consecutive days you wear the 2 activity monitors.

The 3-**day food record** (3dDR) requires you to weigh and record all food and beverages consumed for 2 weekdays and 1 weekend day. You will be given detailed verbal and written instructions on how to properly complete the forms and tips on accurately weighing food. You will be provided with a dietary scale, at no cost to you, to facilitate the process. You may perceive this to be a tedious process; however it is the most accurate means of collecting dietary intake information.

During your first data collection period, your **body composition** (percent body fat) will also be

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measured using the BodPod. Before arriving for the BodPod measurement you will be asked to refrain from eating, drinking, and any exercise 2 hours prior to your visit. At this visit, you will be asked to bring/wear form-fitting clothing (ideally made from spandex or Lycra material) such as spandex-type swimsuit or single layer compression shorts and jog bra (without padding or wires). During the BodPod testing, you will sit in the BodPod chamber for 3 brief 40-second testing periods. The door to the BodPod will be opened between each of the three tests.

Your self-efficacy, competence, motivation and barriers to control weight gain during pregnancy, and exercise beliefs will be measured using **self-administered questionnaires**. In a similar manner, you will complete questionnaires to assess your physical health, psychological health, social relationships and environment, and a Postnatal Depression Scale, which has been used for non-postnatal women as well as a pre-screening scale for depression. Psychological need satisfaction and autonomous support will be assessed through use of standardized questionnaires.

During each initiation visit, you will arrange a time with a project staff member to turn in your data collection bag and all materials (all monitors, 3dDR, scale, etc.) at the completion of each 8-day data collection period.

Between weeks 26-28 of your pregnancy:

Oral Glucose Tolerance Test: Data collection will also include completion of an oral glucose tolerance test to assess how well your body can decrease sugar from your blood; this is a measure of insulin resistance. This is a test that is conducted during all pregnancies. Your medical provider may accept the results of our test instead of requiring you to complete another; you will need to confirm this with your provider. It is important that we conduct our own glucose tolerance test to collect consistent and reliable data since this protocol varies between clinics. The oral glucose tolerance test will consist of providing a fasted blood sample (following an overnight fast of 10-12 hours), consuming a 75g oral glucose solution and a blood sample at 60 and 120 minutes following consumption of the glucose solution. During this 2-hour period you will be asked to remain seated at the research facility. The blood draw will be conducted by a well-trained phlebotomist. Consenting to this study allows the investigators to use blood samples for further analysis of glucose and lipid metabolism.

At your week 34-36 appointment:

Birth outcome data: We will collect birth outcome data including gender, APGAR scores, birth weight, birth length, head circumference, and gestational length at delivery. This information will be obtained from the official medical record at your delivering hospital. You will be asked to fill out a Release of Medical Record form to allow us to contact the hospital to obtain this information after you've delivered. You will need to notify the Blossom Project staff of your delivery. Since the birth outcome data is officially a part of your child's medical record, the child's name will be needed for the hospital to locate the appropriate medical record. Consent to participate in this study allows the investigators to contact you following your due date if we have not heard from you.

The research team will provide you with a medical release form and self-addressed stamped envelope at your week 34-36 appointment. You will return the completed form to the Blossom Project as soon as possible **AFTER** your delivery using the provided envelope. The delivery hospital requires a medical release form be completed after you deliver because your child's information (name, date of birth) is required. Following these procedures fulfills your

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responsibility to notify the research team. If you are not comfortable with providing the researchers access to obtain this information on their own, you may retrieve a copy of the medical record yourself containing the requested information and provide it to the research team.

Follow-up visit 2-months after you deliver your baby

Mom: You will return to the research facility for a follow-up visit. At this visit your weight and body composition will be measured using the BodPod. You will be asked to fill out questionnaires regarding the perceived motivation and self-efficacy to be active after your pregnancy. You will also be asked to complete a postpartum depression survey.

Baby: Your baby will be weighed and his/her length will be measured. His/her body composition will be determined using a safe, non-invasive method called the PEA POD. This piece of equipment is the infant version of the BodPod. Your baby will be placed in a temperature-controlled test chamber with a continuous outside air source for a brief amount of time (approximately one minute or less) while the measurement is taking place. This method has previously been used for infants in other studies in our laboratory. After this visit is completed, your compensation form will be submitted to the accounting offices.

If you are randomized to Group 1:
Your weight will be measured at each obstetric prenatal visit by your health care provider. This is part of your regular prenatal care. We ask that you remove all heavy clothes and shoes as this may not be expected by your obstetric provider.

To reiterate, your weight will be measured and recorded by your obstetric provider and not by Blossom Project Staff. Your weight will be recorded on a "Prenatal Weight" form that you will be asked to sign at the beginning of the study. Your medical provider will fax the "Prenatal Weight" form to the Blossom Project Staff following each prenatal obstetric visit. We will record your current weight on an Institute of Medicine prenatal weight gain growth chart and email this to you no later than 2 days following our receipt of the form. Your weight relative to your expected weight gain will be provided however, no counseling or lifestyle information will be provided.

Additionally, at all data collection visits, you will be provided with a wrist worn activity monitor called a Fitbit Flex. You will be asked to wear this daily (remove when showering or swimming). You will not be provided with a password so you will not have any information about your activity. We expect that you will continue with your normal daily routine. The "window" on this monitor will not be visible so you will not have any feedback on your activity.

If you are randomized to Group 2:
Your participation in the lifestyle intervention will begin no later than week 14 and is expected to last until the delivery of your baby, provided no contraindications or complications of the pregnancy are experienced. You are being asked to participate in a behavioral lifestyle intervention consisting of monthly counseling sessions with a registered dietitian (RD), follow a meal plan, and be physically active each day.

Ideally, your monthly visits with the RD will coincide with your regularly scheduled prenatal appointments. However, when space is not available you may be asked to schedule an alternative site, either on the ISU campus or the NWRC in the Research Park. Your initial counseling session with the RD will take approximately 60 minutes however each subsequent

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session will take approximately 30 minutes.

Your weight will be measured at each obstetric prenatal visit by your health care provider. This is part of your regular prenatal care. We ask that you remove all heavy clothes and shoes as this may not be expected by your obstetric provider.

Your weight will be recorded on a "Prenatal Weight" form. You will be asked to sign this form at the beginning of the study. Your medical provider will fax the "prenatal weight" form to the Blossom Project Staff. We will record your current weight on an Institute of Medicine prenatal weight gain growth chart. If your counseling visit coincides with your prenatal appointment, your current weight will be provided to the RD by your medical provider at that time. The focus of your counseling session with the RD will be to discuss nutrition and physical activity strategies to facilitate appropriate weight gain.

Specifically, you will be asked to do the following:

- Each week, interact with the RD through your preferred method of communication (email, text message, Skype chat, or facetime) to discuss diet, exercise, and health goals;
- Follow a meal plan that is provided to you based on the American Diabetes Association exchange system;
- Walk an average of 10,000 steps per day each week;
- To track your steps, you will wear an activity monitor on your wrist called the Fitbit Flex™;
- You will be asked to record your diet at least two days per week. This will be reviewed by Blossom Project staff. You can enter your diet onto the Fitbit™ website or by hand;
- You will be asked to record your daily step count to be reviewed by Blossom Project staff. Daily step counts can be recorded on the Fitbit™ website or by hand.

Details on the lifestyle intervention:

Nutrition program: Meal plans will be discussed at the beginning of the program and are designed to provide 225 gram carbohydrates. A flexible plan will be created with the registered dietitian to provide the appropriate amount of food and calories based on your individualized needs per the Institute of Medicine dietary recommendations. This meal plan allows you to choose your own foods. You may find that this is less carbohydrates than you are used to eating however, this amount provides 45% of carbohydrate based on a 2000 calorie diet.

Physical activity program: You will be asked to average each week 10,000 steps per day. The first three weeks of the program will allow for a gradual increase in walking time. In the first three weeks, you should strive to walk at least 7500 steps per day. By week 15, you should be at your walking goal, which is 10,000 steps per day. To allow for some flexibility, your weekly average should be 10,000 steps per day.

At the initial baseline data collection visit, you will be provided with a FitBit™ Flex monitor. You will not be able to view your activity on the wristband nor will you be able to view the website. At the initial visit we are assessing your habitual level of activity.

Following the completion of the baseline data collection, you will be provided with a Fitbit.com username and password that will allow you to access the Fitbit.com website; an email address and password will also be provided that are linked to your account. You will be asked to wear

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the Flex monitor daily throughout your participation in the study. It must be removed when showering or submerged in water (e.g. swimming). You will be able to view your steps taken on the Fitbit.com website. You will be responsible for charging your Fitbit approximately every 5 days. Furthermore if you are having any difficulties with your monitor, please contact the Blossom Project staff immediately. You will be asked to return the monitor at the completion of the study (2 months after the baby is born).

What are the possible risks and benefits of my participation?
Risks – There are no foreseeable risks to either you or your fetus by participating in this study. The armband used in this study has been used in other studies within our laboratory with minimal complaints. A few participants have noted a minor skin irritation but it has receded within a couple of days following discontinued use of the monitor. You may experience discomfort from fasting overnight prior to the blood draw and momentary pain may occur during the blood draw. An experienced phlebotomist will conduct all blood draws under strict sanitary conditions to minimize pain and risk of infection.

Benefits – You may not receive any direct benefit from taking part in this study. If assigned to the intervention group, you may make healthier lifestyle choices than you were before. We hope that this research will benefit society by generating data that may contribute to further understanding the health benefits of consuming a healthy diet and being physically active during pregnancy.

How will the information I provide be used?
The findings of this study will be shared throughout the scientific community via oral and poster presentations at scientific meetings, and published research articles.

Will I incur any costs from participating or will I be compensated?
There are no direct costs involved with participating in this study, except your cost of transportation to and from the research facility (e.g. gas money, bus fare). You will be compensated for participating in this study. Upon return of all equipment, the proper communication notifying the research team that the baby was born, and completion of all data collection periods (weeks 8-14, 26-28, 34-36, and 2-month follow-up), you will receive $200. An additional $15 for each of the first three data collection periods can be earned if the activity monitors are not off of the body for more than 90 minutes per day. Therefore, a maximum total of $245 compensation is possible. If you happen to deliver prior to the week 34-36 data collection period you will be compensated $50 ($65 if good monitor wear time) for each period completed. You will need to complete a form at your two-month follow-up visit to receive payment. This form will ask for your social-security number. Please know that payments may be subject to tax withholding requirements, which vary depending upon whether you are a legal resident of the U.S. or another country. If required, taxes will be withheld from the payment you receive.

What measures will be taken to ensure the confidentiality of the data or to protect my privacy?
Records identifying participants will be kept confidential to the extent allowed by applicable laws and regulations. Records will not be made publicly available. However, federal government regulatory agencies, auditing departments of Iowa State University, and the ISU Institutional Review Board (a committee that reviews and approves research studies with human subjects) may inspect and/or copy your records for quality assurance and analysis. These records may contain private information.

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To ensure confidentiality to the extent allowed by law, the following measures will be taken: subjects will be assigned a unique code and letter that will be used on forms instead of their name. If the results are published, your identity will remain confidential. The data obtained from the study will be regarded as privileged and confidential. Your privacy will be maintained in any future analysis and/or presentation of the data with the use of coded identifications for each participant's data. All data will be stored in a locked file cabinet with access only by the principal investigator and project staff. Additionally, any data entered into the computer will be available with restricted password only. This data will be kept on hand until the results of the study have been published in a locked file in the PI's laboratory (HNSB 1109). Identifiers will be kept separate from the data.

What are my rights as a human research participant?
Participating in this study is completely voluntary. You may choose not to take part in the study or to stop participating at any time, for any reason, without penalty or negative consequences. Your choice of whether or not to participate will have no impact on you as a student/employee in any way. You may skip any question during a questionnaire (e.g. medical history, physical activity or self-efficacy questionnaires). You may withdraw consent in person or by phone with the principal investigator, Christina Campbell at any time. Please feel free to ask any questions or express your concerns regarding this study. The investigator will attempt to answer all questions. Contact Dr. Christina Campbell at 515-294-4260. If by chance any aspect of the data (e.g. physical activity monitors, diet record, attendance at counseling sessions) are returned with compliance (e.g. wear time) deemed insufficient to the primary investigator, participation in the study may be terminated.

What if I am injured as a result of participating in this study?
Emergency treatment of any injuries that may occur as a direct result of participation in this research is available at the Iowa State University Thomas B. Thielen Student Health Center, and/or referred to Mary Greeley Medical Center or another physician or medical facility at the location of the research activity.

Whom can I call if I have questions or problems?
You are encouraged to ask questions at any time during this study.

- For further information about the study contact the principal investigator Christina Campbell at 515-294-4260.
- If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office for Responsible Research, Iowa State University, Ames, Iowa 50011.

Consent and Authorization Provisions

Your signature indicates that you voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read the document and that your questions have been satisfactorily answered. You will receive a copy of the written informed consent prior to your participation in the study.

