Fruit and Vegetable Intake and Gestational Weight Gain in OHSU Pregnancy, Exercise, and Nutrition Study Participants

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CERTIFICATE OF APPROVAL

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List of Abbreviations

ADA	American Diabetes Association
AMPM	Automated Multiple-Pass Method
ASA-24	Automated, Self-Administered 24-hour Recall
BMI	Body Mass Index
DHQ	Diet History Questionnaire
DOHAD	Developmental Origins of Health and Disease
DQI-P	Dietary Quality Index for Pregnancy
FIT	Functional Insulin Treatment
GDM	Gestational Diabetes Mellitus
HEI	Healthy Eating Index
HIPPA	Health Insurance Portability and Accountability Act
HTHU	Healthy Team Healthy U
IOM	Institute of Medicine
IRB	Institutional Review Board
LGA	Large for Gestational Age
NCI	National Cancer Institute
NHANES	National Health and Nutrition Examination Survey
OHSU	Oregon Health & Science University
PEN	Pregnancy, Exercise, and Nutrition
RDA	Recommended Daily Allowance
REDCap	Research Electronic Data Capture
TEE	Total Energy Expenditure
USDA	United States Department of Agriculture
WHO	World Health Organization

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Abstract

A nutrient-rich diet during pregnancy is critical to optimize gestation and birth outcomes. To test the effectiveness of a curriculum encouraging a nutrient-rich diet, the Pregnancy, Exercise, and Nutrition study was a randomized, controlled feasibility study of 28 women. The intervention group (n=14) participated in a team-based, peer-led, 20-session curriculum that promoted healthy dietary choices and activity during pregnancy to reduce gestational diabetes risk.

The aim of this research project was to examine differences in gestational weight gain and nutrient intake between control and intervention groups as well as differences between participants who met the 2009 IOM gestational weight gain recommendations and those who exceeded the recommendations. The secondary aim was to determine differences in fruit and vegetable intake between groups and determine the relationship between fruit and vegetable intake and gestational weight gain. As an exploratory measure, the Healthy Eating Index and the Diet Quality Index for Pregnancy were used to assess diet quality and differences in scores between groups were determined. The Automated Self-Administered 24-hour Dietary Recall, a web-based tool was used to efficiently and inexpensively collect dietary intake data during trimesters 1, 2, and 3.

We found no relationship between maternal fruit and vegetable intake and gestational weight gain. However, women who exceeded the 2009 IOM weight gain recommendations had significantly higher mean pre-pregnancy weights and BMI than those who met the recommendations ($p<0.03$). The intervention group had significantly lower energy ($p=0.02$) and fat intakes ($p=0.02$) at Trimester 3 than at Trimester 1 compared to the control. We found no significant differences in gestational weight gain, fruit and vegetable intake, or diet quality scores between control and intervention groups. These findings help to evaluate the effectiveness of the PEN curriculum on pregnancy and diet-related outcomes as well as identify areas of the curriculum to strengthen.

Chapter 1: Introduction

Helping mothers achieve a healthy weight gain during pregnancy has increasing importance for healthcare providers today as evidenced by new parallels being drawn between maternal weight gain and maternal and infant outcomes (1). New recommendations for weight gain during pregnancy based on pre-pregnancy Body Mass Index (BMI) were released by the Institute of Medicine (IOM) in 2009. These guidelines advise that for women entering pregnancy at a "normal" weight, gaining about 25-35 pounds during pregnancy is beneficial for both the mother and the fetus (2). However, gaining too much weight (over 40 lb) is associated with complications putting the mother, the fetus, and subsequently, the neonate at risk. Maternal risks include gestational diabetes, hypertension, cesarean section, and post-partum weight retention (3-5). Perhaps more substantial are the effects to the fetus, which for many of these risks, the full extent of the detriments is not yet understood. Risks to the developing fetus include larger birth size (macrosomia), higher body fat percentage at birth, preterm delivery, and impaired glucose tolerance (6-10). These outcomes additionally put the newborn at increased risk of obesity and its comorbid conditions throughout childhood and even into adulthood (11-13).

As with weight gain in the general population, excessive maternal weight gain during pregnancy is likely due to several factors. Consumption of high fat, highly refined, low fiber diets are proposed to be the root of the problem (14). However, the effects of a lipogenic diet may be confounded by a lack of physical activity, resulting in high energy intake and low energy expenditure (15). A healthful maternal diet may be important for the future of the fetus even without regard to gestational weight gain outcomes. The Developmental Origins of Health and Disease (DOHAD) hypothesis describes the premise that a number of chronic diseases that are first recognized in adults have origins that can be attributed to the intrauterine environment (16). This theory has spurred

several studies exploring maternal diet and fetal outcomes. One such primate study suggests that maternal diets high in saturated fat may be especially detrimental to the health of the fetus. The babies born to mothers on this diet had signs of dyslipidemia and fatty livers (17). These severe findings are rare in human infants. However, this study helps to emphasize the potential costs of unhealthy eating habits during pregnancy.

With such significant findings about the relationship between maternal diet and fetal outcomes, maternal health promotion has become an important area to advance. However, most education and counseling interventions that promote a healthy gestational weight gain have been ineffective. Both one-on-one counseling and group education courses (in high- and low-risk populations) have shown little improvement in maternal weight management and the subsequent fetal outcomes (18, 19). Though some studies show promise of promoting appropriate physical activity for pregnant women, exercise alone may not be sufficient to discourage excessive weight gain. A study of 40 pregnant women in Brazil showed that consistent, low-impact exercise routines (without diet change) was not associated with management of weight gain (20). In the study group, 47% of pregnant women gained more weight than the IOM recommended range which was only slightly fewer than the 57% of the women in the control group. The lack of effective intervention methods resulting in successful maternal weight management leaves room for new, innovative education techniques.

Limited research exists that identifies the specific behaviors which support healthy weight gain during pregnancy. However, one large meta-analysis found that of the compiled studies, the most successful prevention of weight gain occurred with dietary intervention, leading to lower weight gains by as much as eleven pounds (21). Because direct evidence is limited, it is important to draw ideas from studies involving non-pregnant subjects that have demonstrated successful weight loss and weight loss maintenance using dietary intervention. Three of these studies suggest that fruit and

vegetable intake is an important factor in both weight loss and weight loss maintenance (22-24). A large study involving four health centers across the US found that increasing daily servings of fruit and vegetables was associated with weight loss management at both 12 months and 30 months after initial weight loss. The study concluded that each additional serving of fruits and vegetables (as a combined category) was associated with a 1.25 pound greater weight loss per year (22). A similar study found that increased consumption of vegetables (by 140 grams per day) was the strongest predictor of weight loss over a 2-year time period (23). Given the positive outcomes of the studies supporting fruit and vegetable importance in weight management, this topic must be considered to encourage healthy maternal weight gain during pregnancy.

Specific Aims:

Maternal weight gain during pregnancy is an important determinant of fetal outcomes. Gestational diabetes mellitus, maternal hypertension, increased infant size, preterm and cesarean section deliveries, as well as post-partum maternal weight retention are complications associated with excessive weight gain during pregnancy. Maternal diet plays a large role in weight management, and diets high in fruits and vegetables are associated with a lower total energy intake (22, 23). Conversely, inadequate fruit and vegetable intake is associated with excess energy intake and may make it more difficult to achieve a healthy gestational weight gain (23). Studies show that in the Unites States, mothers are not consuming the recommended daily servings of fruits and vegetables (25, 26). Additionally, effective educational programs which facilitate behavior change toward improving diet and increasing fruit and vegetable intake during pregnancy are lacking.

Substantial research exists supporting the relationship between a healthy maternal diet and positive fetal outcomes (16, 17, 27, 28). However, there is limited research noting a correlation between fruit and vegetable intake and appropriate weight gain during pregnancy. In addition, research reporting significant effects of nutrition education on maternal diet is limited. To our knowledge there are no studies specifically testing the effectiveness of team- and web-based pregnancy nutrition education programs. To fill these gaps in the research, the Oregon Health & Science University (OHSU) Pregnancy, Exercise, and Nutrition (PEN) Program evaluated the feasibility of a nutrition and exercise education program for pregnant women. The PEN program is an extension of the OHSU Employee Wellness Program called Healthy Team Healthy U (HTHU), and used the same team- and web-based weekly education tactics to promote positive healthy behavior changes. Participants were recruited during their first trimester of pregnancy and the curriculum began before 20 weeks of gestation. The goal was the

proposed research project is to evaluate the relationship between fruit and vegetable intake and total weight gain during pregnancy as well as fruit and vegetable intake and infant birth weight in participants in the OHSU PEN Program. In addition, we evaluated relationship between diet quality scores, using the Diet Quality Index for Pregnancy (DQI-P) and the Healthy Eating Index (HEI), and total weight gain during pregnancy as well as infant birth weight (29, 30).

A team- and web-based nutrition and exercise curriculum extending from an employee wellness program is an innovative method to promote a healthy diet during pregnancy. Consuming adequate servings of fruit and vegetables each day is a valuable means to manage weight gain which is important to the health of the mother and the child. The evaluation of this curriculum and its contribution to a healthy pregnancy is valuable not only for the participants of the PEN program but also for its ability to inform the design of information for a robust randomized control trial to measure efficacy of the curriculum to reduce GDM, and other pregnancy-related health conditions.

Aim #1: To describe the maternal diet and infant birth weight of PEN study participants and determine differences between the control and intervention groups as well as differences between participants who met the 2009 IOM gestational weight gain recommendations and those who exceeded the recommendations.

Aim #2: To determine the difference in fruit and vegetable intake between the intervention group and the control group at baseline and trimesters 2 and 3 as well as to determine the change in fruit and vegetable intake within groups over time in women participating in the OHSU PEN study.

We hypothesized that the intervention group would report a higher mean fruit and vegetable intake at the 2nd and 3rd trimesters of pregnancy and would report increased fruit and vegetable intake from baseline measurements compared to the control group.

Aim #3: To determine the odds of gaining excessive weight during pregnancy in women participating in the OHSU PEN study who met or did not meet the recommendations for fruit and vegetable intake at the 1st, 2nd, and 3rd trimesters.

We hypothesized that odds of gaining excessive weight during pregnancy would be lower in women who met the recommendations for fruit and vegetable intake.

Aim #4: To determine the relationship between maternal fruit and vegetable intake during the 1st, 2nd, and 3rd trimesters of pregnancy and infant birth weight among women participating in the OHSU PEN study.

We hypothesized that the odds of delivering a large for gestational age infant would be lower among women who met the recommendations for fruit and vegetable intake.

The aims were re-assessed using the Diet Quality Index (DQI-P) for Pregnancy and the Healthy Eating Index (HEI) as an exploratory measure.

We hypothesized that the intervention group would have greater Diet Quality and HEI composite scores at the 2nd and 3rd trimesters of

pregnancy and would have higher positive change in composite scores from baseline measurements compared to the control group.

We hypothesized that odds of gaining excessive weight during pregnancy would be lower in women who have DQI-P and HEI scores in the upper 33rd percentile compared to those in the lower 33rd percentile.

Chapter 2: Background

Introduction and healthy gestational weight gain recommendations

The effect of the intrauterine environment on fetal outcomes and the consequential health outcomes of the child is a developing area of research. The existing research suggests that even chronic diseases such as cardiovascular disease and Type II diabetes may stem from the intrauterine environment during fetal development. In response to these findings, the World Health Organization (WHO) recently added low birth weight as a risk factor for cardiovascular disease (31). In light of this recognition by the WHO and other health authorities, promoting healthy behaviors during pregnancy is now recognized internationally as a critical health initiative. Part of this initiative involves promoting a healthy gestational weight gain. An epidemiological study published in 2003 reported that in all pre-pregnancy BMI (Body Mass Index) categories, only about 50% of US women fell within the recommended range for gestational weight gain. While behaviors like smoking and alcohol consumption during pregnancy have historically been strongly discouraged, promoting a healthy gestational weight gain through dietary intervention is one aspect of maternal health that is gaining attention.

While it is acknowledged that gestational weight gain affects fetal outcomes, defining healthy gestational weight gain is an area of recent advancement and controversy. In 2009, the Institute of Medicine (IOM) released new, updated guidelines for gestational weight gain that can be applied to the general population (see Table 1). The guidelines are based upon maternal pre-pregnancy BMI measurements. The ranges of healthy weight gain extend from as high as 40 pounds for an underweight mother to as little as 11 pounds for a woman classified as obese. However, the recommendation for women in the normal weight BMI category for a healthy gestational weight gain is

about 25-35 pounds, with most of this weight gain occurring in the third trimester (1). Much research has been done to determine the detrimental effects of experiencing a famine during pregnancy or when a women experiences food insecurity during pregnancy. Usually, under these circumstances, the mother gains too little weight and consequently, the neonate is delivered with a low birth weight. The effects of low birth weight range from impaired motor development, to weight and height deficits, to lowered IQ. There have also been links to future obesity and heart disease in low birth weight offspring (32).

Table 1. 2009 Institute of Medicine Guidelines for Weight Gain during Pregnancy Based on Pre-pregnancy BMI

Pre-pregnancy BMI (kg/m^2)	Total Weight Gain
<18.5	12.5-18 kg (28-40 lb)
18.5-24.9	11.5-16 kg (25-35 lb)
25-29.9	7-11.5 kg (15-25 lb)
≥30	5-9 kg (11-20 lb)

With the abundant food supply in the United States (and increasingly in other countries, as well) achieving adequate weight gain during pregnancy is generally not a problem. However, it is now understood that gaining too much weight during pregnancy can be similarly detrimental to the health of the child. Studies have shown that excessive maternal weight gain can be unhealthy for both the mother and child (5, 6, 11, 12, 33-35). New mothers are typically very concerned about the well being of the baby which makes this population especially motivated to adopt healthy behaviors. However, it is important that expectant mothers are also aware of the negative maternal and infant health consequences resulting from excessive weight gain.

Excessive gestational weight gain and maternal outcomes

One of the risks for a woman with a higher-than-recommended gestational weight gain is the increased likelihood of undergoing a cesarean section (c-section) delivery. Not only can a c-section be stressful for the mother and family, it is associated with longer post-partum recovery time and lower rates of breastfeeding, in addition to the normal dangers associated with surgery (36). In a large, retrospective study of 8,293 women, 2,061 neonates were delivered via c-section. Eighty percent of the c-section deliveries were performed on women who exceeded the 2009 IOM recommendations for weight gain during pregnancy; whereas only 13% were performed on women gaining weight within the recommendations (37). A similar retrospective cohort study of 2,495 women reported that c-sections were 50% more likely for women with a normal BMI who gained excessive weight during pregnancy. This relationship may be due to the increased size of the baby. When a larger neonate is delivered there is increased risk for cephalopelvic disproportion, meaning that that child's head is too large to fit through the mother's pelvis (4). An infant who weighs more than 4,000 grams is identified as large for gestational age (LGA). Other explanations for increased c-sections are slow dilation, maternal hypertensive disorders, and an unsafe fetal heart rate, all potentially a result of increased gestational weight gain (4, 34). Due to these complications, one study concluded that for every 5 kg (11 lb) of gestational weight gain above the IOM recommendation, the risk for a cesarean section birth in women with induced labor increases by 13% (34).

Increased postpartum weight retention is also a complication associated with exceeding recommendations for weight gain during pregnancy. A 2003 study demonstrated that maternal fat retention is greatest among mothers who gained the most weight during pregnancy. At 27 weeks after delivery, maternal fat retention was significantly higher in women who gained above the IOM recommendations for weight

gain (5.5 kg) compared with women who gained within IOM recommendations (2.3 kg) (3). A similar study in 2009 tracked 1,656 women classified as obese throughout their pregnancies. The study found that obese women who gained more than 35 pounds during pregnancy were eight times more likely to retain more than 10 pounds one year postpartum (33). While these findings may seem intuitive, they are also valuable as overall body weight and composition are important determinants of a mother's long term health.