Participant's Name (printed) _____

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_____ _____

(Participant's Signature) (Date)

Investigator Statement

I certify that the participant has been given adequate time to read and learn about the study and all of their questions have been answered. It is my opinion that the participant understands the purpose, risks, benefits and the procedures that will be followed in this study and has voluntarily agreed to participate.

_____ _____

(Signature of Person Obtaining Consent) (Date)

APPENDIX E. MEDICAL HISTORY FORM

ISU IRB # 1 14-199
Approved Date: 22 March 2016
Expiration Date: 14 April 2018

Medical History Questionnaire – Blossom Project: Be Well

Please answer the following questions to the best of your knowledge. All information provided here is completely confidential. Please ask for clarification if needed.

Subject ID: _____

Age: _____yrs_____mo Date of Birth:_____

Usual Pre-pregnancy weight:_____lbs Height:_____ft_____in

Weight when you found out you were pregnant:_____lbs

Have you experienced considerable weight gain/loss (5 lbs or more) in the past 6 months prior to pregnancy? Yes No If yes, please explain:

_____

_____

Handedness: Right OR Left

Is this your first pregnancy? Yes No

If no, number of pregnancies (including this one)_____

Number of live births_____

If this is not your first pregnancy and number of pregnancies and live births are not equal to each other, please explain:

_____

Birth dates of children _____
mo/day/yr mo/day/yr mo/day/yr mo/day/yr mo/day/yr

Are you planning to breastfeed? Yes No Not sure

First day of last menstrual period:_____ Due Date:_____

What is your current due date based on? LNMP Ultrasound Other:_____

What is the first day of your next week of pregnancy (i.e. turnover day)? (circle)

Sunday Monday Tuesday Wednesday Thursday Friday Saturday

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Your average number of workouts per week (if any) prior to pregnancy?_____

Average duration of workout_____

Type of activity_____

Your average number of workouts per week (if any) since becoming pregnant?_____

Average duration of workout_____

Type of activity_____

Have you experienced any morning sickness that altered your activity level? Yes No

If yes, please describe_____

Are you following any guidelines regarding exercise during your pregnancy?_____

If yes, please describe_____
If yes, where did you receive the guidelines?_____

Have you met or seen your medical provider since becoming pregnant? Yes No

If yes, please answer the following two questions:
If no, do you have an appointment scheduled and if so, when?:

Has your medical provider discussed exercise during pregnancy with you? Yes No

If yes, please describe his/her recommendations: _____
_____

Has your medical provider discussed weight gain during pregnancy with you? Yes No
If yes, please describe his/her recommendations: _____
_____

Race (circle):

1. American Indian or Alaska Native
2. African American
3. Caucasian
4. Asian
5. Hispanic
6. Other (specify):_____

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Marital Status (circle):

1. single
2. married
3. divorced/separated
4. widowed

Education Level

What is the highest degree in school that you received? Please circle:

1. GED
2. High School Diploma
3. Associate's Degree
4. Bachelor's Degree
5. Graduate or Professional Degree
6. Other (if none, please specify): _____

Employment:

What is your occupation?_____

If employed how many hours a week do you work?_____

How many adults, age 18 years and older, live in your household? Please include yourself. _____

How many children, age 17 years and younger, live in your household? _____

What was your total household gross income in the past year?

1. None	4. $20,001-$30,000	7. $50,001-$75,000
2. $1-$10,000	5. $30,001-$40,000	8. $75,001 or more
3. $10,001-$20,000	6. $40,001-$50,000	

Drug and Alcohol:

1. Do you currently take vitamin supplements on a regular basis? Yes No
   If yes, please specify_____
   Have you in the past? Yes No
   If yes, how long ago?_____
2. Do you currently take herbal supplements on a regular basis? Yes No
   If yes, please specify_____
   Have you in the past? Yes No
   If so, how long ago?_____
3. Do you currently take any medications on a regular basis? Yes No
   If yes, please specify_____
4. Have you taken medication regularly in the past? Yes No
   If yes, please specify_____
   How long ago was medication taken regularly?_____
5. During your pregnancy are you consuming alcohol? Yes No

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If yes, how many drinks each week?_____

Medical History (circle any, and give age at diagnosis):

	Age
1. Diabetes	_____
2. Thyroid Disease	_____
3. Cirrhosis	_____
4. Hepatitis	_____
5. Gall Stones	_____
6. Kidney Stones	_____
7. Nephritis	_____
8. Cancer (specify)	_____
9. High Blood Pressure	_____
10. Angina	_____
11. Allergies (specify)	_____
12. Goiter	_____
13. Cardiovascular Disease	_____
14. Depression requiring medication	_____
15. Insomnia requiring medication	_____
16. Gestational Diabetes	_____
17. Preeclampsia	_____
18. Previous infant with low birth weight	_____
19. Early delivery with previous pregnancy	_____

If so, please explain: _____
_____

APPENDIX F. MEDICAL PROVIDER RELEASE FORM

ISU IRB # 1 14-199
Approved Date: 22 March 2016
Expiration Date: 14 April 2018

"Be-Well"

Dear Medical Provider,

_____ has volunteered to participate in a research study providing a behavioral-lifestyle intervention to prevent excessive gestational weight gain. If assigned to the treatment group, your patient will be asked to take part in one-on-one visits at least once a month with a registered dietitian to discuss nutrition, exercise, and health goals. Your patient will also be asked to walk at least 10,000 steps per day as monitored by a wrist-worn activity monitor, the Fitbit Flex. Participants will also be asked to follow a meal plan developed from previous Blossom Project studies and other successful pregnancy and lifestyle interventions (Mottola et al, MSSE 2010) that provides approximately 225 gram carbohydrate. Participants in the control group will receive their weight plotted on an Institute of Medicine prenatal growth chart following each prenatal appointment. All participants will complete four data collection periods. At weeks 8-14, 26-28 and 34-36 of her pregnancy, your patient will wear a SenseWear® Mini physical activity armband, an accelerometer-based posture monitor known as the activPAL and complete an 8-day physical activity record and a 3-day weighed food record. She will also complete standardized questionnaires to assess self-efficacy, competence, motivation and barriers to control weight gain during pregnancy and exercise safety beliefs during the current trimester of pregnancy.

Each participant will also be weighed at each time period and have her body composition assessed via the BodPod at the beginning of her pregnancy. Between weeks 26-28 of pregnancy, she will undergo a 2-hour, 75-gram oral glucose tolerance test to assess insulin sensitivity. At two months post-partum, your patient will return to our research facility to have her weight and body composition measured (via the BodPod) and complete a Quality of Life scale, a postpartum depression scale and a standardized questionnaire to assess perceived motivation to continue to be physically active. Her child's weight, length, and body composition will be measured at this time. We are also asking that you to provide us with the participant's weight at each prenatal appointment. We will provide you with an additional form that we will ask you to record the participant's weight on and fax it to the Blossom Project at Iowa State University. We will record the participant's current weight on an Institute of Medicine prenatal gain growth chart that will be emailed to her after we receive the weight from you.This study is approved by the Iowa State University Institutional Review Board.

We would like you to confirm that _____ meets the study criteria:

- Between the ages of 18-45;
- BMI between 18.5 and 35.0 kg/m^2;
- Pregnant with only one baby;
- Non-smoker;
- No history of gestational diabetes mellitus, pre-eclampsia, or chronic disease (e.g. Type 1 diabetes, Type 2 diabetes, heart disease, renal disease, untreated thyroid condition);
- No physical restrictions to achieve current physical activity recommendations of 10,000 per day steps; and
- Able to comprehend the information shared during the informed consent process.

Signature of Medical Provider_____

Print Name_____ Date_____

Please return this form via facsimile as soon as possible. Thank you for your help with this project.

Sincerely,
Christina Campbell, PhD, RD; Associate Professor, Nutrition; Iowa State University
Email: ccampbel@iastate.edu; Phone: 515-294-4260; Fax: 515-294-6193

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Approved Date: 22 March 2016
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Behavioral **Well**ness Study in Pregnancy Prenatal Weight Form

Dear Medical Provider,

_____ has consented to participating in a study to observe diet, physical activity, and weight gain during their pregnancy. We are asking that you to provide us with the participant's weight at each prenatal appointment, record it on this document and fax it to the Blossom Project at Iowa State University. We will record the participant's current weight on an Institute of Medicine prenatal gain growth chart that will be emailed to her after we receive the weight from you. This form is asking for you to document the weight at each prenatal appointment. This study is approved by the Iowa State University Institutional Review Board.

Weight of patient at prenatal appointment _____

Date of appointment _____

Signature of Medical Provider_____

Print Name_____ Date_____

Please return this form via facsimile as soon as possible. Thank you for your help with this project.

Sincerely,

Christina Campbell, PhD, RD; Associate Professor, Nutrition; Iowa State University
ccampbel@iastate.edu
Phone: 515-294-4260
Fax: 515-294-6193

Signature of research participant providing permission to contact physician & to receive her weight:

Signature:_____ Date: _____

APPENDIX G. ACTIVITY MONITOR AND PHYSIC AL ACTIVITY RECORD INSTRUCTIONS

Directions for Activity Monitors

- The SenseWear® armband activity monitor should be placed on the back side (over your triceps muscle) of your **left arm** between the elbow and shoulder. Adjust the strap so if fits your arm comfortably. Ensure it is contact with your skin at all times and that the monitor is right side up on your arm (the words should not be upside down when viewed in a mirror).
    - There is no on/off button for the activity monitor. It will be collecting data when it is in direct contact with your skin.
    - When the monitor is correctly placed on your arm it will sound off "dee dee dee, dee dee".
    - If the monitor loses contact with your skin or becomes misplaced from the proper contact site it will sound off "dee dee dee." Readjust the monitor and listen for the "dee dee dee, dee dee" sound to ensure proper placement.

- The Fitbit Flex™ is a wrist-worn pedometer that should be worn on the **non-dominant wrist.**
    - The monitor will need to be charged at least once during the 7 day period (~day 3 or 4).
    - You are provided with a usb charging cord that connects to a computer.

- The activPAL activity monitor should be placed on top center of the **right thigh** approximately 1/3 distance down from the hip bone to the top of the knee cap.
    - The head of the person on the front of the monitor should be right side up.

- Please record each activity as you do it in the physical activity log for 7 days
    - Enter the start and stop time for each activity
    - Include ALL activities throughout your day (showering, eating, driving, sitting at computer, watching tv, cooking dinner, walking to work, etc.)

- After 7 days have passed please be sure to make arrangements with a research investigator to return your materials.

The armband, Fitbit, and activPAL are NOT waterproof! Please do not wear them while showering or swimming or submerge it in other liquid.
Thank you.

****If you develop a skin irritation during the 7 day period, immediately contact a research investigator.**

Christina Campbell at 515-520-2326 OR Lyndi Buckingham at buckingh@iastate.edu

For Official Use Only
Subject ID:

Physical Activity Log

Date___

Start Time	End Time	Activity	Description
7am	7:30am	Getting dressed/showering	Up and down stairs 2 to 4 times
7:30	8:00	Making and Eating Breakfast	
8:00	8:25	Drive to work	
8:25	8:30	Walk from car	Quick walk from parking lot up stairs, one flight, to office
8:30	12:00pm	Working	Mostly sitting at desk or computer
12:00	1:00	Eating Lunch	Ate lunch and read a magazine
1:00	5:00	Working	Mostly sitting at desk or computer
5:00	5:05	Walk to car	Walk to car in parking lot, down one flight of stairs
5:05	5:45	Errands	Walking around stores, and driving
5:45	6:30	Swimming	Lap swim mostly freestyle and backstroke about 1000 yards
6:30	7:30	Making and eating dinner	Standing in kitchen, sitting at table
7:30	8:00	Walking the dog	Stroll around block mostly flat

For Official Use Only
Subject ID:

Physical Activity Log

Date_____

Start Time	End Time	Activity	Description

APPENDIX H. THREE-DAY DIET RECORD INSTRUCTIONS

Directions for 3-Day Weighed Diet Record

- Please use the scale provided to weigh all food that you eat during your 3 day recording period.
- Keep your food record current. List all foods and supplements immediately after they are weighed. Do not wait until the end of the day to record entries.
- Please print all entries.
- Be as specific as possible when describing the food or beverage:
  - Include the method of preparation used (boiled, baked, broiled, fried, grilled, steamed, raw, etc); *example: pork chop, center cut, no bone, grilled*
  - Include a well detailed description of the food item (fresh, canned, packed in heavy or light syrup, packed in water or oil, skinless, boneless, cut of meat, brand name); *examples: peaches in heavy syrup, tuna in oil, broiled T-bone steak, microwave heated canned corn*
  - Include label with the nutritional information for any unusual items or if unsure how to record
- Categorize the food consumed by meal type. Indicate "B" for breakfast, "L" for lunch, "D" for dinner, or "S" for snack.
- Include the name of restaurant if eating out
- Report only the portion of food that was actually eaten*; example: T-bone steak, grilled -100g (do not include the weight of the bone)*

Example: 100g t-bone- 30 g bone=70g actual food consumed
1- 500 mg multivitamin

- Weigh food left on plate that you did not eat and subtract from original total
- Record amount in either grams or ounces (wt) –please be consistent
- Remember to record condiments (ketchup, soy sauce, mustard, ranch dressing, salt, etc) as well as any fats used in cooking (oils, butter, margarine, etc), it is acceptable to measure these (Tbsp, tsp etc)
- Please try not to alter your normal diet during the period that you keep this record ..... **Thank you!!!!!!**
- If there are any questions please email:
  blossomproject@iastate.edu

For Official Use Only
Subject ID:

Date: Wednesday, March 21, 2007

B/L/D/S	Time	Food	Constituents	Description	Weight
B	9 am	Daily Supplements:	Multivitamin	One a Day multivitamin	1-500 mg capsule
B	9am	Grape Nuts		Post Brand	120g
B	9am	Sugar		White	3g
B	9am	Milk		1%	106g
S	9am	Blueberries		Frozen, unsweetened	50g
S	9am	Orange Juice		Tropicana, no pulp, calcium added	120g
S	11:30 am	Almonds		Raw, unsalted, Kirkland brand	60g
L	1:00pm	Sandwich	Bread	Whole Wheat, Wheat Montana	45g
L	1pm		Sprouts	alfalfa	5g
L	1pm		Cheese	Tillamook Sharp Cheddar	33g
L	1pm		Ham	Hillshire Farms Honey Ham	15g
S	1pm	Cottage Cheese		Low fat 2% small curd	55g
S	1pm	Apple Juice		From concentrate, Apple Tree brand, 100% juice	

For Official Use Only
Subject ID:

Date:_____:

B/L/D/S	Time	Food	Constituents	Description	Weight

APPENDIX I. QUESTIONNAIRES

BARRIERS TO EXERCISE

How difficult is it for you to exercise regularly during your pregnancy? Which of the following challenges might prevent (or have prevented) you from exercising regularly during your pregnancy?

Barriers	False	Mostly false	More false than true	More true than false	Mostly true	True
Lack of time	1	2	3	4	5	6
Feeling tired	1	2	3	4	5	6
Experiencing physical pain, discomfort	1	2	3	4	5	6
No motivation to exercise	1	2	3	4	5	6
Lack of support from significant others	1	2	3	4	5	6
Feeling too heavy (gaining weight)	1	2	3	4	5	6
Having physical limitations/ restrictions	1	2	3	4	5	6
Have other children to take care of	1	2	3	4	5	6
Work	1	2	3	4	5	6
Weather	1	2	3	4	5	6
Other:	1	2	3	4	5	6

DIET AND PREGNANCY

Please indicate the extent to which each statement is true for you, assuming that you were intending either to permanently improve your diet now or to maintain a healthy diet. Use the following scale:

1	2	3	4	5	6	7
	not at all true		somewhat true		very true	

1. I feel confident in my ability to gain a responsible weight during my pregnancy. _____

2. I now feel capable of maintaining a healthy diet. _____

3. I am able to maintain a healthy diet permanently. _____

4. I am able to meet the challenge of gaining a responsible weight during my pregnancy. _____

1. I feel confident in my ability to be physically active on a daily basis during my pregnancy. _____

2. I now feel capable of being physically active regularly during my pregnancy. _____

3. I am able to be physically active regularly over all trimesters of my pregnancy. _____

4. I am able to meet the challenge of being physically active during all trimesters of my pregnancy. _____

APPRAISAL INVENTORY TO REGULATE EXERCISE

A number of situations are described below that can make it hard to stick to an exercise routine. Please rate in each of the blanks in the column how certain you are that you can get yourself to perform your exercise routine/daily step count regularly (three or more times a week).

Rate your degree of confidence by recording a number from 0 to 100 using the scale given below:

0 10 20 30 40 50 60 70 80 90 100

Cannot do at all — Moderately can do — Highly certain can do

	Confidence (0-100)
When I am feeling tired	_____
When I am feeling under pressure from work	_____
During bad weather	_____
After recovering from an injury that caused me to stop exercising	_____
During or after experiencing personal problems	_____
When I am feeling depressed	_____
When I am feeling anxious	_____
After recovering from an illness that caused me to stop exercising	_____
When I feel physical discomfort when I exercise	_____
After a vacation	_____
When I have too much work to do at home	_____
When visitors are present	_____
When there are other interesting things to do	_____
If I don't reach my exercise goals	_____
Without support from my family or friends	_____
During a vacation	_____
When I have other time commitments	_____
After experiencing family problems	_____

APPRAISAL INVENTORY TO REGULATE EATING

A number of situations are described below that can make it hard to stick to a healthy diet. Please rate in each of the blanks on the column how certain you are that you can stick to a healthy diet on a regular basis.

Rate your degree of confidence by recording a number from 0 to 100 using the scale given below:

0 10 20 30 40 50 60 70 80 90 100

Cannot do at all — Moderately can do — Highly certain can do

	Confidence (0-100)
While watching television	
Feeling restless or bored	
During holiday times	
Feeling upset or tense over job-related matters	
Eating at a friend's house for dinner	
Preparing meals for others	
Eating at a restaurant alone	
When angry or annoyed	
When very hungry	
When depressed	
When you want to sit back and enjoy food	
When lots of high fat food is available in the house	
Feel like celebrating with others	
Someone offers you high fat foods	
Feel a strong urge to eat foods high in fat that you like	
When you are entertaining visitors	
During vacations	
Eating out with others when they are ordering high fat meals	
Parties where a lot of appetizing high fat food is served	
At recreational and sport events where high fat fast foods are served	
When visiting a city and needing a quick meal	
Airplane meals with high fat items	
When visiting a city and wanting to experience the local food and restaurants	
Holidays and celebrations where high fat foods are served	
When upset over family matters	
When you want some variety in your diet	
When eating breakfast in a restaurant	
Others bring or serve high fat foods	
When you have to prepare your own meals	
When faced with appealing high fat foods in the supermarket	

EXERCISE SAFETY BELIEFS QUESTIONNAIRE (ESBQ)

Please rate the safety of the following activities on a scale from 1-5:

1	2	3	4	5
Very safe	Somewhat safe	neither safe or unsafe	somewhat unsafe	Very unsafe

1 – 5 scale

1. Non-weight bearing exercise (e.g., swimming, water aerobics) _____
2. Weight bearing exercise (e.g., walking running, jogging, weight training) _____
3. High impact exercise (e.g., running, jogging, high impact aerobics) _____
4. Low impact exercise (e.g., walking, swimming, low impact exercising) _____
5. Exercise specifically designed for pregnancy _____
6. Exercise being unsafe _____

Please rate the following 9 items using the above 1-5 scale. You will rate each exercise according to frequency of activity:

7. Low intensity exercise (very comfortable)
   - Less than three times weekly _____
   - Three to five times weekly _____
   - More than five days weekly _____

8. Moderate exercise (lightly puffing, still able to talk)
   - Less than three times weekly _____
   - Three to five times weekly _____
   - More than five days weekly _____

9. Vigorous exercise (puffing, can hardly talk)
   - Less than three times weekly _____
   - Three to five times weekly _____
   - More than five days weekly _____

PREPARTAM EDINBURG SCALE

Instructions for users:
Please UNDERLINE the answer which comes closest to how you have felt IN THE PAST 7 DAYS, not just how you feel today. Here is an example, already completed.

I have felt happy:
Yes, all the time
Yes most of the time
No, not very often
No, not at all
This would mean: "I have felt happy most of the time during the past week". Please complete the other questions in the same way.

In the past 7 days:

1. I have been able to laugh and see the funny side of things
   - As much as I always could
   - Not quite so much now
   - Definitely not so much now
   - Not at all

2. I have looked forward with enjoyment to things
   - As much as I ever did
   - Rather less than I used to
   - Definitely less than I used to
   - Hardly at all

* 3. I have blamed myself unnecessarily when things went wrong
   - Yes, most of the time
   - Yes, some of the time
   - Not very often
   - No, never

4. I have been anxious or worried for no good reason
   - No, not at all
   - Hardly ever
   - Yes, sometimes
   - Yes, very often

* 5. I have felt scared or panicky for no very good reason
   - Yes, quite a lot

Yes, sometimes
No, not much
No, not at all

* 6. Things have been getting on top of me
Yes, most of the time I haven't been able to cope at all
Yes, sometimes I haven't been coping as well as usual
No, most of the time I have coped quite well
No, I have been coping as well as ever

* 7. I have been so unhappy that I have had difficulty sleeping
Yes, most of the time
Yes, sometimes
Not very often
No, not at all

* 8. I have felt sad or miserable
Yes, most of the time
Yes, quite often
Not very often
No, not at all

* 9. I have been so unhappy that I have been crying
Yes, most of the time
Yes, quite often
Only occasionally
No, never

*10. The thought of harming myself has occurred to me
Yes, quite often
Sometimes
Hardly ever
Never

WHO Quality of Life Survey

Instructions

This assessment asks how you feel about your quality of life, health, or other areas of your life. **Please answer all the questions.** If you are unsure about which response to give to a question, **please choose the one** that appears most appropriate. This can often be your first response.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last two weeks.** For example, thinking about the last two weeks, a question might ask:

		Not at all	Not much	Moderately	A great deal	Completely
	Do you get the kind of support from others that you need?	1	2	3	4	5

You should circle the number that best fits how much support you got from others over the last two weeks. So you would circle the number 4 if you got a great deal of support from others as follows.

		Not at all	Not much	Moderately	A great deal	Completely
	Do you get the kind of support from others that you need?	1	2	3	4	5

You would circle number 1 if you did not get any of the support that you needed from others in the last two weeks.

Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

		Very poor	Poor	Neither poor nor good	Good	Very good
1(G1)	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2 (G4)	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about how **much** you have experienced certain things in the last two weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3 (F1.4)	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5
4(F11.3)	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5(F4.1)	How much do you enjoy life?	1	2	3	4	5
6(F24.2)	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7(F5.3)	How well are you able to concentrate?	1	2	3	4	5
8 (F16.1)	How safe do you feel in your daily life?	1	2	3	4	5
9 (F22.1)	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how **completely** you experience or were able to do certain things in the last two weeks.

		Not at all	A little	Moderately	Mostly	Completely
10 (F2.1)	Do you have enough energy for everyday life?	1	2	3	4	5
11 (F7.1)	Are you able to accept your bodily appearance?	1	2	3	4	5
12 (F18.1)	Have you enough money to meet your needs?	1	2	3	4	5
13 (F20.1)	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14 (F21.1)	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15 (F9.1)	How well are you able to get around?	1	2	3	4	5

The following questions ask you to say how **good or satisfied** you have felt about various aspects of your life over the last two weeks.

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16 (F3.3)	How satisfied are you with your sleep?	1	2	3	4	5
17 (F10.3)	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18(F12.4)	How satisfied are you with your capacity for work?	1	2	3	4	5
19 (F6.3)	How satisfied are you with yourself?	1	2	3	4	5
20(F13.3)	How satisfied are you with your personal relationships?	1	2	3	4	5
21(F15.3)	How satisfied are you with your sex life?	1	2	3	4	5
22(F14.4)	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23(F17.3)	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24(F19.3)	How satisfied are you with your access to health services?	1	2	3	4	5
25(F23.3)	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to **how often** you have felt or experienced certain things in the last two weeks.

		Never	Seldom	Quite often	Very often	Always
26 (F8.1)	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	An extreme amount
27 (A)	To what extent do you feel that your physical changes associated with this pregnancy do not allow you to do what you need?	1	2	3	4	5
28 (A)	To what extent do you feel that your psychological changes associated with this pregnancy do not allow you to do what you need?	1	2	3	4	5
30 (A)	How worried are you about not being able to handle household chores?	1	2	3	4	5
31 (A)	How worried are you about carrying out the pregnancy successfully?	1	2	3	4	5
32 (A)	How worried are you about not being able to handle labor and delivery?	1	2	3	4	5
35 (A)	Have you been forced to cut down on your physical activity during this pregnancy?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied or dissatisfied	Satisfied	Very satisfied
36 (Ar)	How satisfied are you with your partner now?	1	2	3	4	5
37 (Ar)	How satisfied are you with your social life?	1	2	3	4	5
38 (Ar)	How satisfied are you with how you manage to adapt to this pregnancy?	1	2	3	4	5

APPENDIX J. USUAL CARE POSTPARTUM SURVEY

ISU IRB # 1 14-199
Approved Date: 22 March 2016
Expiration Date: 14 April 2018

Postpartum Questionnaire – Group 1

Please answer the following questions to the best of your knowledge. All information provided here is completely confidential. Please ask for clarification if needed.