Though the previously mentioned risks affect the mother after or at the very end of gestation, there are additional negative outcomes of high gestational weight gain that occur throughout the pregnancy. One such outcome is pregnancy-induced hypertension, which is also an indicator of preeclampsia (a gestational complication characterized by high blood pressure and excess protein in the urine). Hypertension during pregnancy can play a role in intrauterine growth restriction and preterm delivery (38). A prospective cohort study of 6,902 pregnant women concluded that mothers who gained more than 12 kg (or 26.5 lb) were 1.9 times more likely to have pregnancy-induced hypertension (39). While a weight gain of 26.5 pounds is within the weight gain recommendations for underweight and normal weight women, it exceeds the recommendation for overweight and obese women. These results provide further support for the management of maternal weight gain during pregnancy.

Another condition exacerbated by excessive weight gain in expectant mothers is glucose intolerance. A study of about 8,000 women found that gestational diabetes mellitus (GDM) was significantly higher in women with excessive early gestational weight gain (compared with women with normal early weight gain). Early gestational weight gain was assessed between 15-18 weeks of gestation and was defined using IOM recommendations for first and second trimester weight gain (4.4 pounds during the first trimester and specific weight increments per week of the second trimester based on

BMI). The retrospective study reported that 73% of the participants had a total pregnancy weight gain that exceeded the 2009 IOM recommendations. And of these participants, 93% exceeded weight gain recommendations for early gestation (5). Most researchers agree that excessive weight gain, especially during the first and second trimesters of pregnancy, is associated with an increased incidence of gestational diabetes (5, 35, 40). However, the results of the studies are mixed as to which population is affected most by increased weight gain. Some researchers suggest that women with a BMI indicative of normal weight status are most at risk, while others conclude that mothers with pre-pregnancy overweight and obese BMI classification are most affected (5, 40). One study proposes that overweight, non-white women have a significantly higher risk of developing gestational diabetes when maternal weight gain during pregnancy is greater than 0.41 kg per week (or greater than about 40 total pounds) (35). Given the danger that GDM imposes to both mother and fetus, promoting appropriate weight gain during pregnancy and helping women to achieve these goals is beneficial for all populations.

Excessive gestational weight gain and fetal risks

Similar to the detrimental effects of excessive weight gain on maternal outcomes, the effects of excessive gestational weight gain can be damaging to the health and quality of life of the fetus. One theory suggests that these consequences may even take the form of adult chronic diseases. The Developmental Origins of Health and Disease hypothesis (DOHAD) suggests that the intrauterine environment shapes fetal susceptibility to adult diseases (16). Though there is much advancement to be made in this area, it has been proposed that diseases such as coronary heart disease, type II diabetes, and liver disease may have pre-birth origins (16). A study of primates in 2009 observed Japanese macaque mothers who consumed a chronic high-fat diet, providing

about 30% of the total energy content as fat compared to the control monkeys who consumed standard monkey chow that contained 14% of energy content from fat. During the third trimester of pregnancy, the fetal livers were inspected and showed signs of non-alcoholic fatty liver disease (NAFLD). Generally, NAFLD is considered to be an adult disease. However, regardless of maternal obesity and insulin sensitivity, every infant monkey born to mothers consuming a high fat diet had significantly higher levels of hepatic lipid deposition (17). While this study cannot ethically be recreated in human participants, the findings nonetheless have implications for the repercussions of a sustained, high-fat diet in humans.

Excessive intake of highly refined carbohydrates is another characteristic of the U.S. diet that may lead to negative fetal outcomes. Increased maternal sugar intake is linked to insulin resistance (the diminished ability of cells to respond to insulin by increasing the transport of glucose from the bloodstream into muscle and other tissues) which can manifest as gestational diabetes mellitus (GDM). The aforementioned maternal problems associated with GDM only make up a portion of the outcomes as the fetus is also negatively influenced by this condition. Maternal insulin resistance manifests as chronically increased blood glucose levels. Because a mother's blood supply is the fetus's nutrient source, chronically high maternal blood glucose concentrations lead to increased fetal blood glucose concentrations and subsequently increased insulin production. Immediately after birth, the infant no longer receives nutrients, including glucose, from the maternal blood supply, but still maintains elevated insulin production. As a result, among infants born to mothers with insulin resistance during pregnancy, existing glucose is metabolized leading to hypoglycemia at birth (7). While neonatal hypoglycemia is the most immediate harm, infants born to mothers with GDM are also more likely to have impaired glucose tolerance throughout their life. A study of Pima Indian children demonstrated that, independent of body composition,

intrauterine exposure to elevated blood glucose concentrations was related to increased systolic blood pressure and higher hemoglobin A1c levels (a measure of blood glucose control over the past 3 months) in children 7 to 11 years old (9).

While GDM is associated with gestational weight gain, the dietary intake of mothers who do not develop GDM can also lead to unfavorable health outcomes. A longitudinal study of 3,600 children born in 2001 in the US showed that regardless of the maternal pre-pregnancy weight status, excess gestational weight gain (exceeding the 2009 IOM recommendations according to BMI) was associated with an increase in offspring BMI at age five (11). A comparable study surveyed 11,994 adolescents enrolled in the Growing Up Today Study cohort and their mothers, members of the Nurses' Health Study II. The results showed that children born to women with excessive maternal weight gain during pregnancy (according the 1990 IOM recommendations) had a significantly higher BMI and were 1.4 times more likely to be obese (13). An additional study of 4,234 subjects enrolled in the Copenhagen perinatal cohort (born between 1959-1961) correlated BMI at 42 years of age to maternal gestational weight gain. The results of the analysis demonstrated a positive correlation between gestational weight gain and offspring BMI (14). Thus, a mother's weight gain during pregnancy may be associated with BMI long into adulthood.

Healthy gestational weight gain and dietary intervention

Limited research exists concerning the specific behaviors that support healthy weight gain during pregnancy. However, one large meta-analysis compiled 42 randomized controlled trials that "…evaluated any dietary or lifestyle interventions with potential to influence maternal weight during pregnancy." In total, the studies included 7,278 pregnant women, many of whom were placed in intervention groups to elicit positive behavior changes to help control gestational weight gain. The three categories

of interventions included diet, physical activity, and a combination of diet and physical activity. Dietary intervention resulted in the lowest gestational weight gain and lower weight gain by as much as eleven pounds (95% CI: -5.22 to -2.45 kg). The dietary interventions described in these studies included making use of a food diary and incorporating a calorically “moderate” diet with balanced carbohydrate, protein, and fat content. The interventions included counseling sessions, education about the benefits of a healthy diet and physical activity, and feedback about weight gain during pregnancy (21).

Because there is much more research concerning weight management in the general population, it is necessary to draw weight management tactics from studies involving non-pregnant subjects who have demonstrated successful weight loss and weight loss maintenance using dietary intervention. Many of these studies suggest that fruit and vegetable intake is an important factor in both weight loss and weight loss maintenance. A large study involving four health centers across the US demonstrated that increased fruit and vegetable intake was associated with maintenance of weight loss at 12 months and 30 months after initial weight loss. The article reports that increasing fruit and vegetable intake by one serving per day is associated with a continued weight loss of 2 pounds per year (22). A group of researchers in Israel studied weight loss with the basis that dietary weight loss strategies are related to the inclusion or exclusion of specific food groups. To evaluate this, the researchers measured food group consumption by total weight of the food consumed by both men and women whose BMI was greater than 27 kg/m^2. The study concluded that increased consumption of vegetables by 140 grams per day and a reduction in the consumption of refined carbohydrates like breads, pastas, and cereals by 30 grams per day were the strongest predictors of weight loss (23).

Results of the Project on Diet, Obesity, and Genes, a study published in 2009, may have implications for weight management in the pregnant population. The goal of the study was to analyze whether high fruit and vegetable intake impacted weight in the general population. However, the researchers additionally looked into how increased intake affected individuals particularly susceptible to weight gain, such as those who recently quit smoking. This large study included 89,432 men and women from five countries who participated in the European Prospective Investigation into Cancer and Nutrition. Participants were weighed at baseline and completed country-specific food frequency questionnaires to assess dietary intake. A follow up questionnaire was administered and measurements were taken an average of 3.7 years after baseline. Fruit and vegetable intake was then correlated with weight changes. The results showed that a daily increase in fruit and vegetable intake of 100 grams was associated with an average weight loss of 14 grams (0.3 pounds) per year. This weight loss nearly doubled in participants who had recently quit smoking. Each 100 grams of fruit and vegetable intake was associated with a mean weight loss of 37 grams (0.8 pounds) per year in smokers (24). This study may be pertinent for maternal health as this population is also susceptible to excessive weight gain.

A potential explanation for the weight management benefits of fruits and vegetables is their high content of dietary fiber. Research has shown that meeting or exceeding the recommendations for dietary fiber intake (38 grams for males and 25 grams for females) supports weight management (41-43). One study of 83 women with a BMI greater than 28 kg/m^2 compared the effects of a high protein diet versus a high fiber diet. In the high fiber diet, carbohydrate accounted for 50% of total energy intake including 35 grams of fiber. The results showed that the women consuming the high fiber diet ate significantly fewer calories than participants consuming the high protein diet (1428 vs. 1556 calories per day). Additionally, women consuming the high fiber diet

reported decreased hunger and decreased preoccupation with thoughts of food. During the 8-week span of the study, both groups lost weight. The women consuming the high fiber diet lost an average of 3.3 kg (95% CI: -4.2 to -2.4 kg). The high protein group lost an average of 4.5 kg (95% CI: -3.7 to -5.4 kg) (42).

A larger prospective cohort study similarly analyzed the effects of fiber in the female diet. A study of 252 women assessed the relationship between dietary fiber intake and body fat percentage. The participants' diets and body fat percentages were assessed at baseline and after 20 months with no dietary intervention. Fifty percent of the participants gained weight throughout the 20-month time period. However, the study concluded that for every 1 gram increase in dietary fiber intake, body fat decreased by 0.25%. Therefore, fiber may reduce the risk of gaining weight over time (43). While it is certainly advised that pregnant women gain weight throughout the course of pregnancy, fiber intake via increased consumption of fruits and vegetables may be important means to obtaining a healthy gestational weight gain.

Promoting healthy maternal behaviors

Given the previously mentioned harms of excessive weight gain during pregnancy, it is critical that health professionals become adept in promoting healthy behavior change such as increasing the intake of fruit and vegetables among pregnant women. Unfortunately, research shows that most education and counseling programs promoting a healthy gestational weight gain have been ineffective. In 2007, three maternity clinics in Finland provided five one-on-one counseling sessions to pregnant women on healthy diet changes. In Finland, the maternity clinics are funded by public tax revenue and are used by both high and low-risk women. The counseling consisted of encouraging a regular meal pattern, consuming five or more servings of fruits and vegetables per day, consuming high-fiber bread products, and consuming one or less

servings of high sugar products per day. In addition, the intervention participants were encouraged to partake in “leisure time physical activity.” Three other Finland clinics were used as the control. The control clinics provided standard maternity care which included brief advice regarding dietary choice, physical activity, and weight gain recommendations during pregnancy from a midwife or nurse. It was concluded that overall fruit and vegetable intake increased by 0.8 portions per day and fiber intake increased by 3.6 grams per day in the intervention group as compared to the control group. However, there was no significant difference in weight gain between the intervention and control groups (14.6 ± 5.4 kg vs. 14.3 ± 4.1 kg). The results of the study are unfortunate as most women are seen for prenatal care by a similar clinic or doctor’s office and this would be a practical setting for health intervention. The authors of the study attributed the lack of change in behavior to the “healthy dietary and leisure time physical activity habits” of the women at baseline. The researchers suggested that if high risk groups (i.e. overweight or obese women) were targeted in future studies, there may be a greater possibility for behavior change (18).

An Australian intervention entitled “Healthy Start to Pregnancy” reported comparable results. About 400 pregnant women receiving care at a maternity hospital in New Zealand participated in the study. Half of the women participated in one-time, dietitian-led group education about nutrition, smoking, and other behaviors during pregnancy. The workshop also provided the women with activity sheets to record individual goals to promote self-efficacy for behavior change. The other half of the women only received routine care. Although significantly more women who attended the workshop were aware of the gestational weight gain recommendations, this did not affect overall gestational weight gain (19). This study demonstrates that just providing knowledge of weight gain recommendations may not be an adequate intervention to promote health behaviors.

Additionally, some studies show promise of promoting appropriate physical activity for pregnant women. However, without nutrition intervention, exercise alone may not be sufficient to discourage excessive weight gain. A study of 40 pregnant women in Brazil showed that consistent, low-impact exercise routines (without dietary change) was not associated with management of weight gain (20). The lack of effective methods resulting in successful maternal weight management leaves room for new, innovative behavior change techniques.

Novel techniques for promoting healthy behaviors

Given the time constraints that an expectant mother may have with doctor's appointments, a career, or other children, a time-consuming health education program may not be effective for this population. This was noted in the Healthy Start to Pregnancy program as only 43% of the women offered the free curriculum actually attended (19). Thus, an adapted worksite wellness program that, in addition to regular meetings, has web-based features and, when needed, can be completed via phone call may be well-suited for this population. While there are few published studies recording the efficacy of web-based programs in pregnant women, studies have shown that it may be an effective means for promoting healthy behavior change in the general public. A 12-week web-based weight loss program at the University of Newcastle in Australia demonstrated that significant weight loss occurred in individuals with a BMI greater than 25 kg/m^2. Participants received weekly, online information about behavior change, including self-efficacy, goal setting, and self-monitoring of weight, body measurements, exercise, and diet supplied by a weight-loss program provider in Australia. While the study measured the benefit of personalized e-feedback, the researchers found that both groups, those with feedback and those without it, made positive changes and lost similar amounts of body weight (2.1 ± 3.3 kg vs. 3.0 ± 4.1 kg; $P < 0.001$) (44). Another Australian

web-based weight loss study aimed to determine which features of the website were most associated with total user retention and total weight loss. The different features included social networking, a personalized meal planner, and a “weight tracker” tool. Though no website aspect was related to increased user retention, use of the “weight tracker” tool was most associated with weight loss, potentially due to the accountability that the user feels when interacting with this program. Regardless of website tool use, the users on average reported a loss of about 2.75% ± 0.32% of their initial body weight (45).

Worksite Wellness

In addition to the web-based aspects of the OHSU PEN Program, the curriculum was expanded from the OHSU worksite wellness program entitled Healthy Team Healthy U. Additionally, the PEN study participants were employees and spouses from OHSU, thus the results have implications for future worksite wellness programs, especially those targeting pregnant women. This is valuable as studies including worksite health promotion for pregnant employees are few. However, one study reports the results of a Pregnancy Wellness Program in a North Carolina hospital. The participants included 62 pregnant women who were hospital employees or the spouse of an employee. Twenty women participated in the wellness program and 42 women were in the control group which received standard care. The intervention included pregnancy wellness classes held one day a week for 12 weeks. Classes were led by a clinical nurse specialist and discussed preconception health, nutrition, positive lifestyle behaviors, preparing for labor and delivery, and infant care. Intervention also included follow-up contact with a clinical nurse specialist after the classes were completed. Results showed increased scores on a knowledge survey (85.2% to 92.3%). No significant differences were found between intervention and control groups relating to gestational weight gain,

infant birth weight, or c-section rates. However, there was a significant difference between insurance claims cost per covered employee. The claim cost for participants was 37% less than for non-participants ($3,618 vs. $5,745 average cost per person) (46).

A worksite wellness program in 2001, entitled The Woman to Woman project made use of a peer-led intervention to increase the participation of breast and cervical cancer screening. Twenty six worksites were included ranging from healthcare to academia. Half of the sites were randomized to intervention, the other half were used as the control. Intervention worksites were provided with a 16-month intervention for women over 40 years of age. Each site consisted of a minimum of 60 participants and 3 Peer Health Advisors (PHAs). The PHAs were nominated by their peers to serve as role models for screening behaviors and completed 16 hours of training pertaining to cancer epidemiology, early detection methods, screening guidelines, and community resources. These women were responsible for disseminating information to their peers, providing social support, and encouraging positive social norms towards screening in the workplace. The intervention consisted of six small-group discussions with topics like “talking to your healthcare provider about screening” and “setting goals for your health.” In addition, over the 16 months of the intervention, each site hosted two events including fun activities that encouraged women to partake in screening. Results of the study showed that employees at participating sites were significantly more likely to receive a pap test (4.7% vs. 1.9%) for cervical cancer screening. However, rates of participants who reported a recent mammogram or clinical breast examination were not significantly different. The study suggests that intervention improved cervical cancer screening however did not affect breast cancer screening (47).

Other worksite wellness programs (including both female and male employees) have shown success in improving overall health status of employees as well as similarly

reducing insurance costs. One example is a diabetes prevention program which enrolled employees of BD Medical Systems in Sandy, Utah. The 12-month group curriculum incorporated principles of diet, exercise, and behavior change with specific instruction on 150 minutes of physical activity, portion control, and barriers to change. Sessions were led by two registered nurses and a certified health educator. At the 12-month mark, results showed significant changes in weight (-10.58 lb), body mass index (-1.65 kg/m^2), waist circumference (-1.55 in), 2-hour OGTT (-36.76 mg/dL), and triglycerides (-48.35 mg/dL) from baseline measurements. Furthermore, after the 12-month intervention, 18 of the program participants (51%) were no longer in the pre-diabetes or diabetes categories (48).

An additional study examined the impact of a worksite wellness program on cardiac risk factors. The CRET (Cardiac Rehabilitation and Exercise Training) is a health intervention program whose staff provides on-site worksite wellness services. The study utilized CRET services for 185 employees of a nearby business. The control group included 154 employees receiving usual healthcare. Intervention included 6-month health education program led by CRET staff (nurses, dietitians, and health educators). The education consisted of on-site, weekly classes focusing on nutritional education, fitness counseling, weight control, and worksite safety. CRET additionally provided referrals to health professionals for smoking cessation, stress management, and counseling for hypertension and diabetes. Results of the study showed significant improvements in reported quality of life scores (+10%), body fat (-9%), high-density lipoprotein cholesterol (+13%), and diastolic blood pressure (-2%). Average employee annual costs claims decreased by 48% which was estimated to be a six fold return on investment (49).

Group education

In addition to improving employee health, worksite wellness interventions are also easily developed into group activities. Since it is important that expecting mothers have support to make healthy changes, group education may be an important technique for maternal health education. A group of 15 primiparous Turkish women was asked to evaluate an antenatal health program about breast-feeding, nutrition during pregnancy, and preparing for birth. Seven women participated in nurse-led group education. The 8 remaining women were taught the same information, one-on-one with the nurse. The majority of the feedback from the mothers was positive including the content and structure of sessions; however, the groups session participants were "more satisfied" with the education. The mothers listed reasons such as having the ability to exchange information, learn from group interaction, be together with people experiencing similar problems, provide and receive social support, and learning in an enjoyable environment (50)

An Austrian study similarly incorporated the use of group education in an outpatient setting to determine the effect of the Functional Insulin Treatment (FIT) on pregnancy outcomes in mothers with pre-gestational diabetes (Type I or Type II diagnosed before pregnancy). Each participant attended one or more of the group education sessions. The sessions were led by a diabetes educator and nurses. Each education session included about 12-18 participants. The results showed lowered rates of diabetes-related complications such as neonatal hypoglycemia and low birth weight. This study suggests that groups of no more than 20 women can be an effective group training method for a maternal health education intervention (51).

Since there are only a few small studies showing the impacts of maternal group education, it is relevant to examine other studies that use peer-led sessions as a means for delivering information and promoting positive behavior change. The ATHENA study,

Athletes Targeting Healthy Exercise and Nutrition Alternatives, was a randomized trial of 1,668 female, high school athletes. The goal of the study was to discourage unhealthy body shaping behaviors and lessen intentions for unhealthy weight loss among female high school athletes. The intervention consisted of eight weekly, coach- and peer-led sessions which included topics such as sports nutrition, eating disorders, diet pills and unhealthy weight loss. The groups consisted of six members with one peer leader. While no results showed a change in behavior or peer norms, the study reported decreased intentions to use diet pills and an increased knowledge of detrimental effects of unhealthy weight loss (52).

The PHLAME study, Promoting Healthy Lifestyles: Alternative Models' Effects, similarly used peer-led groups to encourage behavior change. This randomized trial of 599 firefighters in 2007 aimed to promote healthy eating habits (i.e. increasing fruit and vegetable intake) and increase physical activity. The intervention included eleven 45-minute team sessions which included curriculum on nutrition and exercise in addition to group activities. Each participant formulated a personal goal at baseline and reviewed progress towards the goal in later meetings. Compared to the control, the intervention group increased fruit and vegetable intake (1.6 vs. 0.1 servings), gained less weight (0.9 vs.3.4 pounds), increased dietary understanding, and reported greater dietary social support. As these are desirable outcomes for the pregnant population as well, the peer-led group sessions providing nutrition education may be useful for promoting healthy maternal behaviors (53).

Given the research surrounding the importance of healthy behaviors during pregnancy and the impact on outcomes for both mother and fetus, it is crucial that mothers are encouraged to make positive lifestyle changes. The success of some programs including group education, peer-led curriculum, web-based education, and worksite wellness identifies techniques to achieve this. To our knowledge, no research

has been done to evaluate the combination of these intervention techniques and the effects on gestational weight gain.

Methods to assess dietary intake

To gather information about participants' dietary intake and to assess nutritional composition, three dietary recall methods were used: Automated, Self-Administered 24-hour Recall system (ASA-24), National Health and Nutrition Examination Survey (NHANES)/National Cancer Institute (NCI) Diet Screener Questionnaire (DSQ), and the NCI Fruit and Vegetable Screener. All screeners were administered after each trimester visit. In order to evaluate the nutritional quality of dietary intake, Healthy Eating Index and Diet Quality Index for Pregnancy (DQI-P) scores were utilized.

The ASA-24 is a dietary assessment method developed by the NCI, which is based on the validated USDA Automated Multiple-Pass Method (AMPM) 24-hr recall. It is a web-based, self-administered dietary recall method which collects a participant's self-reported food and beverage intake from the last 24 hours including portion sizes. Given that the collection occurs within one day of the time of intake, it minimizes recall bias associated with memory of food consumption. The ASA-24 consists of a respondent web site, which guides the participant through the completion of a 24-hour recall for the previous day from midnight to midnight. As described by the National Cancer Institute, the web application:

- Provides an animated guide to instruct participants
- Asks respondents to report eating occasion and time of consumption
- Asks respondents to provide a meal-based "quick list" of foods and drinks consumed the previous day

- Allows respondents to find foods or drinks to report by browsing food groups or searching from a list of food terms derived from USDA's AMPM
- Guides respondents through detailed questions about food preparation
- Uses images to assist respondents in reporting portion size
- Allows the respondent to add or modify food and drink choices at multiple times during the interview
- Includes a final review of the day's intake
- Includes an optional module to query about dietary supplement intakes based on supplements reported in the 2007-08 NHANES
- Is available in English and Spanish
- Allows for accessibility by individuals with speech and hearing impairments

The ASA-24 researcher website allows researchers to register participants, set parameters specific to the study, and manage the analysis of responses (54).

The accuracy of the USDA AMPM has been verified. An initial study evaluated the AMPM by comparing reported energy intake to total energy expenditure (TEE) using doubly labeled water as a means for determining TEE. The study involved 524 men and women living in the Washington, DC area. Each participant consumed a standardized dose of doubly labeled water at the beginning of the study and completed three 24-hour recalls using the AMPM. The recalls were completed on two weekdays and one weekend day. The results of the study showed that normal weight participants (defined as a BMI under 25) accurately reported energy intake with an average of 3% difference between energy intake and TEE. Including participants in all BMI categories, subjects in the study underreported energy intake by an average of 11% (55).

A second study evaluated the estimation of energy intake as determined by the ASA-24 against that of the Block food-frequency questionnaire and the NCI Diet History

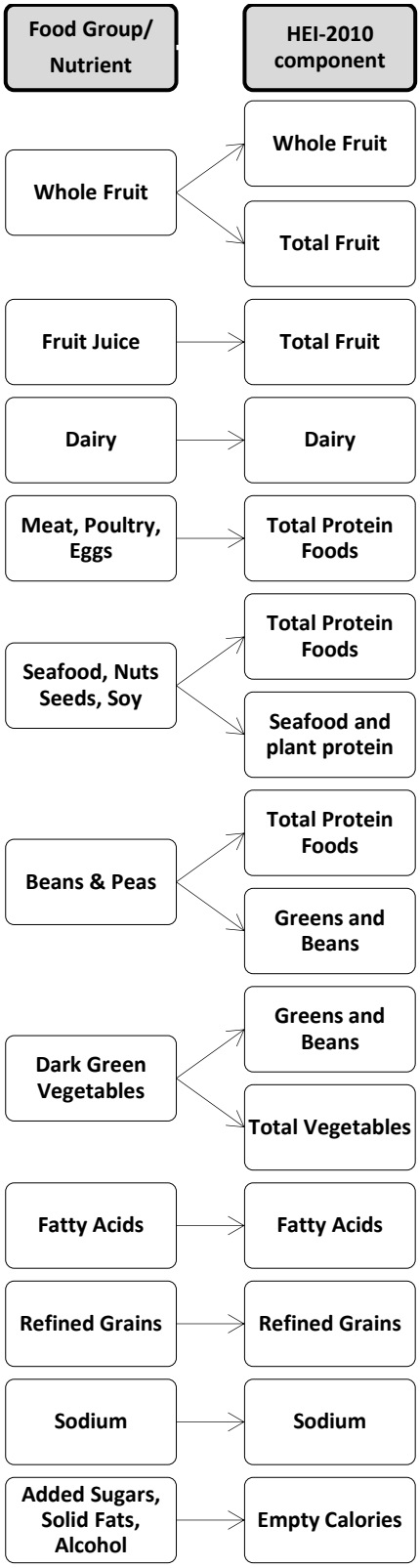
Questionnaire (DHQ) in 20 premenopausal women. The dietary assessment methods were compared to TEE (found using doubly labeled water) and a 14-day written food diary. The 24-hour recall was conducted on two nonconsecutive days, one weekday and one weekend day. Mean energy intake did not differ significantly between TEE and the 24-hour recall. Conversely, mean energy intake, was significantly underestimated by the DHQ and Block questionnaire. The study concluded that in premenopausal women the ASA-24 provided a valid measure of group total energy intake (56).

In the current study, the NCI Fruit and Vegetable Screener were used as an additional means to estimate fruit and vegetable intake. The screener provides dietary intake information relating to the types and quantities of fruits and vegetables consumed in the past month (answers ranging from 1-3 times per month to 5 or more times per day). This screener was developed in 1996 and has been used widely to track changes in fruit and vegetable intake in specific population groups (54). One study compared the fruit and vegetable screener with a complete food frequency questionnaire when estimating median fruit and vegetable intakes. Fruit and vegetable intakes as measured by each screener and the food frequency questionnaire were compared with estimated true usual intake determined using a measurement-error model. After comparing the responses of 800 men and women from the National Institutes of Health-American Association of Retired Persons Diet and Health Study, the study found that the fruit and vegetable screener underestimated true fruit and vegetable intake (3.7 vs. 6.6 servings per day) and that the food frequency questionnaire was significantly better when measuring true intake than the fruit and vegetable screener ($p=0.0009$). The research suggests that this screener is not ideal for determining the median intakes of fruits and vegetables in groups (57). While the fruit and vegetable screener has not been determined to be an accurate measure of fruit and vegetable intake by itself, it was used

as a supplemental screener in the PEN study for comparison purposes and to obtain preliminary data to inform future studies.

In addition to measuring dietary intake, diet quality was also assessed in the current study. The Healthy Eating Index (HEI) is a tool used to measure diet quality based on the 2010 Dietary Guidelines for Americans. The Center for Nutrition Policy and Promotion originally developed the HEI in 1995 and it has since been updated to meet revised dietary recommendations. The HEI takes in to account several dietary components including total fruit, whole fruit, total vegetables, greens and beans, whole grains, dairy, total protein foods, seafood and plant proteins, fatty acids, refined grains, sodium, and empty calories (see Figure 1). The HEI is based on a maximum score of 100 points, with each component accounting for 5-10 points. While the HEI has primarily been used as a tool for the USDA to monitor U.S. diet quality, the HEI is also used to evaluate interventions, to track dietary patterns, and to assess various aspects of the food environment (59). One study used the HEI to determine the relationship between diet quality and postpartum weight retention. The body weight of 1,136 women in the Infant Feeding Practices Study II was recorded at 4, 7, 10, and 14 months post-partum. At four months post-partum, dietary patterns were analyzed using a food-frequency questionnaire. The Healthy Eating Index was used to assign diet quality scores. At 14 months post-partum the mean weight retention was 1.1 kg with a standard deviation of 6.7 kg. The study found no correlation between postpartum weight retention at 14 months and diet quality score (60).

Figure 1. Healthy Eating Index-2010 Components



The Diet Quality Index for Pregnancy (DQI-P) was an additional tool used to assess diet quality. DQI-P includes eight components: % recommended servings of grains, vegetables and fruits, % recommendations for folate, iron and calcium, % energy from fat, and meal/snack patterning score. Each component contributes 10 points meaning that total scores can range from 0 to 80. The DQI-P was published in 2002 by Bodnar and Siega-Riz and was developed to assess adherence to the U.S. dietary recommendations for pregnancy. Originally, the index was used to evaluate variation in diet quality by socio-demographic factors. A food frequency questionnaire was distributed to 2,063 pregnant women attending two public prenatal clinics in North Carolina. The questionnaire was distributed during the women's second trimester. The study found that women who were >30 years old, >350% of the US poverty level, nulliparous and high school graduates had significantly higher overall DQI-P scores. Additionally, the research suggests that the DQI-P may be a useful tool for determining diet quality in public health research studies of pregnant women (29). Since the development of the DQI-P, the tool has been used to evaluate nutrient and food group differences during pregnancy by race and determine the micronutrient status of low-income women (61, 62).

The previously described dietary assessment tools were used in evaluating the dietary intake of women participating in the OHSU Pregnancy Exercise and Nutrition (PEN) Program. The PEN program was a feasibility study of a worksite employee wellness, team-based nutrition and exercise education program for pregnant women. The program used small group education sessions in conjunction with web-based weekly activities and started during the participants' first or second trimester of pregnancy. The effect of the OHSU PEN program on fruit and vegetable intake during pregnancy was evaluated and compared with those receiving standard care. Additionally, the participants' fruit and vegetable intake was related to total gestational

weight gain and infant birth weight. This research provides insight into effective curriculum components as well as education techniques that promote healthy maternal behaviors during pregnancy.

Chapter 3: Methods

General Study Design

This study was a prospective, randomized feasibility trial that targeted women in their first trimester of pregnancy. The intervention included an employee workplace-facilitated, team-based, peer-led curriculum that focused on healthy dietary and physical activity recommendations for pregnant women to reduce the risk of gestational diabetes mellitus (GDM). The relationship between fruit and vegetable intake, diet quality score, maternal weight gain, and infant birth weight in the intervention and control was determined as well as differences in these variables among women meeting or exceeding the 2009 IOM gestational weight gain recommendations.

IRB Approval

This study was reviewed and approved by the OHSU Institutional Review Board and all participants provided written informed consent and Health Insurance Portability and Accountability Act forms prior to participating in any study-related activities.