PARTICIPANT INFORMATION

Subject ID: _____ Date (today):_____

Date of infant delivery: _____ Your due date was: _____

Are you currently breastfeeding? Yes No

If yes, what percentage of the feeding is breastmilk: _____% vs formula:_____%

If yes, for how long do you continue to breastfeed? _____

If no, did you breastfeed initially? Yes No

If yes, please list for how long you breastfed:_____

Please indicate what caused you to stop breastfeeding: _____

_____

RECOMMENDATIONS DURING PREGNANCY

During your pregnancy, did your medical provider ever discuss exercise or physical activity with you? Yes No

If yes, please describe what his/her recommendations were and when you received this information:_____

_____

_____

During your pregnancy, did your medical provider ever discuss weight gain during pregnancy with you? Yes No

If yes, please describe what his/her recommendations were and when you received this information:_____

_____

Has your medical provider discussed postpartum weight loss with you? Yes No

If yes, please describe_____

_____

Do you wish you would have received any additional information on any of these or other topics from your medical provider? Yes No

If yes, please describe_____

_____

_____

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Expiration Date: 14 April 2018

BLOSSOM BE WELL

Did you find the Institute of Medicine weight gain growth chart showing your weight gain during pregnancy helpful? Yes No

MISCELLANEOUS

Would you be interested (either in future pregnancies or past pregnancies had it been available) in receiving the Be Well prenatal counseling that involved individualized diet and physical activity recommendations? Yes No

If yes, in what form would you prefer this counseling to take place (please circle):

1. Online website
2. Face-to-face meeting
3. Email
4. Telephone
5. Other: _____

APPENDIX K. INTERVENTION POSTPARTUM SURVEY

ISU IRB # 1 14-199
Approved Date: 22 March 2016
Expiration Date: 14 April 2018

Postpartum Questionnaire – Group 2

Please answer the following questions to the best of your knowledge. All information provided here is completely confidential. Please ask for clarification if needed.

PARTICIPANT INFORMATION

Subject ID: _____ Date (today):_____

Date of infant delivery: _____ Your due date was: _____

Are you currently breastfeeding? Yes No

If yes, what percentage of the feeding is breastmilk: _____% vs formula:_____%

If yes, for how long do you continue to breastfeed? _____

If no, did you breastfeed initially? Yes No

If yes, please list for how long you breastfed:_____

Please indicate what caused you to stop breastfeeding: _____

_____

RECOMMENDATIONS DURING PREGNANCY

During your pregnancy, did your medical provider ever discuss exercise or physical activity with you? Yes No

If yes, please describe what his/her recommendations were and when you received this information:_____

_____

_____

During your pregnancy, did your medical provider ever discuss weight gain during pregnancy with you? Yes No

If yes, please describe what his/her recommendations were and when you received this information:_____

_____

Has your medical provider discussed postpartum weight loss with you? Yes No

If yes, please describe_____

_____

Do you wish you would have received any additional information on any of these or other topics from your medical provider? Yes No

If yes, please describe_____

_____

_____

ISU IRB # 1 14-199
Approved Date: 22 March 2016
Expiration Date: 14 April 2018

BLOSSOM PROJECT BE-WELL

Did you find the information regarding physical activity during pregnancy provided by the counselor helpful? Yes No

Did you find the information regarding nutrition during pregnancy provided by the counselor helpful? Yes No

If you answered "No" to either of the previous two questions, please describe why you did not find this information helpful and any suggestions you may have for improvement:_____

_____

_____

Did you find the monthly counseling sessions helpful for improving your overall diet quality? Yes No

Did you find the monthly counseling sessions helpful for improving your daily physical activity? Yes No

If you answered "No" to either of the previous two questions, please describe why you did not find this information helpful and any suggestions you may have for improvement:_____

_____

_____

Did you find the weekly emails helpful? Yes No

If you answered "Yes" to the previous questions, please describe why you found them helpful. If you answered "No" to the previous question, please describe why you did not find this information helpful and any suggestions you may have for improvement:_____

_____

_____

Did you find the Institute of Medicine weight gain growth chart showing your weight gain during pregnancy helpful? Yes No

Did you find the Be Well Meal Plan was helpful at improving your overall diet quality? Yes No

If you answered "No" to either of the previous two questions, please describe why you did not find this information helpful and any suggestions you may have for improvement:_____

_____

_____

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Approved Date: 22 March 2016
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Did you find the fitbit was helpful for reaching your physical activity goals? Yes No

If you answered "Yes" to the previous questions, please describe why you found them helpful. If you answered "No" to the previous question, please describe why you did not find this information helpful and any suggestions you may have for improvement:_____

_____

_____

What additional topics would you have liked discussed during the counseling sessions?

_____

_____

Did you find the features of the fitbit to be helpful in increasing your physical activity during pregnancy? Yes No

If no, why not? _____

_____

What features of the intervention were most helpful? Please circle all that apply.

1. Monthly counseling sessions with RD
2. Weekly email contact with RD
3. Institute of Medicine growth charts
4. Goal Setting
5. The Fitbit flex monitor
6. Other: _____

What aspects of the intervention could be improved?

_____

_____

_____

MISCELLANEOUS

In future pregnancies, would you be interested in participating in Be Well prenatal counseling that involved individualized diet and physical activity recommendations?

Yes No

If yes, in what form would you prefer this counseling to take place (please circle):

1. Online website
2. Face-to-face meeting
3. Email
4. Telephone
5. Other: _____

APPENDIX L. POSTPARTUM INTERVIEW

ISU IRB # 1 14-199
Approved Date: 22 March 2016
Expiration Date: 14 April 2018

Be Well Postpartum Interview

Subject ID: _____ **Date:** _____

1) **Type of delivery:** Vaginal Cesarean

2) **Length of active labor** (active/quicker dilation, usually at least 4-5cm dilated; hrs, min):
_____

3) **Was your labor induced?** Yes No
If yes, what method was used:
- Pitocin
- "Broke my water"
- Other: _____

4) **Did you use any pain medications during labor?** Yes No
If yes, what type?
- Epidural
- Narcotics: Demerol Nubain Stadol Other: _____
- Local block
- Other: _____
- Not sure

5) **Did you experience any complications during labor?** Yes No
If yes, what were your complications?
- Breech
- Unplanned cesarean Repeat c-sec: Y/N Reason for c-sec:
- Stalled labor after 4cm dilation
- Difficulty pushing
- Other: _____

6) **Were you diagnosed with any of the following during your pregnancy?**
- Pregnancy-induced hypertension
- Pre-eclampsia or Eclampsia
- Gestational Diabetes Mellitus
- Thyroid condition: _____
- Other: _____

If yes, what treatment or medical plan was used/were you advised to follow, if any?
_____

APPENDIX M. PREGNANCY RELATED INFORMATION SURVEY

Please answer the questions below to help us better understand what, if any, information you sought out during your pregnancy related to nutrition and physical activity. The questions are broken down into different time points of your pregnancy: before, during, and after you were enrolled in the Blossom Project study.

Please rank your interest in seeking additional *prenatal nutrition* information BEFORE enrolling in the Blossom Project study?

1	2	3	4	5
Very uninterested	Somewhat uninterested	Neither interested or disinterested	Somewhat Interested	Very Interested

Please rank your interest in seeking additional *prenatal physical activity* information BEFORE enrolling in the Blossom Project study?

1	2	3	4	5
Very uninterested	Somewhat uninterested	Neither interested or disinterested	Somewhat Interested	Very Interested

Please rank your interest in seeking additional *prenatal nutrition* information DURING the Blossom Project study?

1	2	3	4	5
Very uninterested	Somewhat uninterested	Neither interested or disinterested	Somewhat Interested	Very Interested

Please rank your interest in seeking additional *prenatal physical activity* information DURING the Blossom Project study?

1	2	3	4	5
Very uninterested	Somewhat uninterested	Neither interested or disinterested	Somewhat Interested	Very Interested

While enrolled in the study, did you seek NUTRITION information elsewhere?

€ Yes

- € No

If yes, where did you seek this information? (mark all that apply)

- € Online website (List website[s], blog[s], etc)
- € Print Media (State source):
- € App (State app):
- € Medical provider
- € Family
- € Friends
- € Other (describe)

While enrolled in the study, did you seek PHYSICAL ACTIVITY information elsewhere?

- € Yes
- € No

If yes, where did you seek this information? (mark all that apply)

- € Online website (List website[s], blog[s], etc)
- € Print Media (State source):
- € App (State app):
- € Medical provider
- € Family
- € Friends
- € Other (describe)

What characteristics do you look for to determine a source's reliability in the information that it is providing? (mark all that apply)

- € Medical website
- € University (.edu) website
- € Professional organization website (.org)
- € Credentials of author (e.g., medical doctor, nurse, dietitian, chiropractor, etc)
- € Testimonials
- € Friends/family recommendation of source
- € Other (please describe):
- €

Please rank your interest in seeking additional prenatal nutrition information AFTER the Blossom Project study?

1 Very uninterested	2 Somewhat uninterested	3 Neither interested or disinterested	4 Somewhat Interested	5 Very Interested

Please rank your interest in seeking additional prenatal physical activity information AFTER the Blossom Project study?

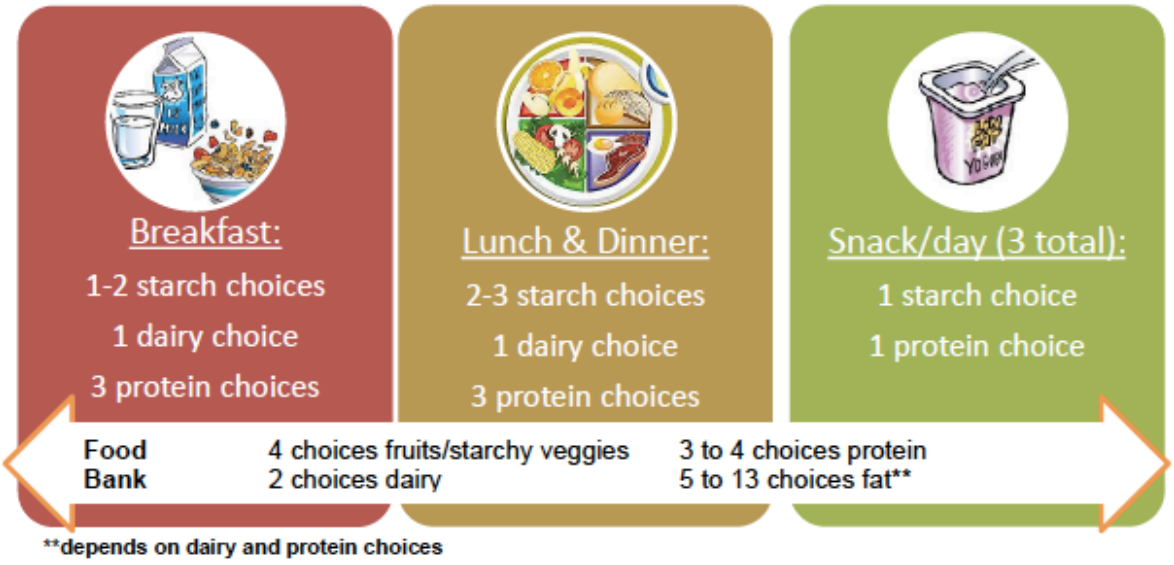
1 Very uninterested	2 Somewhat uninterested	3 Neither interested or disinterested	4 Somewhat Interested	5 Very Interested

APPENDIX N. THE BEHAVIORAL WELLNESS IN PREGNANCY MEAL PLAN MATERIALS

The Blossom Project

Blossom Project Meal Plan:

The Blossom Project meal plan was designed to help you gain the appropriate amount of weight throughout your pregnancy. The diet is based on a 225 gram carbohydrate, 2000 calorie diet that will be individualized to your needs. An average day is designed for three full meals and three snacks plus a food bank which will allow you to place additional food with your meals or snacks. Whether you like to eat three meals and three snacks a day or three meals and only two snacks this diet plan can be made to work for you.



Your meals and snacks are broken down into number of servings for each food source. Throughout the day your meals will be planned around eating a number of "choices" or servings from the following food groups: starch, fruit and starchy vegetables, dairy, protein, and fat. Below is what a typical day's meal plan will look like:

Meal	Food group "choices"
Breakfast	1-2 starch choices, 1 dairy choice, 3 protein choices
Lunch	2-3 starch choices, 1 dairy choice, 3 protein choices
Dinner	2-3 starch choices, 1 dairy choice, 3 protein choices
Snacking	1-3 starch choices for snacking, 1-2 protein choices for snacking
Pick & Choose	4 choices for fruits/starchy veggie, 2 choices for dairy, 3-4 choices for protein, & 5-13 choices fat

To get a better idea of what each food group choice is the table below breaks down each choice by how many grams of either starch, protein, or fat you are getting. So for one carbohydrate choice you will be eating 15 grams of carbohydrate. As mentioned before, this diet is based around a 225 gram carbohydrate per day intake. Since we are aiming for 225 grams carbohydrate total for one day that means throughout the day we can eat 9 starch, 4 fruit & starchy vegetables, and 6 dairy choices or servings.

You may notice that two groups, dairy and protein, have little numbers next to them. What this indicates is that dairy and protein food choices can double up as another food group choice. For example, if you drink ½ cup of 2% milk it will count as one dairy choice and one fat choice. As for protein, if you eat one ounce of ground beef it will count as one protein choice and one fat choice.

Food List	Carbohydrate (grams)	Protein (grams)	Fat (grams)
Starch	15	-	-
Fruit & Starchy Vegetables	15	-	-
Dairy[1]	5	4	Varies
Proteins[2]	-	7	Varies
Fat	-	-	5

[1] If you drink 2% milk take off one fat choice; If you drink whole milk take off two fat choices
[2] Take off 1-2 fat choices depending on protein choice

Overall the table below is what you will be eating throughout the day broken down into food group category, how many choices you can have in one day, the number of grams in each choice, and the total grams for the whole day.

Food Group	Carb/Protein/Fat	# of servings	Grams/Choice	Total Grams/Day	Total calories
Starch	Carbohydrate	9 servings	15 g/serving	135 grams	540 calories
Fruit/Starchy Vegetable	Carbohydrate	4 servings	15 g/serving	60 grams	240 calories
Dairy	Carbohydrate Protein	6 servings	5 g/serving 4 g/serving	30 grams 24 grams	120 calories 96 calories
Protein	Protein	14 servings	7 g/serving	98 grams	392 calories
Fat	Fat	~13 servings[3]	5 g/serving	65 grams	585 calories

Now let's look at what the choices mean when put into real amounts of food. The below tables provide a variety of different foods for each category that match with one choice of the food group.

The following pages breakdown:
Starch

Fruit & Starchy Vegetables

Dairy

Protein

Fat

Free Vegetables

[3] May move fat choices to different groups

Starch Choices

What is a starch? Why is it important to eat enough? Whole grains? What's that?

Starchy food or commonly referred to as carbohydrates, make up the larger portion of our diet. You may not realize it but when you're eating fruits and starchy vegetables we consider those a carbohydrate source. Even our milk choices provide a lot of this needed fuel.

Our brains depend on carbohydrates just like plants depend on sunlight so it is important to spread out your consumption throughout the day to feed the brain. While this is a pretty simple idea we like to keep a few extra ideas in mind:

- **Make half your grains whole**[4]. So what does this really mean? Whole grains are a great source of fiber and nutrients that you won't get if you eat plain white or *wheat* breads. Yes, you read that correctly, *wheat* breads may not be providing you the benefits you receive with **whole wheat or whole grain**. If a food isn't labeled as **whole wheat or whole grain** it might not be what you want. An easy way to check this is to read the ingredients list on the food label. If the only grains in the ingredients list are whole grains, the food is 100% whole-grain food.
- **Whole grains** include the entire grain seed, usually called the kernel. **Whole grain ingredients** include buckwheat, bulgur, millet, oatmeal, quinoa, rolled oats, brown or wild rice, whole-grain barley, whole rye, or whole wheat.
- **Partly whole-grain** products can help you meet the recommendation to make half your grains whole. For example, products that contain at least 51% of total weight as whole grain or those that provide at least 8 grams of whole grains per ounce are partial whole grains. If the bulk of grain that you eat is partly whole-grain then it is possible to make half your total grain intake whole!

Fun Facts & Tips:

- Carbohydrates have 4 calories for every gram. So if we look at one of our 15 gram starch choices we can figure out that…
  - 15 grams carb x 4 calories/gram carb = 60 calories
  - Next time you eat one of your starch choices you can now think "I'm eating 60 calories worth of carbs".
- High fiber foods are considered those with 5 grams or more **fiber** per serving. "100% whole grain" has at least 16 grams of whole grain per serving. This is another chance to read your food label and do some detective work.

What to watch out for:

- Sugar sweetened beverages. Think soda and some fruit juices. Even though 100% fruit juice can be part of a healthy diet, it lacks dietary fiber and can just add to your intake of empty calories. If you are going to drink fruit juice stick with 100% juice but try to limit intake.

[4] Recommendations from Dietary Guidelines for Americans 2010. http://health.gov/dietaryguidelines/dga2010/dietaryguidelines2010.pdf

STARCH CHOICES	
Food	**Serving Size = 1 choice**
Bread	1 slice
Bagel, large	¼ (1 oz)
Hot dog bun or hamburger bun	½ bun (1 oz)
Taco shell, 6"	1
Pancake or waffle	1, small
Cereal	½ cup
Granola	¼ cup
Granola bar	1 bar (1 oz bar)* check label for 15 grams
Trail mix, dried fruit or candy/nut mix	1 oz
Pasta, Rice (brown or white), Quinoa, cooked	⅓ cup
Wild rice	½ cup
Crackers	6
Graham crackers	3
Fruit snacks	¾ oz or 1 small package
Cookie (+ 1-2 fat; 2 for cookies with chocolate or chips such as butterscotch)	2 small cookies
Cake (+ 1 fat)	1 inch square, frosted 2 inch square, unfrosted
Brownie (+ 1 fat)	1 ¼ inch square or 1 ounce
Ice cream (+ 2 fat)	½ cup
Jelly, jam, or honey	1 Tbsp
Melba toast, bagel chips	4 pieces
Popcorn **-Add 1 to 2 fat if buttered popcorn**	3 cups
Pretzels	12, small twists
Rice cakes	2
Snack chips: Tortilla, potato, or pita chips	9-13
Soft drink, regular or sports drink	8 ounces
Fruit drink or lemonade	1 cup or 8 fluid ounces
Hot chocolate (+ 1 fat)	1 envelope
Baked Beans	**⅓ cup**
Beans, cooked (black, garbanzo, kidney, lima, navy, pinto, white)	**½ cup**
Lentils, cooked	**½ cup**
Peas, cooked (black-eyed, split)	**½ cup**
Refried beans, canned	**½ cup**

**Bolded also count as 1 protein

Fruit/Starchy Vegetable Choices

Fruit and vegetables are excellent sources of nutrients, relatively low in calories, and are associated with reduced risk for chronic disease. In addition to that, fruits and veggies are delicious!

Incorporating them into our daily diet is important for many reasons especially when you're pregnant. Fruits and vegetables are the major contributors of folic acid and iron, two important nutrients during pregnancy. More so than that, fruits and vegetables provide magnesium, potassium, dietary fiber, and vitamins A,C, and K.

What you may not know is that half a cup of fruit or a starchy vegetable can have as many carbohydrates in it as one piece of bread. Well this isn't a negative aspect to fruits and starchy vegetables, it is important to know this if you are monitoring your carbohydrate intake or eating within a certain carbohydrate range.

With that said, fruit and starchy vegetables are essential components of the diet and should not be avoided because of the amount of carbohydrates they supply. Both fruit and starchy vegetables are loaded with dietary fiber. Eating three to four servings of fruit per day is one of the easiest ways to meet the recommended 14 grams of dietary fiber per 1000 calories per day.

Fun Fact: Did you know that blackberries and raspberries have almost twice as much dietary fiber per cup when compared to broccoli? Blackberries and raspberries come in at around 8 grams of fiber per cup with broccoli containing just over 4 grams per cup.

Some tips for eating more fruit:

- Buy fresh fruits in season when they may be less expensive and at their peak taste.
- Buy fruits that are dried, frozen, and canned (in water or 100% juice) as well as fresh so that you always have some on hand.
- Make a salad that includes fruit such as strawberries with spinach and balsamic vinaigrette.
- Try unsweetened applesauce as a lower calorie substitute for some of the oil when baking cakes.
- As a snack, spread peanut butter on apple slices or top plain fat-free or low-fat yogurt with berries or slices of your favorite fruit!
- Frozen juice bars (100% juice) make healthy alternatives to high-fat snacks or ice cream bars.

FRUIT AND STARCHY VEGETABLES	
Food	**Serving Size = 1 choice**
Corn	½ cup or ½ large cob
Carrots	8 baby carrots
Mixed vegetables with corn, peas, or pasta	1 cup
Parsnips	½ cup
Peas, green	½ cup
Potato	¼ large baked with skin ½ cup mashed (beware of added milk/fat) 1 cup French fries (**oven baked**)
Pumpkin, canned, no sugar added	1 cup
Squash, winter (acorn, butternut)	1 cup
Yam, sweet potato	½ cup
Apple	1, small 4 rings, dried
Applesauce	½ cup, unsweetened ¼ cup, sweetened
Banana	1/2, medium
Blackberries	¾ cup
Cantaloupe, small	1/3 melon or 1 cup cubed
Cherries	½ cup sweet, canned 12 sweet, fresh
Dates	3
Dried fruits (blueberries, cherries, cranberries, mixed fruit, raisin)	2 Tbsp
Fruit cocktail, fruit juice (orange, grape, etc)	½ cup
Grapefruit	½, large
Grapes, small	17
Honeydew melon	1 slice or 1 cup cubed
Kiwi	1
Mandarin oranges, canned	¾ cup
Mango, small	½ cup or ½ small
Nectarine, small	1 (5 oz)
Orange, small	1
Peaches	½ cup canned 1 medium, fresh
Pears	½ cup canned 1 large, fresh
Pineapple	½ cup canned ¾ cup fresh
Plums	½ cup canned 2 small
Raspberries	1 cup
Strawberries	1 ¼ cup whole berries
Tangerines	2 small
Watermelon	1 slice or 1 ¼ cups cubes

Dairy

We've been instructed since we were children to drink our milk because we need them to grow strong bones. This is in fact true; our growing bodies need the calcium and as we age calcium has potential to reduce risk of cardiovascular disease and type 2 diabetes.

Consuming milk and other dairy products is important but it is also important to consider the type of milk or dairy product you are consuming. Choosing fat-free or low-fat milk and milk products (think cheese) provides the same nutrients with less fat and fewer calories. Let's break this down, below is a table of our dairy serving (1/2 cup or 4 fluid ounces) broken down into fat-free (skim)/low-fat (1%), reduced fat (2%), and whole milk:

	Carbohydrate (grams)	Protein (grams)	Fat (grams)	Calories
Skim or 1%	5	4	**0-1**	**50**
2%	5	4	**2.5**	**60**
Whole	5	4	**4**	**80**

As you can see above the amount of fat and calories increase as you go from skim/1% to whole milk. This relationship is also true with cheese and yogurt, if you pick fat-free or made with 2% milk cheese you will eat fewer calories and fat but still get the same nutrients you would with regular cheese.

If you're having a hard time making the shift from whole or 2% milk try doing it gradually. Mix half a cup of whole or 2% milk with half a cup 1% or skim until you adjust to the different taste.

Tips for Making Wise Choices in the Dairy Group[5]:

- If you drink cappuccinos or lattes, ask for them with fat-free (skim) milk
- Add fat-free, low-fat milk, soy or almond milk instead of water to oatmeal and hot cereals
- Use fat-free or low-fat milk when making cream based soups (such as cream of tomato)
- Make fruit-yogurt smoothies in the blender
- Make a dip for fruits or vegetables from yogurt
- Substitute Greek yogurt for sour cream in recipes
- Top casseroles, soups, stews, or vegetables with shredded reduced-fat or low-fat cheese
- Top a baked potato with fat-free or low-fat yogurt

Need to Know:

1/2 cup equals 4 fluid ounces

1 oz of cheese looks like two double AA batteries or three playing dice

[5] http://www.choosemyplate.gov/food-groups/dairy-tips.html

DAIRY	
Food	**Serving Size = 1 choice**
Milk (all varieties) -Add 1 fat for 2% milk or whole milk	1/2 cup or 4 fluid ounces
Chocolate milk	¼ cup or 2 fluid ounces
Yogurt** -Add 2 protein for 1/3 cup Greek yogurt	1/3 cup or 3 ounces ¼ cup flavored yogurt
Soy milk	1/2 cup or 4 fluid ounces
Almond milk	1/2 cup or 4 fluid ounces
Eggnog, whole milk	¼ cup
Cheese (all varieties) -Add ½ fat for 2% cheese, feta, mozzarella, or string -Add 1 fat for regular cheese: American, bleu, brie, cheddar, hard goat, Monterey jack, queso and Swiss -If less than 3 gram of fat per oz no fat added	½ oz
Cottage Cheese -2% cottage cheese add ½ fat	¼ cup
Ricotta cheese -Add 1 fat	¼ cup

If Greek= 2 protein

**If Greek yogurt, count as 2 protein

Protein Choices

Protein foods provide exactly what they say, protein! Protein can come from a wide variety of sources including meat, poultry, eggs, beans and peas, soy products, nuts, and seeds. In America we consume mostly meat, poultry, and eggs as our main protein source which means we are getting less protein from seafood, beans and peas, soy products, nuts, and seeds.

Eating a variety of protein food sources can be beneficial to our health, especially during pregnancy. Current recommendations suggest that pregnant or breastfeeding women should consume *at least 8* and *up to 12 ounces* of a variety of seafood per week. Seafood is important because of its omega-3 fatty acid content. Two notable fatty acids that come from seafood are EPA and DHA. DHA is of special interest to pregnant women because of its importance during fetal growth and development. If you do choose to eat seafood steer clear of fish that are high in methyl mercury which include tilefish, shark, swordfish, ahi tuna, and king mackerel. If you do choose to eat tuna be aware that the level of mercury varies depending on what type of tuna you are eating and where the tuna was caught. It is recommended that during pregnancy you only eat 1 can of light canned tuna every 3 days and 1 can of albacore tuna every 9 days. Some seafood sources lower in mercury that you are encouraged to eat include: salmon, mackerel, trout, crab, catfish, and cod.

While picking from a variety of sources is important, it is also important to get enough throughout the day. Eating enough protein is as important as making the smart choices when you pick out what you want to eat.