Recruitment and Sample Size

Thirty pregnant women in their first trimester of a single gestation pregnancy were recruited from the population of OHSU employees and their spouses. Recruitment methods included displaying advertisement fliers and posters around the campus and hospital, and providing the obstetric clinic with pamphlets for distribution to their patients or for display in their waiting areas for women attending prenatal appointments. To more directly recruit participants, obstetricians, midwives and/or nursing staff at the OHSU Center for Women's Health provided potential participants (newly pregnant OHSU employees or spouses of employees) with an

informational brochure to invite women to participate in the study. The PEN Research Coordinator used Epic Electronic Medical Records to view the charts of women who were scheduled for first-time OB appointments at the Center for Women's Health. The eligible patients were flagged to receive the informational brochures from their healthcare provider. These individuals were then sent an email that encouraged them to contact the PEN study research staff by phone or email. Eligibility was defined by the inclusionary and exclusionary criteria, which is summarized in Table 2.

Table 2: Inclusionary and Exclusionary Criteria

Inclusionary Criteria	**Exclusionary Criteria**
OHSU employee or spouse	Type I or type II diabetes mellitus
Healthy, uncomplicated single gestation pregnancy	Cardiovascular disease
5-12 weeks gestation at enrollment	Obstructive lung disease
	Musculoskeletal dysfunctions
	Use of anti-hypertensive medications
	Fasting blood glucose concentration (>110 mg/dL) at screening visit
	Exceeding 40 years of age
	Smoking and/or drinking during pregnancy

Once participants expressed interest in the PEN study, they were scheduled for a baseline study visit. The baseline study visit consisted of obtaining participant consent, a list of current medications and dietary supplements, height and weight measurements, a urine sample, and a blood sample. A note was obtained from the care provider agreeing that their patient could be enrolled in the program and confirming that they would share patient data. This was obtained shortly after the

baseline study visit. This agreement by the pregnancy care provider was a study enrollment requirement. Appendix 1 and 2 include the participant consent and provider approval forms.

Randomization

Eligible participants were enrolled into the study in groups of 10. Each group of 10 new participants was entered into a spreadsheet organized by participant identification number, BMI, and age. The table was ordered by BMI, and participants with the same or similar BMIs were grouped by age. Participants with similar BMI and age were then paired and assigned to the control or intervention group using the iPhone application “Coin Flip +”. The program was used twice. First, it was used to determine the order of the participant pair. Heads indicated the participant to be listed first, and tails indicated the participant to be listed second. Next, the program was used to assign the first participant to one of the two study groups. Heads indicated that the first participant was to be assigned to the intervention group, and tails indicated that the first participant was to be assigned to the control group.

Data Collection, Management and Analysis

Participant data was collected at the baseline study visit during the 1st trimester as wells as during follow-up visits during the 2nd trimester at approximately 22 weeks and again during the 3rd trimester at approximately 32 weeks of gestation. Demographic characteristics of each subject were collected at baseline. This included age, self-reported pre-pregnancy weight, education level, employment status, and socioeconomic status. Comprehensive medical history was collected at the baseline visits and included: medication use, smoking status, alcohol intake,

prior pregnancies, birth weight of previous children, family history of diabetes and/or hypertension, and physical activity level by standard questionnaire.

At each study visit, a brief physical examination was performed by one of the study physicians. Height, weight, blood pressure (taken three times, with one minute between repeated measures, after a 3 minute seated rest, by a calibrated, automated sphygmomanometer), and heart rate were measured. Weight was obtained with an electronic scale (Fairbanks; HS 110AX Class III; Kansas City, MO) while participants were dressed in light clothing without shoes. Height was measured at the first visit with a stadiometer (Invicta Plastics Limited; Design Application No. 2007246; Leicester, England) while participants were not wearing shoes. BMI was calculated by dividing the participant's weight (in kilograms) by squared height (in meters). Appendix 3 and 4 include the check lists used at each trimester visit.

Gestational weight gain was calculated as the difference between the self-reported pre-pregnancy weight and the latest weight taken before delivery obtained through the electronic medical record system at OHSU, or as provided by the physician of record if the delivery occurred at a hospital other than OHSU. Newborn birth weight was obtained through the electronic medical record system at OHSU or as provided by the physician of record if the delivery occurred at a hospital other than OHSU .

Team-Based Curriculum

The PEN curriculum was used to facilitate 20 weekly group sessions. Group sessions were roughly 30 minutes long, and were held at a time that was agreed upon by members of the group. Participants were between 5-20 weeks of gestation when they started the curriculum. The PEN curriculum was developed by the faculty and staff of the Division of Health Promotion & Sports Medicine at OHSU, based on

methods shown to successfully improve health behaviors in other workplace wellness interventions. A key component of these, and specifically the PEN and Healthy Team Healthy U (HTHU) programs, is the team-based learning and social support paradigm. The curriculum included nutrition and physical activity guidelines during pregnancy. Curriculum materials included a scripted team leader manual (the team leader rotates each session), a team member workbook, and a Health & Wellness Guide. The 12-session OHSU employee general wellness program, HTHU, provided the foundation of the 20 PEN sessions. The 12-session HTHU program was modified to be pregnancy-specific, and eight additional pregnancy-related topics were developed and added. Additionally, a pregnancy chapter was added to the wellness guide from HTHU, which was available to the participants to supplement the curriculum. All materials were tailored for pregnancy, with input from obstetricians, midwives, registered dietitians, and other women's health experts. Appendix 5 provides a summary of objectives and goals for each session. The self-selected team-leader conducted the session, reading through the Team Leader Manual and facilitating discussion; participants completed activities as a team while following the curriculum in their individual Team Workbook. A member of the research team was present at each session as an observer to record fidelity to the curriculum.

Dietary and physical activity recommendations were based on the American Diabetes Association (ADA) guidelines, and included: 1) eating three small meals and two to three snacks at regular times during the day; 2) consuming meals composed of 40-45% of total energy from lower glycemic index carbohydrates; 3) eating high-fiber carbohydrates including, whole-grain breads, cereals, pasta, rice, fruits, and vegetables; 4) consuming breakfast and bedtime snacks containing 15-30 grams of low glycemic carbohydrates; 5) consuming 30-40% of total energy from

fat, with 10% or less of total energy from saturated fat; 6) consuming 64 ounces of liquids each day, while avoiding beverages containing added sugar, limiting caffeine, and limiting fruit juice intake to 4 ounces at each meal.

Personal goal-setting and self-assessment, along with individual and group goal attainment are cornerstones of the program. Scripted goals were provided at the end of each session and the following week individual progress made towards goal attainment was reviewed as a team. The group setting provided social support and group accountability for positive behavior change. Successes and challenges regarding attainment of weekly goals were discussed allowing encouragement or guidance to be provided from one teammate to another. Emails and text messages enriched the program, were tied to the curriculum goals, and acted as reminders to attain goals between sessions. A PEN-specific website offered healthy recipe options and was available for participants to track their attendance and progress towards meeting weekly goals.

Control Arm

Women randomized to the control condition received a pregnancy handout produced by the U.S. Department of Health and Human Services Office on Women's Health, entitled *Pregnancy: Staying healthy and safe.* The handout included information on diet and fitness recommendations, smoking cessation, substance abuse and other health information. The handout also included information about tips for safe physical activity and symptoms identifying when they should stop exercising and contact their health care provider. Members of the control group also received standard care by their health care provider during pregnancy.

Confidentiality

Study data was collected and managed using REDCap (Research Electronic Data Capture). REDCap is a secure, web-based application designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks), audit trails and a de-identified data export mechanism to common statistical packages. The system was developed by a multi-institutional consortium, which included Oregon Health & Science University and was initiated at Vanderbilt University. The system is protected behind a login and Secure Sockets Layer encryption.

Computer data files were made by optically scanning surveys and/or typing data into the database. All data was linked to an individual, randomly assigned participant identification number. Data was stored by the study number, not the subject's name. Data was stored both in the password-protected database and on paper in a locked drawer.

Dietary Assessment and Analysis

The Automated, Self-Administered 24-hour Recall system (ASA-24) was used to estimate maternal dietary intake. This recall system has been validated in numerous populations to assess usual dietary intake (55, 56). The ASA-24 was available for self-administered online use and was available in English or Spanish. The program asked respondents to report all food and beverage consumption for the last full day (from midnight to midnight). The program used images to assist participants in estimating and reporting portion sizes and included a final review and list of frequently forgotten foods.

The ASA-24 was administered within 2-5 days after each trimester visit. To administer the recall, an OHSU bionutritionist sent each participant an email with a login and password for the ASA-24 website. Emails were sent in the morning to provide ample

time for completion within the day. While the participants were aware that they would provide a 24-hour recall after each study visit, the exact timing of the recall request was not announced to limit purposeful food intake that would misrepresent the participant's usual intake. 24-hour recalls were only requested on weekdays (Tuesday through Friday), reflecting dietary intake of the previous day (Monday through Thursday). Due to the work schedules of our hospital-based employees, the recall may have been a working or non-working day. After completing the ASA-24 the participants were asked to notify the bionutritionist of their completion via email, note whether the recorded day was a working or non-working day, and report any issues they had completing the recall.. When the full set of participant recalls was complete for each trimester visit, the bionutritionist logged into the ASA-24 researcher website and requested to have the 24-hour dietary data exported. Within 1-2 days, the data was returned in a spreadsheet which provided an analysis of the participant's self-reported 24-hour dietary intake including: energy, macronutrient, micronutrient, fiber, and caffeine content. The ASA-24 uses the USDA's Food and Nutrient Database for Dietary Studies (Version 4.1) to derive the dietary intake data.

In addition to the ASA-24, the NCI Fruit and Vegetable Screener, a validated, calibrated, and web-based dietary screener that captures fruit and vegetable consumption during the past month, was emailed to participants within a day after completion of each study visit. The screener inquires about intakes of juice, fruit, potato, legume, and vegetable consumption, totaling 10 different questions. The participant answered in terms of monthly, weekly, or daily consumption and also provided her usual serving size (54).

Diet quality was assessed using the Healthy Eating Index (HEI) and the Diet Quality Index for Pregnancy (DQI-P). Diet quality scores were calculated based on dietary intake information from the ASA-24. The HEI was developed by the United

States Department of Agriculture (USDA) and NCI and is used to assess diet quality as specified by the 2010 Dietary Guidelines for Americans. The total score is the sum of the 12 component scores and has a maximum of 100 points (see Table 3). Intakes between the minimum and maximum standards are scored proportionately. Using Statistical Analysis System software (SAS Version 9.3; Cary, NC), the ASA-24 data was incorporated into an algorithm that calculated HEI scores for each participant.

Table 3. Dietary Components of the Healthy Eating Index (59)

Component	Standard for Maximum Score	Maximum Score
Total fruit[1]	≥0.8 cup equiv/1,000 kcal	5
Whole fruit[2]	≥0.4 cup equiv/1,000 kcal	5
Total vegetables[3]	≥1.1 cup equiv/1,000 kcal	5
Greens and beans[3]	≥0.2 cup equiv/1,000 kcal	5
Whole grains	≥1.5 cup equiv/1,000 kcal	10
Dairy[4]	≥1.3 cup equiv/1,000 kcal	10
Total protein foods[5]	≥2.5 oz equiv/1,000 kcal	5
Seafood and plant proteins[5,6]	≥0.8 oz equiv/1,000 kcal	5
Fatty acids[7]	(MUFAs+PUFAs)/SFAs ≥ 2.5	10
Refined grains	≤1.8 oz equiv/1,000 kcal	10
Sodium	≤1.1 gram/1,000 kcal	10
Empty calories[8]	≤19% of energy	20

[1]Includes 100% fruit juice

[2]Includes all forms except juice

[3]Includes any beans and peas not counted as total protein foods

[4]Includes all milk products such a fluid milk, yogurt, and cheese, and fortified soy beverages

[5]Beans and pods are included here (and not with vegetables) when the total protein foods is otherwise not met

[6]Includes seafood, nuts, seeds, soy products (other than beverages) as well as beans and peas counted as total protein foods

[7]Ratio of poly- and monounsaturated fatty acids (PUFAs and MUFAs) to saturated fatty acids (SFAs)

[8]Calories from solid fats, alcohol, and added sugars, threshold for counting alcohol is >13 grams per 1000 kcal

The DQI-P was published in 2002 by Bodnar and Siega-Riz and was developed to reflect US dietary recommendations for pregnancy (29). This diet quality assessment tool takes into account eight dietary components as shown in Table 4. Each component was scored on a scale of 1-10 points with a possible total score of 80 points. Four components were based on 2010 USDA Dietary Guidelines for Americans. Three components were based on the Recommended Daily Allowance (RDA) for key nutrients during pregnancy (calcium, iron, folic acid). The

last component related to the IOM recommended meal pattern of three meals and two snacks for pregnant women. For the current study, there was no way to objectively determine a meal from a snack. Instead, “eating occasions” were observed with a goal of 5 eating occasions.

Table 4. Dietary Components of the Dietary Quality Index for Pregnancy (29)

Component	Definition of Score
6-11 servings of grains	% recommended servings[1]
3-5 servings of vegetables	% recommended servings[1]
2-4 servings of fruits	% recommended servings[1]
Total fat	≤ 30% energy intake[2]
Folate intake	% RDA[1]
Iron intake	% RDA[1]
Calcium intake	% AI for age[1]
Meal pattern	Goal of 3 meals/2 snacks[3]

[1]Used as a continuous percentage (0%-100%) corresponding to a continuous DQI-P score of 0-10 points
[2]Scoring based on categories: ≤30%= 10 points, >30%, ≤35%=7 points, >35%, ≤40%=4 points, >40%=0 points
[3]Scoring based on categories: 5 eating occasions= 10 points; 4 eating occasions= 8 points; 3 eating occasions = 6 points; 2 eating occasions= 4 points; 1 eating occasion=2 points

Calculations

For this analysis, total gestational weight gain, percent of recommended weight gain based on pre-pregnancy BMI, and infant birth weight percentile based on gestational age at birth were calculated. Total gestational weight gain was defined as the difference between the last recorded weight before delivery (per medical record review or health provider report) and self-reported pre-pregnancy weight. The last weight before

delivery was not available for three participants, so self-reported weight before delivery was used for those participants.

Maternal Weight Gain

Recommended weight gain was indexed to week of gestation at delivery using the specific IOM recommended weight gain ranges assigned to each week of pregnancy (2). For example a participant with a normal weight pre-pregnancy BMI who delivered at 40 weeks of gestation would have a recommended weight gain range of 25-35 pounds. However, a woman in the same BMI category who delivered at 37 weeks of gestation would have a recommended weight gain range of 22-32 pounds (accounting for a one pound per week weight gain in the third trimester).

Percent recommended weight gain was calculated as the percent of the upper value of the recommended weight gain range. For example, if a participant with a pre-pregnancy BMI in the normal weight range had a recommended weight gain range of 25-35 pounds and gained 35 pounds, this would equate to 100% of recommended weight gain [(35/35)*100=100%].

Infant Birth Weight

Infant birth weight percentile was calculated by plotting infant birth weight and week of gestation at birth on the 2013 Fenton growth charts specific to the newborn's sex. Large for gestational age was defined as a birth weight above the 90^{th} percentile and small for gestational age was defined as a birth weight below the 10^{th} percentile on the growth chart (63).

Dietary Intake

Participant diets were described by reporting the macronutrient (e.g., protein, fat, carbohydrate, and alcohol) distribution (percent of total energy), nutrient density (intake per 1000 kcals) and percent of Recommended Dietary Allowance or Adequate Intake. Macronutrient distribution was calculated by converting macronutrient intake (in grams) into kilocalories (i.e. each gram of protein consumed was multiplied by 4 kcal/g to calculate energy intake from protein). Energy intake of each macronutrient was then divided by total daily energy intake and multiplied by 100 to calculate percent of energy from that macronutrient:

[((70 g Protein * 4 kcal/g Protein)/1950 kcal) * 100 = 14.4% of energy from protein].

Nutrient density was calculated as the intake of the nutrient in grams, milligrams, or micrograms per 1000 kcals. For example, if a participant reported a daily intake of 70 grams of protein and 1950 kcal of total energy, the nutrient density was calculated as 36 grams of protein per 1000 kcal of energy intake,

[70 g Protein / (1950 kcal / 1000 kcal) = 36 g Protein / 1000 kcal].

Percent of RDA or AI was calculated by dividing participant intake of a nutrient by the RDA or AI of that nutrient established for pregnant women and multiplying by 100. For example, the RDA of folic acid is 600 mcg per day. If a participant reported an intake of 525 mcg of folic acid, the percent of RDA for folic acid would be 87.5% [(525 mcg folic acid / 600 mcg folic acid) * 100 = 87.5% of the RDA].

Data Cleaning

Data collected from nutrient analysis, weight gain calculations, birth weight, and both HEI and DQI-P calculations were transferred into spreadsheets (Excel [Microsoft; Seattle, WA]) Microsoft Office 2010 [Microsoft; Seattle, WA] and Statistical Package for

Social Sciences [IBM; Armonk, NY]). A standard distribution curve was generated to assess normality of each outcome variable. Weight gain, birth weight, HEI and DQI-P data were approximately normally distributed as assessed by visual inspection; however nutrient intake data was not normally distributed.

Participants with incomplete data sets were excluded from analysis. This included two participants who withdrew from the study and were not replaced. In addition, one participant reported an energy intake of less than 500 kcal in the 3rd trimester and that data was not used in the analysis.

Statistical Analysis

To analyze differences in nutrient and food group intake between groups at each trimester and differences in change over time within and between groups throughout pregnancy, participants (n=28) were divided into two sets of groups: intervention and control and met or exceeded IOM gestational weight gain recommendations. Mean (+/- SD) and median nutrient and food group intake values were calculated for each group. Because the nutrient data was not normally distributed, Mann Whitney non-parametric tests were run to compare median values of each set of groups at trimester 1, trimester 2, and trimester 3. Change between trimesters was also compared using Mann Whitney tests to determine the significance of differences in change between groups. P-values less than 0.05 were considered significant. The same analyses were completed between sets of groups for HEI and DQI-P diet quality scores.

To analyze the relationship between nutrient and food group intake and excessive maternal gestational weight gain, participants were divided into two groups: those who exceeded the 2009 IOM weight gain recommendations and those whose weight gain was within the recommendations. For the purposes of this analysis, the four participants who gained less weight than the recommended range were included in the

"Met Gestational Weight Gain Recommendations" group. Mann Whitney U tests were used to compare median values of nutrient and food group intake between the two groups. Change in median values between trimesters was also calculated and Mann Whitney U tests were used to determine significance of change between groups. The same analysis was completed between groups for HEI and DQI-P diet quality scores

Odds ratios were calculated to determine the odds of exceeding the 2009 IOM gestational weight gain recommendations for participants who did not meet the recommendations for fruit and vegetable intake at baseline and trimesters 2 and 3 compared to those who did meet the fruit and vegetable recommendations. Odds ratios were also calculated to determine the odds of giving birth to a large for gestational age infant for participants who did not meet the recommendations for fruit and vegetable intake at trimester 1 and trimesters 2 and 3 compared to those who did meet the fruit and vegetable recommendations. Finally, odds ratios were calculated to determine the odds of exceeding the 2009 IOM pregnancy weight gain recommendations for women who had HEI and DQI-P scores in the lower tertile compared to those in the upper tertile.

Chi-square tests were used to determine significant differences in counts of categorical data between groups when comparing:

- Demographic information
- Number of large- or small for gestational age infants
- Number of women below and above the weight gain recommendations
- Number of women demonstrating dietary improvements from trimester 1 to trimester 3
- Number of women meeting fruit and vegetable recommendations each trimester

Chapter 4: Results

An analysis of maternal gestational weight gain, nutrient intake throughout pregnancy, and infant birth weight was performed to determine differences between control and intervention groups as well as differences between groups of participants who met or did not meet the 2009 IOM gestational weight gain recommendations. Of the 30 participants enrolled in the PEN study, two withdrew from the study (one intervention and one control) and were not replaced. The data from those participants were not included in this analysis. For participants in the intervention group (n=14), 93% attended at least 15 of the 20 PEN program sessions as logged by participants on the PEN website.

Demographic Characteristics of PEN Participants

Table 5 presents demographic characteristics of women in the control and intervention groups as well as for all participants in the PEN program. The average (± SD) age at enrollment was 32.9 ± 2.9 years with a range of 27-37 years. Given that being 25 years of age or older during pregnancy is a risk factor for gestational diabetes, all participants in this study had some risk for developing gestational diabetes (64). Eighty-nine percent of participants were white. Fifty-seven percent of participants had a pre-pregnancy BMI reflecting normal weight status and 43% were categorized as overweight or obese. Sixty four percent of participants were nulliparous, 29% of participants were primiparous and 7% reported a parity of two. All participants reported some college education and 61% had obtained a graduate degree. Eighty-two percent of participants were employed full-time and 78% reported an annual household income of greater than $75,000. There were no statistically significant differences in means or percentages between control and intervention groups for any of the demographic characteristics.

Table 5: Participant Characteristics

Demographic Characteristics	Control (n=14)	Intervention (n=14)	Total (n=28)
Age at enrollment (yr)*	32.4 ± 3.5 (27-37)	33.4 ± 2.1 (30-37)	32.9 ± 2.9 (27-37)
Race (% white)	93%	86%	89%
Pre-pregnancy Body Mass Index			
Normal (18.5-24.9 kg/m^2)	50%	64%	57%
Overweight or Obese (≥25.0 kg/m^2)	50%	36%	43%
Parity			
0	79%	50%	64%
1	14%	43%	29%
2	7%	7%	7%
Education Level			
4-year degree or less	36%	43%	39%
Graduate degree	64%	57%	61%
Employment Status			
Full-time	93%	71%	82%
Part-time	7%	21%	14%
Unemployed	0%	7%	4%
Household Size**			
2 or less	71%	36%	54%
3	14%	36%	25%
4 or more	7%	14%	11%
Annual Household Income Level†			
Less than $75,000	29%	15%	22%
$75,000-100,000	43%	39%	41%
More than $100,000	29%	46%	37%

*Mean ± SD (Range)

**Data not available for 2 intervention, 1 control participant

†Data not available for one intervention participant

Chi-squared tests or Fischer's Exact tests were used to compare counts of categorical data between groups

Maternal and Infant Characteristics of PEN Participants

Table 6 displays maternal and infant characteristics of control and intervention groups at baseline and at delivery. There were no statistically significant differences in means between control and intervention groups for any characteristic. Average (± SD) week of gestation at enrollment of all participants (n=28) was 9.7 ± 2.1 weeks with a range of 5-12 weeks of gestation (data not shown). The average (± SD) pre-pregnancy weight and BMI for all participants was 67.5 ± 11.9 kg and 24.9 ± 3.6 kg/m^2, respectively.

The average (± SD) week of gestation at delivery was 39.6 ± 2.1 weeks with a range of 33-42 weeks and 93% of participants delivered at term (at least 37 weeks). Average (± SD) total gestational weight gain was 16.1 ± 5.3 kg (35.4 ± 11.7 lb) with a range of 2.8-25.9 kg (6.2-57.0 lb; data not shown). While the average pre-delivery weight of the intervention group (79.6 ± 14.1 kg) was lower than the average pre-delivery weight of the control group (87.5 ± 13.8 kg) the difference was not statistically significant. Comparing weight gain to the 2009 IOM recommendations, participants gained an average of 123 ± 53% of the gestational weight gain recommendations based on week of gestation at delivery and pre-pregnancy BMI. Sixteen women (57%) exceeded the IOM weight gain recommendations, 8 (29%) met the recommendations and 4 (14%) women gained less weight than the recommended amount.

Infant birth weights were indexed to gestational age and are shown as percentiles derived from the 2013 Fenton growth charts (63). There were no significant differences in mean birth weights between groups. The average (± SD) weight for gestational age percentile was 55.1 ± 29.7% which ranged from the 1st to the 99th percentile. The birth weights of 22 (79%) of the infants were considered appropriate for gestational age. The birth weights of 4 (14%) of the infants were considered large for gestational age (defined as greater than the 90th percentile on the growth chart) and 2

(7%) of the infants were considered small for gestational age (defined as lower than the 10th percentile on the growth chart).

Table 6 also displays maternal and infant characteristics at delivery for women who met or exceeded the 2009 IOM gestational weight gain recommendations. Between these groups, there were significant differences in self-reported pre-pregnancy weight, pre-pregnancy BMI, last weight before delivery and maternal weight gain (displayed as percent of the IOM gestational weight gain recommendations). Among women who were overweight or obese before becoming pregnant, 92% of participants exceeded the weight gain recommendations compared to 31% of participants in the normal weight pre-pregnancy BMI category. No significant differences in infant birth weight, the number of large for gestational age infants, or the number of small for gestational age infants were observed between groups meeting or exceeding the weight gain recommendations.

Table 6: Maternal and Infant Characteristics

	Control (n=14)	Intervention (n=14)	Weight Gain Within Guidelines (n=12)	Weight Gain Exceeding Guidelines (n=16)	Total (n=28)
Week of gestation at delivery	39.4 ± 1.8 (35-41)	39.2 ± 2.4 (33-42)	38.8 ± 2.2 (33-41)	39.7 ± 2.0 (35-45)	39.6 ± 2.1 (33-42)
Self-reported pre-pregnancy weight (kg)	64.4 ± 13.0 (51.0-86.8)	70.6 ± 10.3 (45.5-97.3)	61.2 ± 5.8 (50.9-70.5)	72.2 ± 13.2* (45.5-97.3)	67.5 ± 11.9 (45.5-97.3)
Pre-pregnancy BMI (kg/m^2)	25.3 ± 3.1 (21.0-30.0)	24.5 ± 4.2 (18.9-35.1)	22.7 ± 1.8 (18.9-25.1)	26.6 ± 3.8* (20.9-35.1)	24.9 ± 3.6 (18.9-35.1)
Latest pre-delivery weight	87.5 ± 13.8 (63.1-106.9)	79.6 ± 14.1 (59.6-113.4)	72.9 ± 6.6 (59.6-85.2)	91.6 ± 13.2* (67.1-113.4)	83.6 ± 14.3 (59.6-113.4)
Maternal weight gain (% recommendation indexed to GA at delivery)	135 ± 58 (63-252)	112 ± 46 (26-186)	76 ± 21 (8-97)	159 ± 40* (105-252)	123 ± 53 (26-252)
Number exceeding weight gain guidelines indexed to GA at delivery	8 (57%)	8 (57%)	0 (0%)	16 (100%)	16 (57%)
Number gaining weight below the guidelines indexed to GA at delivery	1 (7%)	3 (21%)	4 (33%)	0 (0%)	4 (14%)
Infant birth weight indexed to GA at delivery (%ile)	57.1 ± 36.2 (8-99)	53.1 ± 22.7 (1-92)	55.6 ± 32.4 (8-97)	54.8 ± 28.6 (1-99)	55.1 ± 29.7 (1-99)
Number of large for gestational age infants**	3 (21%)	1 (7%)	3 (25%)	1 (6%)	4 (14%)
Number of small for gestational age infants †	1 (7%)	1 (7%)	1 (8%)	1 (6%)	2 (7%)

Mean ± SD (Range) or Frequency (%)
*Significantly different than participants within weight gain guidelines
**Large for gestational age defined as >90th %ile on 2013 Fenton growth chart
†Small for gestational age defined as <10th %ile on 2013 Fenton growth chart
T-tests were used to compare differences in means between groups
Chi-squared tests or Fischer's Exact tests were used to compare counts of categorical data between groups

Nutrient Intake During Pregnancy

Tables 7 and 8 present average (± SD) and median dietary intake of energy, macronutrients, fruits and vegetables, fiber, sugar, calcium, iron, and folic acid during trimester 1 as derived from the Automated, Self-Administered 24-Hour Dietary Recall (ASA-24) for the control and intervention groups and the groups based on maternal weight gain, respectively. Additionally, the tables display change in dietary intake from the 1st trimester 1 to the 2nd and 3rd trimesters for each set of groups.

Energy, Macronutrient and Micronutrient Intakes of Women in the Control and Intervention Groups

In Table 7, average (± SD) energy intake at baseline was 1889 ± 515 kcal/d and 2117 ± 688 kcal/d in the control and intervention groups, respectively, which were not significantly different. At the 3rd trimester, the control group reported an energy intake that was 381 ± 576 kcal/d higher than the 1st trimester while the intervention group reported an energy intake that was 199 ± 695 kcal/d lower than the 1st trimester. The changes in energy intake over time between groups were significantly different (p=0.02).

During the 1st trimester, both groups reported mean macronutrient intakes within the acceptable macronutrient distribution ranges (AMDR) established by the Food and Nutrition Board of the IOM for protein (10-35%) and carbohydrate (45-65%) but both groups reported higher than the acceptable range for fat (20-35%) (65). However, in the 3rd trimester, compared to the 1st trimester, the intervention group reported a lower mean percent of energy from fat by 5.5 ± 0.1%. Therefore, in the 3rd trimester, the intervention group's average percent of energy from fat was within the AMDR. In addition, the intervention group had a lower median fat intake (decrease of 14 grams) where as the control group had a higher median fat intake (increase of 16 grams) from trimester 1 to trimester 3 and this difference was significant (p=0.02).

Comparison to the IOM Recommended Dietary Allowances (RDAs) for protein (71 g/day) and carbohydrate (175 g/day) and the Adequate Intake (AI) for fiber (28 g/day) are also presented in Table 7 (66). Intakes of these nutrients are presented as percentages of the RDA or AI. While not significantly different, at trimester 1, the mean protein intake of the intervention group exceeded the RDA (103 ± 39%) while the control group did not (94% ± 29) although the median for each exceeded the RDA. Both the control and intervention groups exceeded the RDA for carbohydrate intake (140 ± 42% and 143 ± 41%, respectively) however neither met the AI for fiber (96% ± 43 and 78 ± 23, respectively). The mean percent of RDA did not change significantly for protein, carbohydrate, or fiber, from trimester 1 to trimester 3 in either group.

Dietary intakes of calcium, iron, and folic acid were also assessed throughout pregnancy. Average (±SD) and median intakes of these nutrients are presented in Table 7. These nutrients are highlighted because they are critical for appropriate development of the fetus during pregnancy and are thus used in the calculation of the Diet Quality Index for Pregnancy. The RDAs for calcium, iron, and folic acid during pregnancy are 1000 mg/d, 27 mg/d, and 600 mcg/d, respectively. During the 1st trimester, the mean and median intakes of calcium exceeded the RDA in both the control (1214 ± 570 mg/d; 1108mg/d) and intervention groups (1187 ± 351 mg/d; 1153mg/d). The mean and median intakes of iron was lower than the RDA for both groups with average intakes of 16 ± 8.2 g/d and 16 ± 9.1 g/d in the control and intervention, respectively. In addition, the mean and median intakes of folic acid was lower than the RDA with an average intake of 492 ± 229 mcg/d in the control group and 480 ± 278 mcg/d in the intervention group. There were no statistically significant differences in median intake of any of these micronutrients between groups during the trimester 1 or in the change in their intake over time. It's important to note that assessment of micronutrient intake only accounted for intake from foods and beverages and did not include intake derived from the use of

dietary supplements. All participants reported taking a prenatal vitamin to supplement their dietary intake during pregnancy.