- Pick the lean choice: the leanest cuts include round steaks and roasts, top loin, top sirloin, and chuck shoulder and arm roasts in beef; pork loin, tenderloin, center loin for pork; skinless and boneless chicken breasts and turkey cutlets for poultry.
- Keep it lean: remove any excess visible fat from meat before cooking and use leaner cooking methods such as broil, grill, roast, poach, or boil instead of frying.
- Eat a variety of choices: try a new protein source every day! There is so much to choose from: salmon, trout, pinto beans, black beans, garbanzo beans, lentils, split peas, and tofu.

In the table below many of the protein choice serving sizes are in ounces which can be a problem if you aren't familiar with how to determine what one ounce looks like. In general, 1 ounce of meat, poultry or fish will look like a matchbox or 3 ounces of meat looks like a deck of playing cards.

Remember that the bean and pea choices in this group can also count as one starch choice. Beans and Peas are not only unique because of the variety they provide in your diet, they are an excellent source of dietary fiber and nutrients such as folate and potassium. To increase your intake of beans:

- Try eating hummus with vegetables for a snack or putting it on a sandwich or wrap as a spread.
- Include beans or peas in flavorful mixed dishes, such as chili or minestrone soup.
- Substitute whole beans or refried beans for meat in tacos or enchiladas.
- Add whole beans such as garbanzo or white beans to a mixed green salad.
- Substitute a veggie burger for a regular burger. You may be surprised at how good they taste!

PROTEIN	
Food	**Serving Size = 1 choice**
Lower Fat Protein Options: No fat choices	
Beef, trimmed of fat: ground round, roast (chuck, rib, rump), round, sirloin, steak (cubed, flank, porterhouse, T-bone), tenderloin	1 ounce
Beef jerky	½ ounce
Egg whites	2
Fish, fresh or frozen: catfish, cod, flounder, haddock, halibut, orange roughy, salmon (smoked or canned), canned sardines, tilapia, trout, tuna	1 oz
Low-fat hot dog (3 grams or less fat/ounce)	1
Lamb: chop, leg, or roast	1 oz
Pork, lean	1 oz
Poultry, without skin: chicken, duck or goose, turkey	1 oz
Sandwich meat, low fat (less than 3 grams/oz)	1 oz
Shellfish: clams, crab, lobster, scallops, shrimp	1 oz
Baked beans	**1/3 cup**
Beans: black, garbanzo, kidney, lima, navy, pinto, white, refried beans	**½ cup**
Edamame	**½ cup**
Lentils, brown, green, or yellow	**½ cup**
Meatless burger, soy-based	**3 oz**
Meatless burger, vegetable- and starch based	**½ patty**
Peas, cooked: black-eyed and split peas	**½ cup**
Soy nuts	**¾ ounce**
Medium Fat Protein Options: Add one fat choice	
Beef: corned beef, ground beef, meatloaf, prime grades trimmed of fat (prime rib), short ribs	1 ounce
Egg	1
Fish, any fried type	1 ounce
Lamb: ground, rib roast	1 ounce
Pork: cutlet, shoulder roast	1 ounce
Poultry: chicken with skin	1 ounce
Sausage (4-7 grams of fat/oz)	1 ounce
Tofu	½ cup or 4 ounces
High Fat Protein Options: Add two fat choice	
Bacon	2 slices
Hot dog	1
Pork: ground, sausage, spareribs	1 ounce
Processed sandwich meat (8 grams of fat/oz)	1 ounce
Sausage (8 grams of fat/oz)	1 ounce
Falafel	**3, 2 inch patties**
Hummus	**1/3 cup**
Nut spreads: almond butter, cashew butter, peanut butter, soy nut butter	1 Tbsp

Bolded also counts as 1 starch choice

1 starch

Fat and Oil Choices

The dreaded word "fat" doesn't *have* to be a bad thing. Fat is an essential part of our diet and helps us absorb the fat soluble vitamins, A/D/E/K, that we need. Instead of thinking about fat as one thing it's better to look at fat as different fatty acids: saturated, monounsaturated, polyunsatured, or trans fatty acids.

Some look at fat as *the good, the bad, and the ugly:*

1. ***The Good:*** monounsaturated and polyunsaturated fatty acids (the "Oils") are usually liquid at room temperature and contribute essential fatty acids and vitamin E to the diet. Unsaturated fats are linked to better heart health and could help lower blood cholesterol levels. These are found in *olive oil, peanut oil, canola oil, flaxseeds, salmon, trout, tuna, sunflower oil, sesame oil, peanuts, and cashews*.

2. ***The Bad:*** saturated fatty acids can be found in butter, whole milk, cheese, and certain vegetable oils (palm and coconut) and unlike unsaturated fats that can be beneficial for heart health, saturated fatty acids are associated with higher levels of LDL (bad) cholesterol and increased risk for cardiovascular disease. It is recommended that **less than 10 percent of calories** come from saturated fatty acids. Furthermore, when appropriate saturated fats should be replaced with unsaturated fats and most situations are appropriate for this substitution.

3. ***The Ugly:*** trans fatty acids is a whole other kind of fatty acids. Unlike unsaturated and saturated fats, trans fat is formed during food processing. Trans fats are formed during a process referred to as hydrogenation in which unsaturated fatty acids are converted to saturated fatty acids in order to make it a stable and solid product. Trans fatty acids can be found in margarines, snack foods, and prepared desserts. Many products today are moving towards being "trans fat free" because of the known negative health effects such as raising LDL cholesterol. Trans fats are required by law to be on the Nutrition Facts label making it that much easier to avoid them!

Take home message about fats:

Fat isn't bad, it can be bad and ugly but it is still an essential nutrient. In order to get the most from your fat intake reduce the amount of saturated fat you eat to less than 10 percent of total calories and try replacing saturated fat sources with unsaturated fats such as using olive oil instead of butter and instead of sour cream use plain, non-fat yogurt. A few more tips:

- Frozen yogurt instead of ice cream
- Skim or 1% milk instead of whole milk
- Make your own salad dressing with unsaturated fats such as olive oil
- Snack on nuts instead of snack crackers or prepared desserts that may have trans fat
- Cook with olive oil

FATS	
Food	**Serving Size = 1 choice**
Monounsaturated Fats (unsaturated)	
Nuts	Almonds, 6 Cashews, 6 Mixed (50% peanuts), 6 nuts Peanuts, 10 Pecans, 6 halves Pistachios, 16
Oil: canola, olive, peanut	1 tsp
Polyunsaturated Fats (unsaturated)	
Margarine	1 tsp
Mayonnaise	1 tsp 1 Tbsp reduced-fat
Walnuts	4 halves
Oil: corn, cottonseed, flaxseed, grape seed, safflower, soybean, sunflower	1 tsp
Salad dressing	1 Tbsp, regular 2 Tbsp, reduced-fat
Seeds: flaxseed, pumpkin, sesame seeds	1 Tbsp
Saturated Fats	
Bacon	1 slice
Butter	1 tsp
Coconut milk	1 ½ Tbsp
Cream	1 Tbsp 2 Tbsp, half & half
Cream cheese	1 Tbsp or ½ oz 1 ½ Tbsp, reduced-fat
Shortening, solid	1 tsp
Sour cream	2 Tbsp 3 Tbsp reduced fat

Free (Extra) Vegetable Choices

You read the above heading correctly, it says **free** vegetables. Food for free, how is that possible? Well technically it isn't free but what they are is naturally low in fat and calories allowing you to enjoy more without breaking your food bank. Even though they are considered free try not to exceed more than 2 servings of free vegetable choices with meals. That doesn't mean limit your vegetable intake, instead try and include at least 1 serving per meal!

The previously mentioned starchy vegetables are not a part of the free vegetables category because of the carbohydrates they provide.

FREE VEGETABLES	
Food	**Serving Size**
Broccoli	½ cup
Romaine lettuce	1 cup
Dark green leafy lettuce	1 cup
Spinach	1 cup
Green mesclun mix	1 cup
Kale	1 cup
Tomato	½ cup
Asparagus	1 cup
Brussel sprouts	½ cup
Mushrooms	1 cup
Raw cabbage	1 cup
Celery	1 cup
Cucumber	1 cup
Cauliflower	½ cup
Eggplant	½ cup
Iceberg lettuce	1 cup
Leeks	½ cup
Sweet peppers	½ cup
Onions	½ cup
Turnips	1 cup
Wax beans	½ cup
Zucchini	½ cup

Free (Extra) Condiment Choices

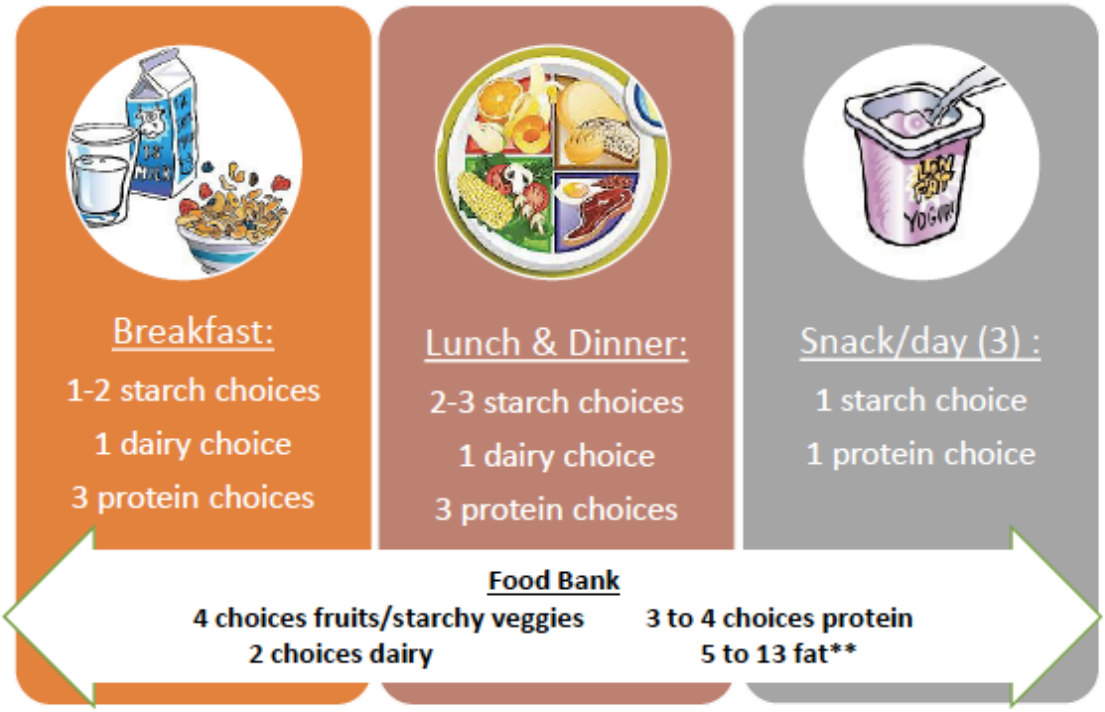
"Free" condiments are considered free but not when eaten in excess. Each free food choice has less than 20 calories and 5 grams or less of carbohydrate per serving but you should limit these "free" choices to 3 servings per day.

FREE (EXTRA) CONDIMENTS	
Food	**Serving Size**
Jam or jelly, light or no sugar added	2 tsp
Syrup, sugar-free	2 Tbsp
Barbecue Sauce	2 tsp
Ketchup	1 Tbsp
Honey mustard	1 Tbsp
Pickles	4 slices
Salsa	¼ cup
Soy sauce, light or regular	1 Tbsp
Sweet chili sauce	2 tsp
Taco sauce	1 Tbsp
Vinegar	unlimited

Common Measurement

Dry:	Liquid:
3 tsp = 1 Tbsp	4 Tbsp = ¼ cup
2 oz = ¼ cup	8 oz = ½ pint
3 oz = 1/3 cup	1 pint = 2 cups
4 oz = ½ cup	1 quart = 4 cups
8 oz = 1 cup	4 quarts= 1 gallon

Blossom Project Meal Plan Quick Facts



***depends on dairy and protein choices*

Food Group	Carb/Protein/Fat	# of servings	Grams/Choice	Total Grams/Day	Total calorie
Starch	Carbohydrate	9 servings	15 g/serving	135 grams	540 calories
Fruit/Starchy Vegetable	Carbohydrate	4 servings	15 g/serving	60 grams	240 calories
Dairy	Carbohydrate Protein	6 servings	5 g/serving 4 g/serving	30 grams 24 grams	120 calories 96 calories
Protein	Protein	14 servings	7 g/serving	98 grams	392 calories
Fat	Fat	~13 servings*[1]	5 g/serving	65 grams	585 calories

[1] May move fat choices to different groups

Food List	Carbohydrate (grams)	Protein (grams)	Fat (grams)
Starch	15	-	-
Fruit & Starchy Vegetables	15	-	-
Dairy (subgroups?)[2]	5	4	varies
Proteins (subgroups?)[3]	-	7	varies
Fat	-	-	5

Starch Choice: 15 g carb/choice	Fruit & Starchy Veggies: 15 g carb/choice	Dairy: 5 g carb/choice	Proteins: 7 g protein/choice	Fats: 5 g fat/ choice
1 Choice Equals:	1 Choice Equals:	1 Choice Equals:	1 Choice Equals:	1 Choice Equals:
• 1 slice of bread • ¼ bagel • ½ pita, English muffin, hotdog or hamburger bun • 1 6" taco shell • ½ cup cereal • ¼ cup granola • 1 granola bar • 1/3 cooked pasta, rice, quinoa • 3 cups popcorn • 9-13 tortilla chips • 6 crackers • ½ legumes (black, kidney, garbanzo, navy, refried beans, lentils, peas) • 2 small cookies • 1 ¼ inch brownie	• ½ cup corn or ½ large cob • 8 baby carrots • ½ cup mashed, medium baked • 1 cup squash or sweet potato • 1 small apple • ½ cup unsweetened applesauce • ½ medium banana • 17 grapes • 1 cup raspberries, strawberries • ½ cup blackberries or blueberries • 1 cup cubed cantaloupe or honeydew melon • 1 medium peach • 1/3 cup fresh pineapple • 1 small orange • 1 slice watermelon	• ½ cup or 4 fl oz. milk (all varieties) or soy/almond milk • ¼ cup chocolate milk • 3 oz or 1/3 cup yogurt • ½ oz cheese • ¼ cup cottage cheese or ricotta cheese	• 1 oz meat, fish, or poultry • 1/3 cup Legumes (black, garbanzo, kidney, pinto, white beans, edamame, lentils, soy nuts) • 1 egg • 1 hot dog • 2 slices bacon • 3 oz or 1/3 cup Greek yogurt • 1 tbsp nut butters (peanut, almond, cashew) • 1/3 cup hummus • 4 oz tofu	• 1 tsp oil, margarine, butter • 1 Tbsp cream cheese, salad dressing, sesame or sunflower seeds • 6 almonds or cashews • 10 peanuts • 16 pistachios • 4 walnut halves • ¼ small avocado
• Free Vegetables Choices: Try to eat at least one choice with every meal and/or snack				
• ½ cup broccoli, tomato, brussel sprouts, eggplant, cauliflower, sweet peppers, leeks, onions, zucchini • 1 cup lettuce or dark leafy greens, asparagus, mushrooms, celery, cucumber, turnips				

[2] If you drink 1% take off 1 fat choice; If you drink 2% take off 2 fat choices

[3] Take off 1-2 fat choices depending on protein intake

The Blossom Project

BE-WELL BLOSSOM PROJECT MEAL PLAN: FLEXIBLE 3 DAY SAMPLE MENU

To jumpstart the use of the Be-Well Blossom Project Meal Plan we want you to try using the Plan three days in the upcoming week. Below is a table outlining what three different days could look like on the Meal Plan. You can mix and match the meal options for each of your three days. For example, if you wanted your day one to have eggs for breakfast, a sandwich for lunch, and pasta for dinner you can pick breakfast option three, lunch option one, and dinner option three. If you wanted to eat this combination of options on Monday and again on Thursday you can do that. Or if you want to eat eggs for breakfast every day during the three days you can do that. Pick whatever combination of options looks most appealing to you.

The Plan also allows you to have three snacks throughout the day. Pick one snack option from each of the three snack categories. Again, if you like having peanut butter and crackers for a snack every day you can do that just make sure you are including an option from snack 1, 2, and 3 for each day. For example, you can pick snack #1 option 1, snack #2 option 3, and snack #3 option 1 to have in one day.

The table below represents the food group categories, how many choices you can have in one day, the number of grams in each choice, and the total grams for the whole day for the food that you will be eating throughout the day,.

Food Group	Carb/Protein/Fat	# of servings	Grams/Choice	Total Grams/Day	Total calories
Starch	Carbohydrate	9 servings	15 g/serving	135 grams	540 calories
Fruit/Starchy Vegetable	Carbohydrate	4 servings	15 g/serving	60 grams	240 calories
Dairy	Carbohydrate Protein	6 servings	5 g/serving 4 g/serving	30 grams 24 grams	120 calories 96 calories
Protein	Protein	14 servings	7 g/serving	98 grams	392 calories
Fat	Fat	~13 servings[1]	5 g/serving	65 grams	585 calories
Totals:	Carbohydrate Protein Fat			225 grams 122 grams 65 grams	~2000 calories

[1] May move fat choices to different groups

Breakfast 2 Starch 3 Protein 1 Dairy 4 Fat	**Lunch** 2 Starch 3 Protein 1 Dairy 1 Fruit/Starchy Veggie 3 Fat	**Dinner** 3 Starch Choices 3 Protein Choices 1 Dairy Choice 2 Fruit/Starchy Veggie 2 Fat	**Snack #1:** 4 Protein 2 Dairy 1 Fruit/Starchy Veggie	**Snack #2:** 1 Starch 1 Protein 2 Fat	**Snack #3:** 1 Starch 1 Dairy 2 Fat
Option 1	**Option 1**	**Option 1**	**Option 1**	**Option 1**	**Option 1**
½ cup cooked Oatmeal 1 Tbsp honey or sugar 3 oz lean sausage patty ½ cup 1% milk	Smoked Turkey Sandwich: 2 slices of bread 3 oz smoked turkey breast ½ oz low fat cheese (½ slice) 2 tsp mayo Lettuce, tomatoes, red onions 1 small apple	Chicken Stir Fry: 3 oz skinless chicken breast ½ cup veggie mix (broccoli, bell pepper, and onions) + 2 tsp oil for sauté-ing 1 Tbsp lite soy sauce 1 cup brown rice 2 cup mixed strawberries and raspberries ½ cup 1% milk	1 5 oz (2/3 cup) container of plain Greek yogurt ½ cup blackberries or blueberries (can make into smoothie)	12 small pretzels twists 1Tbsp Peanut Butter	2 small cookies (size of a regular oreo) ½ cup 1% milk
Option 2	**Option 2**	**Option 2**	**Option 2**	**Option 2**	**Option 2**
2 slices whole wheat bread 2 Tbsp Peanut Butter ½ cup 1% milk	Chicken Quesadilla: 3 oz grilled chicken ½ cup stir-fried onions and peppers ¼ cup shredded cheese 2 6" corn tortillas ¼ cup salsa 2 Tbsp sour cream 1/3 cup pineapple	Pulled Pork Sandwich: 2 small (1.5 oz) whole wheat buns 3 oz pulled lean pork 2 cup (~40 count) baked sweet potato fries ¼ cup cottage cheese 1 ½ cups lettuce 2 Tbsp salad dressing	1 5 oz (2/3 cup) container of plain Greek yogurt 1 T dill 8 baby carrots Sliced bell peppers	10 pita chips 4 Tbsp hummus	3 cups popcorn 2 tsp melted butter ½ cup 1% milk or ¼ cup cheese to sprinkle on popcorn
Option 3	**Option 3**	**Option 3**	**Option 3**	**Option 3**	**Option 3**
2 scrambled eggs 1 small (2oz) bagel 1 Tbsp Peanut Butter ½ cup 1% milk	Taco Salad: 1 cup lettuce 3 oz lean ground beef ¼ cup 2% cheese ½ cup diced tomato, bell pepper, and onion ½ cup corn 22 tortilla chips ¼ cup salsa	Chicken & Vegetable Penne: 3 oz skinless roasted chicken 2/3 cup cooked pasta ½ cup cooked spinach ½ cup mixed vegetables (corn and peas) ½ oz shredded parmesan cheese ½ slice garlic bread 2 tsp butter for garlic bread ½ cup blueberries	1 5 oz (2/3 cup) container of plain Greek yogurt Pick a or b: a: 1 T taco seasoning 8 baby carrots + sliced veggies b: 17 grapes	6 crackers 1 Tbsp Peanut Butter	¼ cup granola ½ cup 1% milk

Sample Week Menu					
	Monday	Tuesday	Friday	Saturday	Sunday
Breakfast	1/2 c oatmeal with ¼ c raisins 3 oz lean sausage patty ½ c orange juice	1 slice WW bread 2 Tbsp PB ½ c Milk or soymilk	2 scrambled eggs 1 slice WW bread 1 Tbsp PB 1 c milk or soymilk	Breakfast Burrito: 2 large eggs scrambled 1 WW tortillas Mixed veggies	Yogurt Parfait: ½ c Granola ½ c Greek yogurt 1 c raspberries or strawberries
Snack	2/3 c greek yogurt ½ cup Mango	8 Tbsp hummus 10 WW pita chips	½ cup edamame 1 Tbsp lite soy sauce	2/3 c greek yogurt + 1 T taco seasoning Sliced veggies	2 Tbsp PB 1 small apple
Lunch	Turkey melt: 2 slices WW bread 1 oz chz 3 oz roasted turkey 2 tsp spread (mayo) 17 grapes	Taco Salad: 2 c lettuce 3 oz ground beef ¼ c 2% cheese 11 Tortilla chips ¼ c salsa Diced tomato, bell peppers, and onion 2 slice watermelon	Soup & Salad: 1 ½ c lentil soup 1 c dark leafy greens ½ c mushrooms 1 c strawberries 1 Tbsp dressing 1 oz parmesan ½ c 1% milk	Grilled Cheese: 2 slices WW bread 1 oz cheese 1 c black bean soup ½ c unsweetened applesauce	Chicken Quesadilla: 3 oz grilled chicken 1 c stir-fried onions and peppers ½ c 2% cheese 2 small corn tortillas ¼ c salsa
Snack	1 Tbsp PB 6 WW crackers	2/3 c greek yogurt + 1 T dill Slice veggies	1 small apple 1 Tbsp PB	4 Tbsp hummus 10 WW pita chips	1 c edamame 1 Tbsp lite soy sauce
Dinner	Chicken and Vegetable Penne: 1 c cooked pasta 1 c cooked spinach 1 c mixed veggies 3 oz roasted chicken ½ oz shredded parmesan cheese ½ slice garlic bread 3 tsp olive oil for dipping/prep	Veggie Jambalaya: 1 c black beans 2/3 c rice ½ c summer squash ½ c tomatoes ¼ c onion ¼ c bell pepper 2/3 c fresh pineapple 1 c 1% milk	Salmon with Cucumber-Dill Sauce 4 oz Salmon Fillet 1 Tbsp sour cream 2 Tbsp Greek yogurt 1/3 c quinoa 1 c roast asparagus 1 ½ tsp olive oil ½ c Mixed berries (blue, black, & raspberries)	Burger & Fries: 4 oz burger 1 medium bun 1 oz cheese 2 cup baked French fries 2 Tbsp Ketchup Burger toppings: onion, lettuce, tomato	Cashew Chicken Coconut Curry: 3 oz chicken breast ¾ c brown rice 1 c broccoli ¼ c red onion ¼ c lite coconut milk ¼ c cashews 2 tsp olive oil 1/3 c fresh pineapple
Snack	2 sm cookies (oreos) ½ 1% milk	3 cups popcorn 1 tsp melted butter	1 c vanilla ice cream 2 Tbsp syrup ½ c Mixed berries	1 small brownie 1 cup blackberries	1 c 1% milk 1 cup blueberries

BE-WELL BLOSSOM PROJECT MEAL PLAN: CHOICES CHECKLIST

STARCH

9 Starch Choices

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
☐	☐	☐	☐	☐	☐	☐
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PROTEIN

14 Protein Choices

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
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DAIRY

6 Dairy Choices

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
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FRUIT & STARCHY VEGETABLES

4 Fruit & Starchy Veggie Choices

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
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FAT

13 Fat Choices

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
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BE-WELL BLOSSOM PROJECT MEAL PLAN: CHOICES CHEC