Table 7: Change in Dietary Intake Parameters Assessed using ASA24 Methodology of Participants in the Control and Intervention Groups

Dietary Variable	Units	Trimester 1		Change from Trimester 1-2		Change from Trimester 2-3		Change from Trimester 1-3	
		Control n=14	Intervention n=14	Control n=14	Intervention n=14	Control n=14	Intervention n=13	Control n=14	Intervention n=13
Energy	kcal/day	1889 ± 515 (1871)	2117 ± 688 (2100)	218 ± 705 (-241)	-252 ± 651 (-499)	163 ± 573 (262)	53 ± 744 (218)	381 ± 576 (346)	-199 ± 695 (-290)*
Protein	g/day	67 ± 20 (66)	74 ± 27 (68)	16 ± 43 (6.8)	-1.0 ± 29 (-2.6)	2.7 ± 34 (7.1)	5.2 ± 32 (-3.0)	19 ± 27 (13)	4.2 ± 32 (-5.7)
	g/1000 kcal	37 ± 11 (36)	35 ± 7.0 (34)	3.4 ± 12 (3.4)	3.5 ± 12 (7.4)	-1.9 ± 10 (-5.8)	1.8 ± 7.2 (2.7)	1.6 ±11 (1.4)	5.3 ± 15 (8.8)
	Percent total energy (%)	15 ± 2.8 (15)	14 ± 4.2 (14)	1.5 ± 0.1 (1.4)	1.4 ± 0.1 (3.0)	-0.8 ± 0.0 (-2.3)	0.7 ± 0.0 (1.1)	0.7 ± 0.1 (0.6)	2.1 ± 0.1 (3.5)
	Percent RDA (71 g/d)	94 ± 29 (93)	103 ± 39 (96)	22 ± 61 (10)	-1 ± 40 (-1%)	4 ± 48 (10)	7 ± 45 (-4)	26 ± 38 (19)	6 ± 45 (-8)
Fat	g/day	77 ± 25 (73)	97 ± 48 (103)	-1.5 ±28 (-1.5)	-31 ± 39 (-27.3)	18 ± 34 (19)	6.4 ± 35 (17.6)	16 ± 33 (16)	-24 ± 54 (-14)*
	g/1000 kcal	40 ± 5.7 (43)	43 ± 12 (45)	-4.5 ± 8.8 (-2.9)	-7.4 ±11 (-10)	4.5 ± 8.1 (3.5)	1.2 ± 8.9 (0.1)	-0.04 ± 8.0 (0.1)	-6.1 ± 13 (-3.6)
	Percent total energy (%)	36 ± 11 (39)	39 ± 5.2 (40)	-4.0 ± 0.1 (-2.2)	-6.6 ± 0.1 (-9.3)	4.1± 0.1 (3.1)	1.1 ± 0.1 (0.1)	-0.1 ± 0.1 (0.1)	-5.5 ± 0.1 (-3.2)
Carbohydrate	g/day	245 ± 74 (240)	250 ± 71 (227)	43 ±102 (34)	9.8 ± 102 (-9.6)	-2.2 ± 79 (12)	-14 ± 104 (-10)	40 ± 83.0 (44)	-4.6 ± 77 (19)
	g/1000 kcal	129 ± 14 (128)	123.1 ± 27 (118)	6.7 ± 24 (5.6)	15.2 ± 24 (12)	-9.4 ± 19 (-9.5)	-7.6 ± 18 (-9.6)	-2.7 ± 23 (2.5)	7.6 ± 32 (-4.5)
	Percent total energy (%)	52 ± 11 (51)	49 ± 5.8 (47)	2.7 ± 0.1 (2.2)	6.0 ± 0.1 (4.8)	-3.8 ± 0.1 (-3.8)	-3.1 ± 0.1 (-3.8)	-1.1 ± 0.0 (1.0)	3.0 ± 0.0 (-1.8)
	Percent RDA	140 ± 42 (137)	143 ± 41 (130)	24 ± 58 (19)	6 ± 56 (4)	-1 ± 45 (7)	-8 ± 59 (-6)	23 ± 47 (25)	-3 ± 44 (-11)

	(175 g/d)								
Calcium	mg/day	1187 ± 351 (1108)	1214 ± 570 (1153)	91 ± 619 (13.9)	-217 ± 472 (-126)	-44 ± 587 (-65)	211 ± 613 (89)	47.1 ± 552 (-19)	-5.9 ± 545 (-96)
	mg/1000kcal	641 ± 136 (602)	576 ± 174 (610)	-21 ± 213 (8.8)	-42 ± 154 (29)	-49 ± 18.2 (-78)	112 ± 324 (21)	-70.0 ± 214 (-103)	70 ± 299 (64)
	% RDA (1000 mg/d)	119 ± 35 (111)	121 ± 57 (115)	9 ± 62 (1)	-15 ± 51 (-11)	-4 ± 59 (-7)	12 ± 78 (9)	5 ± 55 (-2)	-1 ± 55 (-10)
Iron	mg/day	16 ± 8.2 (14)	16 ± 9.1 (14)	0.5 ± 8.8 (0.4)	-0.02 ± 7.7 (-1.2)	4.6 ± 14 (1.4)	0.03 ± 10 (2.4)	5.2 ± 13.0 (2.8)	0.004 ± 11 (4.2)
	mg/1000kcal	8.2 ± 3.5 (6.9)	7.4 ± 2.5 (6.8)	-0.3 ± 4.3 (-0.3)	1.0 ± 2.8 (0.4)	1.2 ± 5.5 (-0.4)	0.5 ± 5.4 (1.7)	0.8 ± 5.4 (1.4)	1.5 ± 5.1 (2.1)
	% RDA (27 mg/d)	59 ± 30 (50)	58 ± 34 (50)	2 ± 33 (2)	1 ± 27 (-2)	17 ± 51 (5)	0 ± 38 (9)	19 ± 48 (10)	-0 ± 42 (15)
Folic Acid	mcg/day	492 ± 229 (488)	480 ± 278 (455)	-7.6 ± 274 (35)	86 ± 344 (106)	56 ± 277 (96)	-46 ± 478 (128)	48.0 ± 265 (112)	39.7 ± 415 (-25)
	mcg/ 1000kcal	257 ± 104 (227)	226 ± 89 (217)	-18 ± 140 (-6.3)	65 ± 113 (61)	5.2 ± 134 (5.0)	-5.2 ± 195 (51)	-13 ± 139 (19)	60 ± 92 (71)
	% RDA (600 mg/d)	43 ± 17 (38)	38 ± 15 (36)	38 ± 34 (44)	58 ± 46 (46)	9 ± 46 (16)	8 ± 80 (21)	47 ± 40 (47)	50 ± 49 (45)
Fruit	serv/day**	1.8 ± 1.3 (1.4)	1.9 ± 1.5 (1.5)	0.2 ± 2.1 (0.35)	0.2 ± 0.9 (0.0)	-0.03 ± 1.7 (-0.3)	-0.03 ± 1.5 (0.3)	0.2 ± 1.9 (0.4)	0.1 ± 1.2 (0.2)
	serv/1000 kcal	1.0 ±0.6 (0.9)	1.0 ± 1.3 (0.7)	0.03 ± 1.0 (-0.0)	0.0 ± 1.0 (0.2)	-0.1 ± 0.9 (-0.2)	0.1 ± 0.7 (0.2)	-0.1 ± 0.7 (0.1)	0.1 ± 0.9 (0.2)
Vegetable	serv/day	1.8 ± 1.3 (1.4)	1.8 ± 0.7 (1.7)	0.4 ± 1.6 (0.4)	0.4 ± 1.2 (0.4)	-0.1 ± 1.2 (-0.3)	-0.1 ± 1.3 (0.04)	0.3 ± 1.3 (0.4)	0.3 ± 1.4 (0.4)
	serv/1000 kcal	1.0 ± 0.8 (0.7)	1.0 ± 0.4 (0.9)	0.1 ± 1.1 (0.2)	0.2 ± 0.6 (0.25)	-0.2 ± 0.6 (-0.2)	0.03 ± 1.0 (0.01)	-0.1 ± 0.9 (0.1)	0.2 ± 1.1 (0.0)
Fruit and Vegetable	serv/day	3.6 ± 1.8 (3.3)	3.7 ± 1.6 (3.5)	0.6 ± 2.2 (0.3)	0.5 ± 1.1 (0.2)	-0.2 ±1.6 (-0.1)	-0.1 ± 1.8 (0.2)	0.5 ± 2.4 (1.3)	0.4 ± 1.9 (0.6)
	serv/1000 kcal	2.0 ± 1.0 (1.8)	2.0 ± 1.5 (1.7)	0.1 ± 1.6 (0.2)	0.2 ± 1.2 (0.71)	-0.2 ± 1.0 (-0.2)	0.1 ± 1.0 (0.1)	-0.1 ± 1.3 (0.2)	0.4 ± 1.7 (0.7)
Fiber	g/day	22 ± 6.5 (24)	27 ± 12 (23)	1.8 ± 8.2 (-0.1)	1.4 ± 15.5 (-1)	0.5 ± 7.0 (-(0.1)	-3.9 ± 15.8 (0.8)	2.3 ± 9.2 (4.8)	-2.4 ± 9.0 (-1.8)

	g/1000 kcal	12 ± 3.4 (13)	13 ± 4.3 (13)	0.07 ± 6.2 (0.75)	1.6 ± 4.5 (1.5)	-1.0 ± 2.9 (-0.9)	-1.1 ± 4.8 (-0.5)	-0.9 ± 5.0 (-0.3)	0.5 ± 5.3 (-1.2)
	% AI (28 g/d)	79 ± 23 (87)	96 ± 43 (81)	7 ± 29 (0)	6 ± 54 (-4)	2 ± 25 (0)	-14 ± 57 (3)	8 ± 33 (17)	-9 ± 32 (-6)
Added Sugar	tsp equivalents /day	102 ± 40 (86)	93.3 ± 44 (87)	25.5 ± 51 (0.0)	13.3 ± 67 (20)	7.2 ± 38 (2.4)	-7.9 ± 61 (-6.3)	32.7 ± 7.4 (30)	5.4 ± 58 (6.0)
	tsp equivalents /1000 kcal	54 ± 9.7 (54)	45 ± 20 (39)	6.4 ± 11 (6.8)	11 ± 19 (15)	-1.2 ± 18 (1.6)	-3.6 ± 20 (-5.1)	5.2 ± 21 (6.1)	7.2 ± 23 (7.5)
*Significantly different from control (p-value <0.05) **Serv=serving Mann-Whitney Test was used to determine differences in medians between groups									

Energy, Macronutrient and Micronutrient Intakes of Women who Met or Exceeded the IOM Weight Gain Recommendations

As previously stated, 16 participants exceeded the IOM gestational weight gain recommendations, 8 participants met the recommendations, and 4 participants gained less than the recommended amount. Average (± SD) and median change in energy and nutrient intakes between groups who "met" or exceeded the weight gain recommendations are presented in Table 8.

Average (± SD) energy intake at baseline was 1880 ± 536 kcal/d and 2096 ± 658 kcal/d in the groups meeting and exceeding the weight gain recommendations, respectively, which were not significantly different. Additionally, there were no significant differences in energy intake over time.

During trimester 1, both groups reported mean macronutrient intakes within the acceptable macronutrient distribution ranges (AMDR) established by the Food and Nutrition Board of the IOM for protein (10-35%) and carbohydrate (45-65%) but both groups reported higher than the acceptable range for fat (20-35%) (65). Participants who met the weight gain recommendations reported an average of 38 ± 6% of energy from fat intake. Participants exceeding the weight gain recommendations reported an average of 38 ± 10% of energy from fat intake. No significant differences in total macronutrient intake or macronutrient distribution were observed between groups at trimester 1 or over time.

The IOM Recommended Dietary Allowances (RDAs) for protein (71 g/day) and carbohydrate (175 g/day) and the Adequate Intake (AI) for fiber (28 g/day) are also presented in Table 8 (67). Intakes of these nutrients are presented as percentages of the RDA or AI. Both participants who met and exceeded the weight gain recommendations met the RDA for protein (100 ± 38% and 104 ± 33%, respectively). In addition, both participants who met and exceeded the weight gain recommendations met the RDA for

carbohydrate intake (130 ± 36% and 160 ± 40%, respectively) however neither group met the AI for fiber (78% ± 26 and 44 ± 18, respectively). The mean percent of RDA did not change significantly for protein, carbohydrate, or fiber, from trimester 1 to trimester 3 in either group.

Dietary intakes of calcium, iron, and folic acid were also assessed throughout pregnancy between participants meeting and exceeding the weight gain recommendations for pregnancy (Table 8). During the 1st trimester, the mean and median intakes of calcium exceeded the RDA in both participants within weight gain guidelines (1103 ± 405 mg/d) and those exceeding the guidelines (1274 ± 505 mg/d). The mean and median intakes of iron were lower than the RDA for both groups with average intakes of 13 ± 7.1 g/d and 18 ± 9.2 g/d in participants within and exceeding the weight gain guidelines, respectively. In addition, the mean and median intakes of folic acid were lower than the RDA with an average intake of 403 ± 221 mcg/d in participants within weight gain guidelines and 547 ± 265 mcg/d in those exceeding the guidelines. There were no statistically significant differences in median intakes of any of these micronutrients between groups during the trimester 1 or in the change in their intake over time.

Fruit and Vegetable intake of Women in the Control and Intervention Groups or who Met or Exceeded the IOM Weight Gain Recommendations

Average (± SD) and median fruit and vegetable intakes at each trimester derived from the ASA-24 for intervention and control groups as well as for participants meeting or exceeding the 2009 IOM gestational weight gain recommendations are presented in Tables 7 and 8, respectively. The median daily fruit and vegetable intake for all participants at trimester 1 was 3.4 servings, which is below the recommended 5 servings of fruits and vegetables per day. There was no significant difference in fruit and

vegetable intake between groups at baseline. However, participants meeting the weight gain recommendations had significantly higher change in median vegetable intake from trimester 1 to trimester 2 (1.2 servings) compared to participants exceeding weight gain recommendations (-0.2 servings; p=0.03). The median daily intake of fruits and vegetables did not change significantly over time between control and intervention groups or between groups meeting or exceeding the gestational weight gain recommendations. Furthermore, no significant differences in median fruit and vegetable intake were observed between groups at any time point.

Table 8: Change in Dietary Intake Parameters Assessed using ASA24 Methodology Between Groups Meeting and Exceeding the 2009 Institute of Medicine Gestational Weight Gain Recommendations