STARCH

9 Starch Choices

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	S

PROTEIN

14 Protein Choices

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	S

DAIRY

6 Dairy Choices

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SU

FRUIT & STARCHY VEGETABLES

4 Fruit & Starchy Veggie Choices

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	S

FAT

13 Fat Choices

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	S

APPENDIX O. INSTITUTE OF MEDICINE PRENATAL WEIGHT GAIN CHART

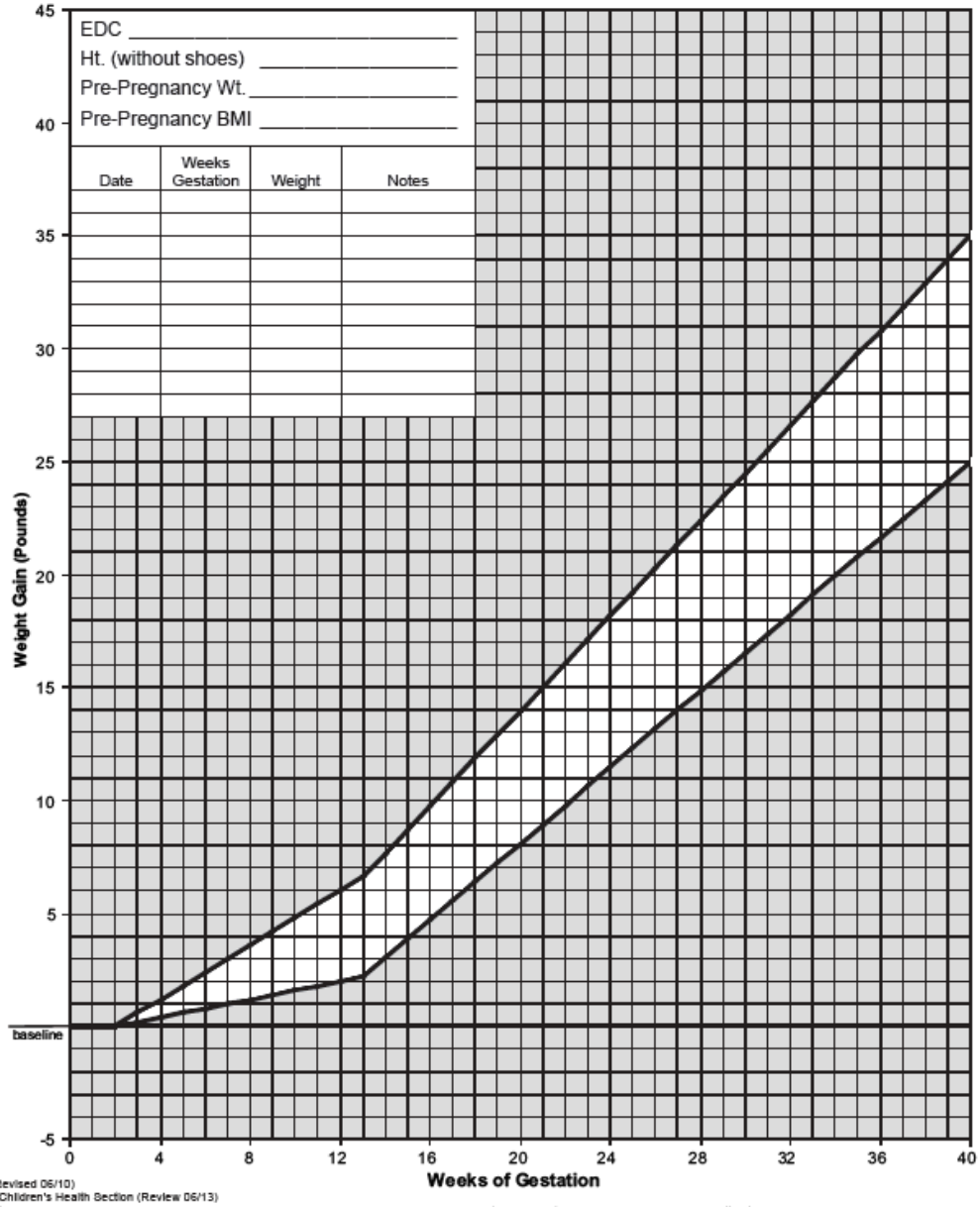
1. Last Name	First Name	MI
2. Patient Number		
3. Date of Birth (MM/DD/YYYY)	Month Day Year	
4. Race ☐ American Indian or Alaska Native ☐ Asian ☐ Black/African American ☐ Native Hawaiian/Other Pacific Islander ☐ Unknown ☐ White		
5. Ethnic Origin ☐ Hispanic Cuban ☐ Hispanic Mexican American ☐ Hispanic Other ☐ Hispanic Puerto Rican ☐ Not Hispanic/Latino ☐ Unreported		
6. Gender ☐ Female ☐ Male		
7. County of Residence		

PRENATAL WEIGHT GAIN CHART

Pre-Pregnancy Normal Weight
BMI 18.5–24.9

Weight Gain Recommendations (singleton):

- 2.2–6.6 lb. gain 1st trimester
- 1 lb. gain per week 2nd and 3rd trimesters
- 25–35 lb. total weight gain



DHHS 2388 (Revised 06/10)
Women's and Children's Health Section (Review 06/13)
Source: Institute of Medicine, 2009. *Weight Gain During Pregnancy: Reexamining the Guidelines*. Washington, DC. National Academies Press; Committee to Reexamine IOM Pregnancy Guidelines.

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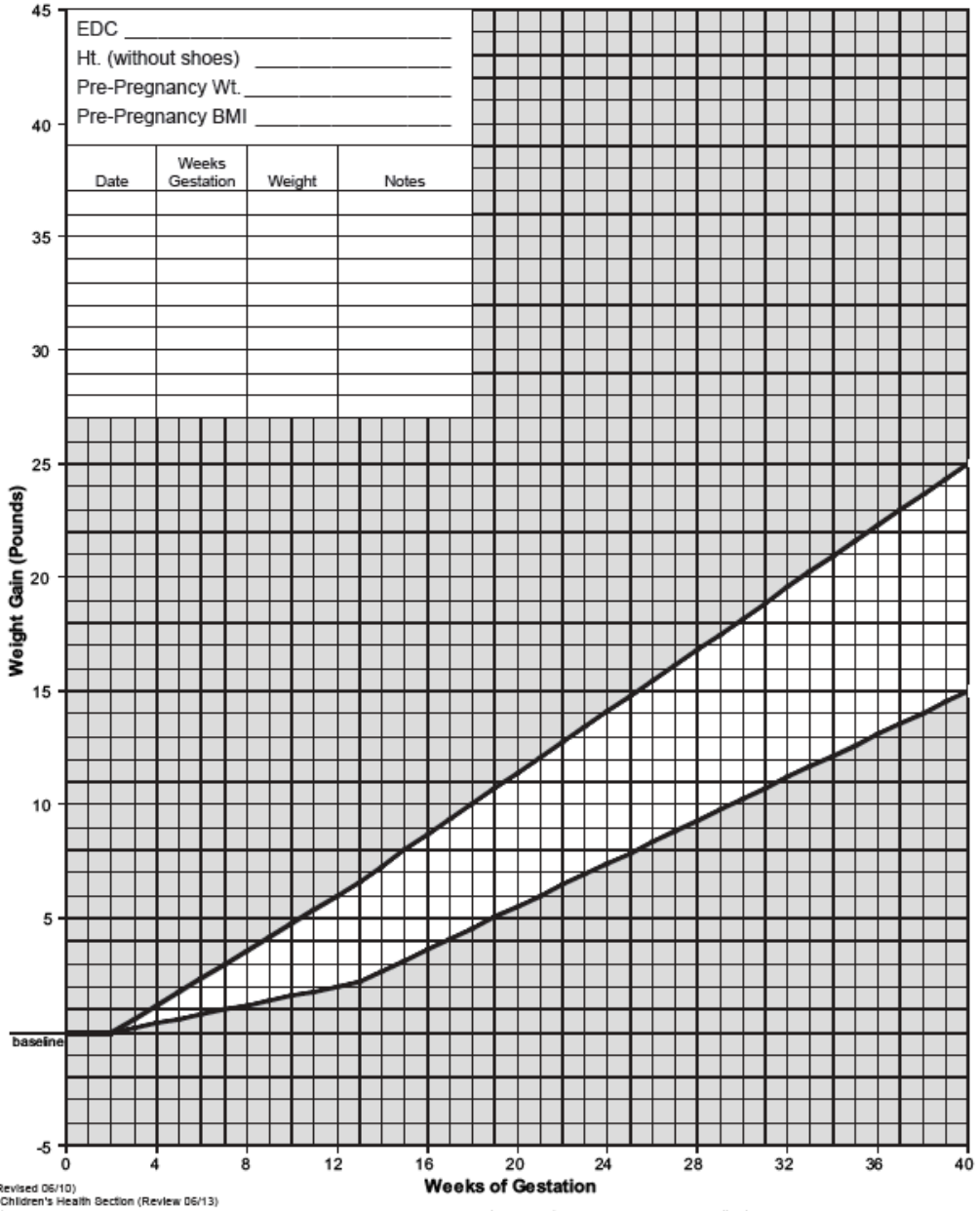
2. Patient Number		
3. Date of Birth (MM/DD/YYYY)	Month Day Year	
4. Race ☐ American Indian or Alaska Native ☐ Asian ☐ Black/African American ☐ Native Hawaiian/Other Pacific Islander ☐ Unknown ☐ White		
5. Ethnic Origin ☐ Hispanic Cuban ☐ Hispanic Mexican American ☐ Hispanic Other ☐ Hispanic Puerto Rican ☐ Not Hispanic/Latino ☐ Unreported		
6. Gender ☐ Female ☐ Male		
7. County of Residence		

PRENATAL WEIGHT GAIN CHART

Pre-Pregnancy Overweight
BMI 25.0–29.9

Weight Gain Recommendations (singleton):

- 2.2–6.6 lb. gain 1st trimester
- 0.6 lb. gain per week 2nd and 3rd trimesters
- 15–25 lb. total weight gain



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1. Last Name	First Name MI
2. Patient Number	
3. Date of Birth (MM/DD/YYYY)	Month Day Year
4. Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black/African American ☐ Native Hawaiian/Other Pacific Islander ☐ Unknown ☐ White
5. Ethnic Origin	☐ Hispanic Cuban ☐ Hispanic Mexican American ☐ Hispanic Other ☐ Hispanic Puerto Rican ☐ Not Hispanic/Latino ☐ Unreported
6. Gender	☐ Female ☐ Male
7. County of Residence	

PRENATAL WEIGHT GAIN CHART

Pre-Pregnancy Obese
BMI ≥ 30.0

Weight Gain Recommendations (singleton):

- 1.1–4.4 lb. gain 1st trimester
- 0.5 lb. gain per week 2nd and 3rd trimesters
- 11–20 lb. total weight gain

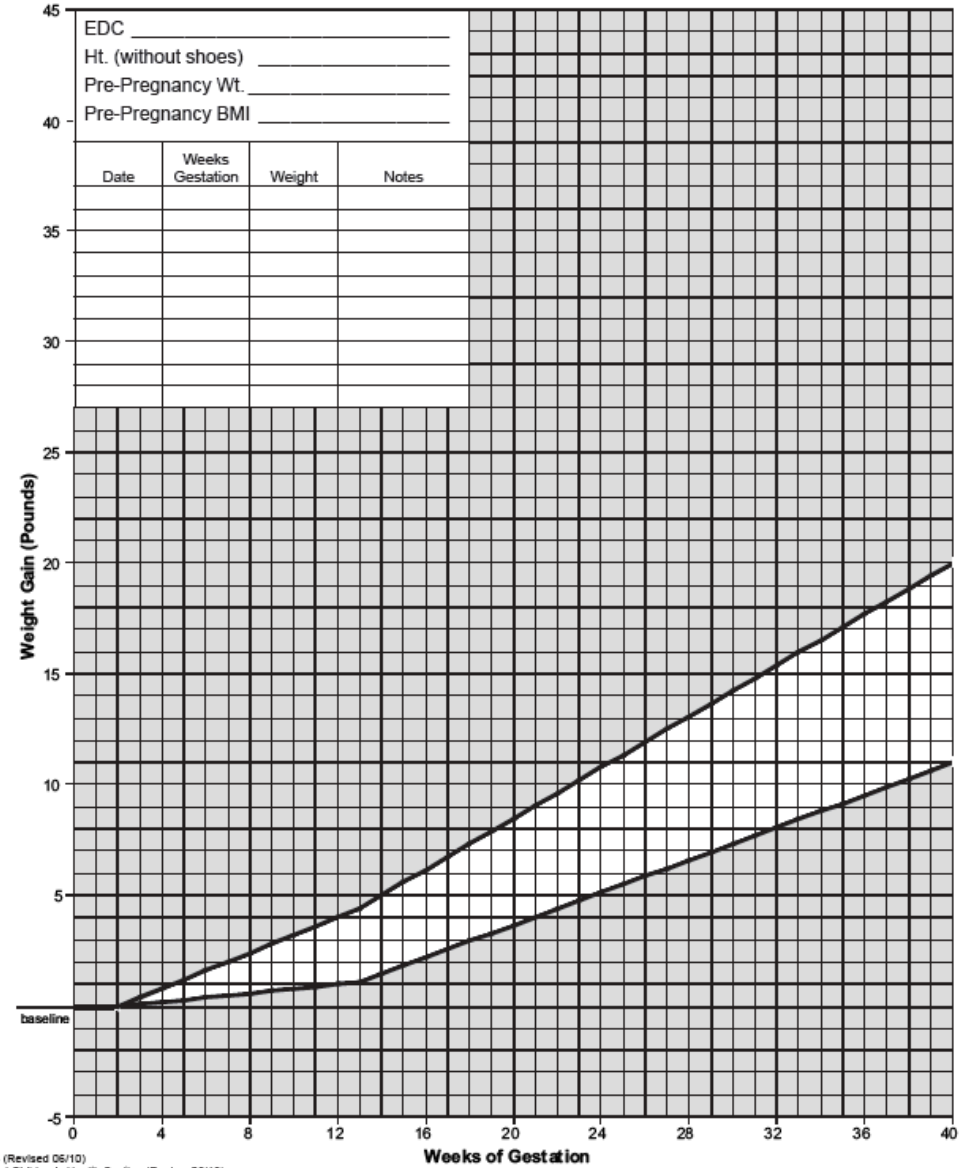
EDC _____

Ht. (without shoes) _____

Pre-Pregnancy Wt. _____

Pre-Pregnancy BMI _____

Date	Weeks Gestation	Weight	Notes



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