Dietary Variable	Units	Trimester 1		Change from Trimester 1-2		Change from Trimester 2-3		Change from Trimester 1-3	
		Weight Gain Within Guidelines n=12	Weight Gain Exceeding Guidelines n=16	Weight Gain Within Guidelines n=12	Weight Gain Exceeding Guidelines n=16	Weight Gain Within Guidelines n=12	Weight Gain Exceeding Guidelines n=15	Weight Gain Within Guidelines n=12	Weight Gain Exceeding Guidelines n=15
Energy	kcal/day	1880 ± 536 (1892)	2096 ± 658 (2014)	8.8 ± 737.5 (-51.4)	-21 ± 710 (-33.0)	223 ± 634 (310)	20 ± 670 (217)	232 ± 793 (277)	-1.5 ± 603 (165)
Protein	g/day	71.3 ± 26.9 (70)	70 ± 22 (63)	9.9 ± 38.8 (3.7)	5.9 ± 38 (3.9)	4.5 ± 29 (7.1)	3.5 ± 36 (-2.9)	14.4 ± 27.3 (12)	9.4 ± 32 (13)
	g/1000 kcal	37.7 ± 9.9 (36)	34 ± 7.9 (33.2)	5.1 ± 11.5 (7.7)	2.1 ± 12 (5.1)	-1.5 ± 6.8 (1.4)	1.1 ± 11 (2.2)	3.6 ± 10.5 (2.5)	3.2 ± 15 (4.0)
	Percent total energy (%)	15 ± 4 (15)	14 ± 3.2 13)	2.1 ± 4.5 (3.1)	0.9 ± 4.7 (2.0)	-0.6 ± 2.7 (0.5)	0.4 ± 4.2 (0.9)	1.5 ± 4.2 (1.0)	1.3 ± 6.0 (1.6)
	Percent RDA (71 g/d)	100 ± 38 (99)	104 ± 33 (103)	14 ± 55 (5)	5 ± 58 (0)	6 ± 41 (10)	12 ± 54 (11)	20 ± 38 (16)	17 ± 49 (42)
Fat	g/day	79.7 ± 26.8 (79)	92 ± 46 (83)	-14.1 ± 22.8 (-15)	-17 ± 45 (-12)	20 ± 30 (19)	5.8 ± 37 (18)	6.0 ± 44.6 (6.2)	-11 ± 50 (5.5)
	g/1000 kcal	42.1 ± 6.3 (44)	42 ± 11 (43)	-6.6 ± 9.4 (-2.5)	-5.3 ± 11 (-7.2)	4.9 ± 8.8 (3.8)	1.3 ± 8.2 (2.4)	-1.7 ± 9.5 (-0.7)	-4.0 ± 12 (-1.7)
	Percent total energy (%)	38 ± 6 (40)	38 ± 10 (39)	-5.9 ± 8.5 (-2.2)	-4.8 ± 9.7 (6.5)	4.4 ± 7.9 (3.4)	1.2 ± 7.4 (2.2)	-1.6 ± 8.5 (-0.7)	-3.6 ± 11 (-1.6)
Carbohydrate	g/day	228 ± 64 (217)	263 ± 75 (252)	29.2 ± 120 (12.9)	25 ± 88 (32)	-0.1 ± 103 (34)	-15 ± 81 (-10)	29 ± 99 (21)	10 ± 69 (36)
	g/1000 kcal	122 ± 12 (120)	129 ± 27 (125)	12.5 ± 20.3 (11)	9.4 ± 27 (12)	-13 ± 14 (-12)	-5.2 ± 21 (-3.1)	-0.2 ± 22 (-5.4)	4.2 ± 32 (5.2)
	Percent total energy (%)	49 ± 5 (48)	52 ± 11 (50)	5.0 ± 8.1 (4.3)	3.8 ± 11 (4.9)	-5.1 ± 5.5 (4.8)	-2.1 ± 8.3 (-1.2)	-1.5 ± 8.6 (2.2)	1.7 ± 13 (2.1)
	Percent RDA (175 g/d)	130 ± 36 (124)	160 ± 40 (158)	17 ± 69 (7)	8 ± 53 (14)	0 ± 59 (19)	-12 ± 50 (-13)	17 ± 56 (12)	0 ± 42 (0)
Calcium	mg/day‡	1103 ± 405 (1034)	1274 ± 505 (1164)	-45.4 ± 577 (-78)	-67 ± 575 (-27)	134 ± 675 (261)	35 ± 558 (-199)	89 ± 567 (91)	-32 ± 529 (-87)
	mg/ 1000kcal	587 ± 156 (567)	624 ± 161 (624)	-34.0 ± 143 (29)	-28 ± 215 (-93)	45.1 ± 190 (73)	15 ± 343 (-92)	11.1 ± 203 (66)	-13.4 ± 310 (-59.6)

	% RDA (1000 mg/d)	110 ± 41 (103)	134 ± 56 (116)	-5 ± 58 (-8)	-4 ± 67 (-6)	13 ± 67 (26)	13 ± 59 (4)	9 ± 57 (9)	1 ± 58 (-7)
Iron	mg/day	13.4 ± 7.1 (12)	17.6 ± 9.2 (16)	1.2 ± 8.9 (-0.4)	-0.5 ± 7.7 (-1.6)	2.4 ± 9.1 (1.6)	2.4 ± 15 (2.4)	3.6 ± 5.6 (4.3)	1.9 ± 16 (1.8)
	mg/1000kcal	6.9 ± 2.2 (6.6)	8.4 ± 3.4 (7.1)	0.9 ± 3.5 (0.2)	-0.2 ± 3.8 (0.2)	0.5 ± 3.8 (0.0)	1.1 ± 6.5 (-0.3)	1.4 ± 2.8 (1.5)	1.0 ± 6.6 (2.1)
	% RDA (27 mg/d)	50 ± 26 (44)	70 ± 34 (60)	4 ± 33 (-2)	-5 ± 24 (-8)	9 ± 34 (6)	16 ± 58 (16)	13 ± 21 (16)	7 ± 67 (12)
Folic Acid	mcg/day	403 ± 211 (386)	547 ± 265 (515)	34.3 ± 293.4 (111)	40 ± 328 (30)	96.6 ± 278 (146)	-65 ± 446 (-62)	131 ± 198 (254)	-26 ± 412 (-30)
	mcg/ 1000kcal	210 ± 72 (202)	265 ± 108 (250)	21.9 ± 123 (40)	22 ± 144 (-6.8)	44 ± 123 (36)	-35 ± 190 (-19)	65.4 ± 127 (19)	-13 ± 191 (63)
	% RDA (600 mcg/d)	35 ± 12 (34)	44 ± 16 (42)	38 ± 42 (27)	59 ± 39 (52)	16 ± 46 (24)	-2 ± 80 (26)	54 ± 21 (60)	52 ± 61 (51)
Total Fruit	serv/day**	1.3 ± 1.1 (1.3)	2.3 ± 1.5 (1.8)	0.6 ± 1.5 (0.3)	-0.1 ± 1.6 (-0.1)	-0.2 ± 1.5 (0.2)	0.1 ± 1.7 (-0.8)	0.4 ± 1.2 (0.2)	0.0 ± 1.9 (0.3)
	serv/1000 kcal	0.7 ± 0.5 (0.7)	1.2 ± 1.2 (1.0)	0.3 ± 0.7 (0)	-0.2 ± 1.1 (0.0)	-0.2 ± 0.7 (0.1)	0.2 ± 0.9 (0.0)	0.1 ± 0.5 (0.1)	0.0 ± 1.0 (0.1)
Vegetable	serv/day	1.8 ± 1.1 (1.5)	1.8 ± 0.9 (1.6)	0.5 ± 1.8 (0.8)	0.3 ± 1.0 (0.4)	0.4 ± 1.1 (0.3)	-0.5 ± 1.2 (-0.3)	0.8 ± 1.4 (1.1)	-0.2 ± 1.1 (0.1)
	serv/1000 kcal	1.1 ± 0.8 (1.0)	0.9 ± 0.5 (0.6)	0.2 ± 1.2 (0.4)	0.1 ± 0.5 (0.3)	0.1 ± 1.0 (-0.1)	-0.2 ± 0.5 (-0.3)	0.4 ± 1.3 (0.3)	-0.1 ± 0.7 (-0.1)
Fruit and Vegetable	serv/day	3.1 ± 1.6 (2.8)	4.1 ± 1.7 (3.9)	1.0 ± 2.1 (1.2)	0.2 ± 1.4 (-0.2)*	0.2 ± 0.9 (0.2)	-0.4 ± 2.1 (-0.4)	1.2 ± 1.8 (1.5)	-0.2 ± 2.2 (1.0)
	serv/1000 kcal	1.7 ± 1.0 (1.5)	2.1 ± 1.4 (1.8)	0.5 ± 1.6 (0.9)	-0.1 ± 1.2 (0.2)	0.0 ± 1.1 (-0.2)	-0.1 ± 0.9 (-0.1)	0.5 ± 1.5 (0.5)	-0.2 ± 1.4 (0.2)
Fiber	g/day	21.7 ± 7.2 (21)	27 ± 11 (25)	3.1 ± 13.2 (0.5)	0.4 ± 11 (-1.9)	-0.8 ± 14 (-0.1)	-2.2 ± 11 (0.8)	2.3 ± 7.6 (2.9)	-1.7 ± 10 (-0.1)
	g/1000 kcal	12.1 ± 4.3 (12)	13 ± 3.7 (14)	1.8 ± 6.7 (1.3)	0.0 ± 4.1 (1.5)	-1.9 ± 3.5 (-1.7)	-0.3 ± 4.1 (-0.6)	-0.1 ± 4.6 (-0.6)	-0.3 ± 5.6 (-1.7)
	% AI (28 g/d)	78 ± 26 (76)	99 ± 43 (86)	11 ± 47 (2)	4 ± 43 (-1)	-3 ± 50 (0)	-11 ± 41 (2)	8 ± 27 (11)	-11 ± 32 (12)
Added Sugar	tsp equivalents	86.3 ± 35.2 (86)	106 ± 45 (93)	26.3 ± 61.3 (16)	14 ± 58 (20)	-1.4 ± 43 (2.4)	1.0 ± 57 (-6.3)	25.0 ± 64.8 (4.2)	15 ± 64 (23)

	/day								
	tsp equivalents /1000 kcal	45.5 ± 14.9 (44.1)	52 ± 17 (54)	12.4 ± 17.3 (16.3)	5.4 ± 14 (8.0)	-7.5 ± 11 (-3.4)	1.0 ± 57 (-6.3)	4.9 ± 16.7 (4.2)	7.2 ± 25 (8.0)
*Significantly different form control (p-value <0.05) **Serv=serving Mann-Whitney Test was used to determine differences in medians between groups									

Fruit and Vegetable intake Assessed Using the NCI Fruit and Vegetable Screener

Average (± SD) and median fruit and vegetable intakes at each trimester derived from the NCI Fruit and Vegetable Screener are presented in Table 9. At trimester 1, median daily intake of fruits and vegetables was 3.1 servings among all women regardless of group classification. Median intake was not different between groups at any time nor did median intake change significantly over time in any group. No group achieved a median intake at or above the recommended 5 servings of fruits and vegetables per day at any time.

To consider adequacy of fruit and vegetable intake on an individual basis, we assessed the number of participants meeting the recommendations for fruit and vegetable intake (at least five servings per day) at each trimester. Both the ASA-24 and NCI Fruit and Vegetable Screener were used to obtain fruit and vegetable intakes and the results of the two methods were compared. These results are presented in Table 10. Based on the ASA-24, 4 (14%), 11 (39%), and 9 (33%) participants met the fruit and vegetable recommendations in trimesters 1, 2, and 3, respectively. In comparison, based on the NCI Fruit and Vegetable screener, 5 (18%), 8 (29%), and 4 (14%) participants met the fruit and vegetable recommendations in trimesters 1, 2, and 3, respectively. There were no significant differences in the number of participants who met the fruit and vegetable consumption recommendations between control and intervention groups or between groups meeting or exceeding the gestational weight gain recommendations as determined by either assessment tool.

Table 9: Fruit and Vegetable Intake Between Groups as assessed using the NCI Fruit and Vegetable Screener					
	Control (n=14)	Intervention (n=14)	Within weight gain recommendations (=12)	Exceeded weight gain recommendations (n=16)	Total (n=28)
Trimester 1	3.1 ± 2.6 (2.0)	3.7 ± 2.0 (3.3)	3.7 ± 2.7 (2.9)	3.2 ± 2.0 (3.3)	3.4 ± 2.3 (3.1)
Trimester 2	4.0 ± 3.5 (3.1)	4.5 ± 2.2 (4.2)	4.3 ± 3.5 (3.8)	4.2 ± 2.4 (3.9)	4.2 ± 2.9 (3.9)
Trimester 3*	3.9 ± 3.5 (2.9)	3.1 ± 1.5 (3.0)	4.1 ± 3.7 (3.0)	3.1 ± 1. (2.9)	3.5 ± 2.7 (2.9)
Mean ± SD (Range) of servings per day *One participant excluded for reporting low energy intake (< 500 Kcal/d) No significant differences between group medians based on Mann-Whitney Test					

Table 10: Participants Meeting 5 serving per day Fruit and Vegetable Intake Recommendations					
Methodology/ Time Period	Control (n=14)	Intervention (n=14)	Within weight gain recommendations (n=12)	Exceeded weight gain recommendations (n=16)	Total (n=28)
ASA-24					
Trimester 1	2 (14%)	2 (14%)	1 (8%)	3 (19%)	4 (14%)
Trimester 2	6 (43%)	5 (36%)	6 (50%)	5 (31%)	11 (39%)
Trimester 3*	5 (36%)	4 (31%)	4 (36%)	5 (31%)	9 (32%)
NCI Fruit and Vegetable Screener					
Trimester 1	2 (14%)	3 (21%)	4 (33%)	1 (6%)	5 (18%)
Trimester 2	4 (29%)	4 (29%)	3 (21%)	5 (31%)	8 (29%)
Trimester 3*	3 (21 %)	1 (8%)	2 (17%)	2 (13%)	4 (15%)
*One participant excluded for reporting low energy intake (< 500 Kcal/d) No significant differences between groups based on Fischer's Exact test					

Dietary Improvements During Pregnancy

Differences in the number of participants demonstrating any improvement in dietary intake from trimester 1 to trimester 3 are presented in Table 11. Improvements were determined from ASA-24 output and were defined as any increase in fruit intake, vegetable intake, fiber intake, HEI score, and DQI-P score or decrease in added sugar intake. Ten of 13 participants in the intervention group increased their fiber intake (g/1000 kcal) from trimester 1 to trimester 3 compared to the 5 of 14 participants who increased fiber intake in the control group, which was significantly different between groups (p=0.03). Additionally, total sugar intake (measured in teaspoon equivalents) was improved (was lower) in 9 out of 13 intervention participants compared to 3 out of 14 control participants which was statistically significant between groups (p=0.04).

To quantify the degree to which consumption of fruits and vegetables improved, Table 12 displays the number of additional servings reported by participants who increased fruit and vegetable intake from trimester 1 trimester 3. This representation serves to identify participants who reported increased intake of fruit and vegetables by at least one or two servings per day. Forty-one percent (n= 7) intervention participants increased their combined fruit and vegetable intake by one or more servings per day and 26% (n=4) of control participants increased their combined fruit and vegetable intake by one or more servings. There were no statistically significant differences in the number of participants who increased servings of fruits and vegetables from trimester 1 to trimester 3 between control and intervention.

Table 11: Number of women reporting dietary improvements from Trimester 1 to Trimester 3

Component	Units	Control (n=14)	Intervention (n=13)
Fruit ‡	serv/d**	7 (50%)	8 (57%)
	serv/1000 kcal	6 (43%)	8 (57%)
Vegetables‡	serv/d	8 (57%)	8 (57%)
	serv/1000 kcal	7 (50%)	10 (71%)
Fruits and Vegetables‡	serv/d	7 (50%)	8 (57%)
	serv/1000 kcal	5 (36%)	8 (57%)
Fiber‡	g/d	8 (57%)	6 (43%)
	g/1000 kcal	5 (36%)	10 (71%)*
Total Sugar Intake‖	tsp equivalents/d	3 (21%)	9 (64%)*
	tsp equivalents /1000 kcal	5 (36%)	5 (36%)
Healthy Eating Index‡		6 (43%	10 (71%)†
Diet Quality Index for Pregnancy‡		7 (50%)	6 (43%)

*Significantly different from control (p-value <0.05)
**Serv=serving
†Modestly different from control (p-value =0.07)
‡Improvement defined as any increase
‖Improvement defined as any decrease
Chi-squared tests or Fischer's Exact tests were used to compare counts of categorical data between groups

Table 12: Number of participants who increased fruit and vegetable intake from Trimester 1 to Trimester 3

Servings/ day	Fruit		Vegetable		Fruit and Vegetable	
	Control (n=14)	Intervention (n=13)	Control (n=14)	Intervention (n=13)	Control (n=14)	Intervention (n=13)
<1	3	3	6	3	3	1
1-2	1	2	1	3	0	4
≥1	4	5	2	5	4	7
≥2	3	3	1	2	4	3

Chi-squared tests or Fischer's Exact tests were used to compare counts of categorical data between groups
No statistically significant differences between groups were observed

Healthy Eating Index and Diet Quality Index for Pregnancy Scores

Table 13 presents HEI component and total scores at each trimester for the control and intervention groups. At trimester 1, the mean HEI score for all participants was 62.0 ± 14.0 out of a potential 100 points. While participants scored at least 50% of the maximum points for most components each trimester, sodium component scores were below 50% for both the control and intervention group in trimester 1 (4.6 ± 3.3 and 3.3 ± 3.2, respectively, out of a possible 10 points) and trimester 2 (3.7 ± 3.3 and 4.3 ± 3.0, respectively, out of a possible 10 points). There were no statistically significant differences between control and intervention groups at any time point in total or component scores of HEI or in change in scores over time.

Table 14 shows the component and total DQI-P scores for each trimester between control and intervention groups. At trimester 1, the mean DQI-P score for all participants was 54.0 ± 8.9 out of a potential 80 points. Total vegetable scores at trimester 1 were below 50% for both control and intervention groups (4.4 ± 2.8 and 4.7 ± 1.8, respectively, out of a possible 10 points). Total fruit scores were above 50% but also showed room for improvement in both the control and intervention groups (6.0 ± 3.3 and 5.4 ± 3.3, respectively, out of a possible 10 points). Folate scores were below 75% of maximum points in the control and intervention groups (7.4 ± 2.6 and 7.1 ± 2.4, respectively) as were iron scores (5.8 ± 2.8 and 5.4 ± 2.0, respectively). However, calcium scores were above 85% of maximum points in both control (9.6 ± 0.9) and intervention (8.9 ± 1.9) groups. There were no statistically significant differences between control and intervention groups at any time point in total or component scores of DQI-P or in change in scores over time.

Table 15 presents the change in HEI and DQI-P scores from trimester 1 to trimesters 2 and 3 between control and intervention groups. At trimester 1 mean HEI scores for control and intervention groups were 64 ± 16 and 60 ± 11, respectively. The

USDA Center for Nutrition Policy and Promotion considers an HEI score of 80 to represent a “good” diet and a score between 51-79 to represent a diet that needs improvement. Thus, mean HEI scores for both groups at each trimester suggested diets that need improvement. While not statistically significant, the intervention group improved HEI (p=0.07) and DQI-P (p=0.15) scores from trimester 1 to trimester 3 while the control group scores both decreased from baseline to third trimester.

As shown in Table 11, the frequency of intervention participants improving their HEI score from trimester 1 to trimester 3 compared to control participants approached significance (p=0.07).

Table 13: Healthy Eating Index Component and Total Scores of Intervention and Control Groups at each Trimester*

		Trimester 1		Trimester 2		Trimester 3	
Component	Max points	Control (n=14)	Intervention (n=14)	Control (n=14)	Intervention (n=14)	Control (n=14)	Intervention (n=13)
Total fruit	5	4.2 ± 1.5 (5.0)	3.6 ± 1.7 (4.2)	3.6 ± 1.7 (4.7)	3.9 ± 1.8 (5.0)	3.8 ±1.9 (5.0)	4.1 ± 1.2 (5.0)
Whole fruit	5	4.4 ± 1.4 (5.0)	3.8 ± 2.1 (5.0)	3.7 ± 1.9 (5.0)	4.3 ± 1.5 (5.0)	4.0 ± 1.8 (5.0)	4.8 ± 0.5 (5.0)
Total vegetables	5	3.2 ± 1.6 (2.8)	3.8 ± 1.3 (4.2)	3.9 ± 1.6 (5.0)	4.0 ± 1.5 (5.0)	3.8 ± 1.3 (3.9)	3.7 ± 1.9 (4.8)
Greens and beans	5	2.5 ± 2.4 (2.7)	3.4 ± 2.3 (5.0)	3.1 ± 2.2 (4.2)	3.1 ± 2.4 (4.8)	3.1 ± 2.2 (4.3)	3.3 ± 2.2 (5.0)
Whole grains	10	5.1 ± 3.9 (5.1)	4.5 ± 3.8 (4.8)	4.9 ± 3.6 (4.6)	5.2 ± 4.0 (5.5)	4.3 ± 4.1 (3.6)	4.6 ± 2.8 (4.5)
Dairy	10	8.1 ± 1.8 (8.0)	7.1 ± 3.3 (7.8)	6.9 ± 3.4 (8.1)	6.6 ± 3.4 (7.2)	7.0 ± 3.2 (7.8)	6.0 ± 3.7 (5.5)
Total protein foods	5	3.0 ± 2.1 (3.5)	3.9 ± 1.4 (4.3)	3.7 ± 2.0 (5.0)	3.9 ± 1.6 (4.7)	4.1 ± 1.0 (4.8)	4.2 ± 1.2 (4.9)
Seafood and plant proteins	5	2.7 ± 2.2 (2.8)	3.5 ± 2.2 (5.0)	3.0 ± 2.3 (3.9)	3.3 ± 2.0 (4.0)	3.3 ± 2.4 (5.0)	2.8 ± 2.2 (2.5)
Fatty acids	10	5.4 ± 3.2 (5.5)	4.0 ± 3.5 (3.2)	5.8 ± 3.4 (6.0)	4.5 ± 4.0 (3.6)	4.7 ± 3.8 (5.4)	5.0 ± 4.3 (4.2)
Refined grains**	10	5.2 ± 3.6 (4.2)	6.3 ± 3.4 (6.5)	6.8 ± 3.7 (8.4)	6.3 ± 3.3 (6.8)	6.1 ± 3.7 (6.5)	5.7 ± 3.6 (6.8)
Sodium**	10	4.6 ± 3.3 (5.7)	3.3 ± 3.2 (3.2)	3.7 ± 3.3 (3.6)	4.3 ± 3.0 (4.2)	5.5 ± 3.3 (6.1)	3.5 ± 4.1 (2.0)
Empty Calories**	20	15.3 ± 4.4 (16.5)	12.9 ± 5.5 (12.3)	14.1 ± 4.4 (13.6)	15.1 ± 4.4 (15.3)	13.6 ± 4.9 (13.8)	15.6 ± 4.5 (17.2)

Total HEI score	100	63.9 ± 16.4 (61.0)	60.2 ± 11.3 (61.6)	63.2 ± 15.5 (59.1)	64.6 ± 9.8 (67.0)	63.4 ± 16.5 (64.6)	63.3 ± 9.4 (65.6)

* Mean ± SD (Median)
For all components intakes at the level of the standard or better are assigned the maximum number of total points allotted. Scores for amounts between zero and the standard are prorated linearly (divided by the standard and multiplied by the total possible number of points).
**For the moderation components, zero points represent a value at approximately the 85th percentile of the population distribution and amounts between the 85th percentile and the standard are prorated linearly.

Table 14: Diet Quality Index for Pregnancy Component and Total Scores between Intervention and Control Groups at Each Trimester

	Trimester 1		Trimester 2		Trimester 3	
Component	Control	Intervention	Control	Intervention	Control	Intervention
Grains (6-11 servings)[1]	8.3 ± 1.8* (8.6)	7.9 ± 1.9 (7.9)	7.1 ± 2.5 (7.0)	7.9 ± 1.9 (7.9)	7.0 ± 3.3 (8.4)	7.8 ± 2.6 (8.4)
Vegetables (3-5 servings)[1]	4.4 ± 2.8 (3.4)	4.7 ± 1.8 (5.0)	5.6 ± 2.9 (6.4)	5.8 ± 3.2 (7.0)	5.0 ± 2.2 (5.1)	5.4 ± 3.3 (6.4)
Fruit (2-4 servings)[1]	6.0 ± 3.3 (6.5)	5.4 ± 3.3 (4.7)	5.6 ± 3.5 (5.3)	6.6 ± 3.6 (7.9)	6.2 ± 3.9 (7.1)	6.6 ± 3.1 (7.7)
Total fat[2]	5.5 ± 3.8 (5.5)	3.1 ± 3.7 (2.0)	7.2 ± 2.2 (7.0)	6.9 ± 3.3 (7.0)	3.9 ± 3.6 (4.0)	5.9 ± 3.4 (7.0)
Folate[1]	7.4 ± 2.6 (8.2)	7.1 ± 2.4 (7.6)	7.4 ± 2.3 (7.6)	7.8 ± 2.2 (8.2)	7.9 ± 2.2 (8.5)	7.5 ± 2.4 (7.0)
Iron[1]	5.8 ± 2.8 (5.1)	5.4 ± 2.0 (5.1)	6.1 ± 2.2 (5.7)	5.8 ± 2.5 (4.8)	6.6 ± 2.8 (6.1)	5.9 ± 1.9 (5.7)
Calcium[1]	9.6 ± 0.9 (10)	8.9 ± 1.9 (10)	9.2 ± 1.7 (10)	8.9 ± 2.2 (10)	9.0 ± 1.6 (10)	8.6 ± 2.2 (10)
Meal pattern[3]	9.6 ± 0.9 (10)	9.1 ± 1.3 (10)	9.3 ± 1.5 (10)	8.9 ± 1.3 (9.0)	9.1 ± 1.7 (10)	8.8 ± 1.3 (8.0)
Total DQI-P score	56.5 ± 9.8 (56.7)	51.5 ± 7.4 (51.8)	57.5 ± 9.4 (60.5)	58.5 ± 10.7 (59.7)	54.8 ± 10.2 (53.5)	56.5 ± 7.6 (56.6)

*Mean ± SD (Median)
[1]Used as a continuous percentage (0%-100%) corresponding to a continuous DQI-P score of 0-10 points
[2]Scoring based on categories: ≤30%= 10 points, >30%, ≤35%=7 points, >35%, ≤40%=4 points, >40%=0 points
[3]Scoring based on categories: 5 eating occasions= 10 points; 4 eating occasions= 8 points; 3 eating occasions = 6 points; 2 eating occasions= 4 points; 1 eating occasion=2 points

Table 15: Diet Quality Change from Baseline				
Diet Quality Indices		Trimester 1	Change from Trimester 1 - 2	Change from Trimester 1 - 3
HEI (max 100)	Control	64 ± 16*	-0.7 ± 26	-0.5 ± 18
	Intervention	60 ± 11	4.3 ± 18	0.8 ± 9
DQI-P (max 80)	Control	56 ± 10	1.0 ± 13	-1.7 ± 13
	Intervention	52 ± 7	6.9 ± 9	4.1 ± 12
*Mean ± SD No significant differences between groups based on independent t-tests				

Odds of Exceeding the IOM Weight Gain Recommendations Based on Diet Quality

The odds of exceeding the IOM weight gain recommendations were determined for participants who met the fruit and vegetable recommendations of 5 or more servings per day compared to those who did not at each trimester. The same analysis was performed to determine the odds of delivering a large for gestational age infant. The odds of exceeding the weight gain recommendations were no higher for those who did not meet the recommendations for fruit and vegetable intake than those who did at trimesters 1 (2.5; 95% CI: 0.2-28.0), 2 (0.5; 95% CI: 0.1-2.1), and 3 (0.8; 95% CI: 0.2-4.0). Additionally, the odds of delivering a large for gestational age infant were not higher for those who did not meet the recommendations for fruit and vegetable intake than those who did at trimesters 1 (2.3; 95% CI: 0.2-30.3), 2 (1.7; 95% CI: 0.2-14.0), and 3 (2.1; 95% CI: 0.1-38.5).

The odds of exceeding the IOM weight gain recommendations were determined for participants in the lower tertiles of HEI and DQI-P scores compared to participants with scores in the upper tertiles at each trimester. Using the HEI scores, the odds of exceeding the weight gain recommendations were not higher for participants in the lower tertile of HEI scores than participants in the upper tertile at trimesters 1 (0.8; 95% CI: 0.1-6.1), 2 (0.6; 95% CI: 0.1-4.2), and 3 (1.0; 95% CI: 0.2-6.4). Similarly, the odds of exceeding the weight gain recommendations were not higher for participants in the lower

tertile of DQI-P scores than participants in the upper tertile at trimesters 1 (4.3; 95% CI: 0.6-33.9), 2 (2.5; 95% CI: 0.4-16.9), and 3 (0.4; 95% CI:0.1-2.7).

The same analysis was performed to determine the odds of delivering a large for gestational age infant. The odds of delivering a large for gestational age infant were not higher for participants with HEI scores in the lower tertile than participants with scores in the upper tertile at trimesters 1 (1.1; 95% CI: 0.1-21.9), 2 (6.3; 95% CI: 0.3-153) and 3 (10.2; 95% CI: 0.5-233). Similarly, the odds of delivering a large for gestational age infant were not higher for participants in the lower tertile of DQI-P scores than participants in the upper tertile at trimesters 1 (1.0; 95% CI: 0.1-9.2), 2 (0.3; 95% CI: 0.2-3.0), and 3 (0.1; 95% CI: 0.01-2.2).

Chapter 5: Discussion

Summary

This study examined gestational weight gain, infant birth weight, and nutrient intake throughout pregnancy in 28 participants (14 intervention, 14 control) of the Pregnancy, Exercise, & Nutrition (PEN) study. The PEN study served as a feasibility study, focusing on pilot testing of an employee-wellness, pregnancy-specific curriculum to promote healthy dietary patterns and physical activity during pregnancy. The primary aim of this study was to analyze differences in gestational weight gain and nutrient intake between control and intervention groups as well as differences between participants who met the 2009 IOM gestational weight gain recommendations and those who exceeded the recommendations. The secondary aim was to determine differences in fruit and vegetable intake between groups and determine the relationship between fruit and vegetable intake and gestational weight gain, and infant birth weight. As an exploratory measure, diet quality scores were calculated and differences in scores between groups were determined. In addition we examined the relationship between diet quality scores and gestational weight gain. The results reported are being used to identify areas of the curriculum that are strong and areas that could be strengthened and will inform on-going curricular and program-based revision.

We rejected our hypothesis that the intervention group would report a higher mean fruit and vegetable intake at the 2nd and 3rd trimesters of pregnancy. We also rejected the hypothesis that the intervention group would report increased fruit and vegetable intake from baseline measurements compared to the control group. Likewise, we rejected our hypothesis that the odds of gaining excessive weight during pregnancy and the odds of delivering a large for gestational age infant would be significantly lower in women who met the recommendations for fruit and vegetable intake compared to those who did not meet these recommendations.

The exploratory hypotheses of this study were also rejected. The intervention group did not have higher HEI and DQI-P composite scores at the 2nd and 3rd trimesters of pregnancy and did not have higher changes (improvements) in composite scores from baseline measurements compared to the control group. Furthermore, the odds of gaining excessive weight during pregnancy were not lower in women who had HEI and DQI-P scores in the upper tertile compared to those in the lower tertile. This work and these findings are critical as they provided an opportunity to develop a research platform and to evaluate the use of the web-based, self-administered 24-hour recall method in a sample of pregnant women participating in the PEN program and to identify areas of the PEN curriculum that can be strengthened for inclusion in a broad-reaching employee wellness program.

Participant Demographics

The participant population of the PEN study was mostly white, older women from the Pacific Northwest with a higher socioeconomic status and education level than the general population. This limits how generalizable the results are to other populations. The average age of participants in the PEN study was 32.9 ± 2.9 years, which is higher than the national average of first time pregnant women (25.8 years of age) in the US. Seventy-eight percent of PEN participants reported an annual household income of $75,000 or greater, which is higher than the national median annual household income of $53,046. Ninety-three percent of PEN participants had at least a 4-year college degree which is higher than the 28.5% of the US adult population with 4-year college degrees. Finally, 89% of PEN participants were Caucasian which is consistent with the population distribution in the Pacific Northwest, but higher than the national percentage of 63% (68).

Maternal Weight Gain During Pregnancy

According to the CDC's Pregnancy Risk Assessment Monitoring System (PRAMS) women with a pre-pregnancy BMI in the overweight and obese categories exceed the IOM gestational weight gain guidelines more often than women in the normal or underweight categories. The PRAMS 2002-2003 data has been used to analyze maternal weight gain in a sample representative of the US population. Gestational weight gain was calculated as the difference between maternal weight at delivery (as reported on birth certificates) and self-reported pre-pregnancy weight. The study found that 63% of overweight women and 46% of obese women exceeded the weight gain guidelines whereas our study found that 92% of combined overweight and obese participants exceeded the weight gain guidelines. (69). An additional study by Brawarsky et al. analyzed a longitudinal cohort of 1100 pregnant women in San Francisco. Using medical records, gestational weight gain was calculated as maternal weight at the last prenatal visit within one week of delivery minus weight obtained and recorded prior to pregnancy. The study found that 53% of participants exceeded gestational weight gain recommendations and that women with an overweight pre-pregnancy BMI had significantly higher odds of excessive weight gain compared to women with a normal pre-pregnancy weight (OR: 2.26; 95% CI: 1.43–3.56) (70). This study differed from ours in that pre-pregnancy weight was derived from medical records and there was no adjustment for week of gestation at delivery. However, similar to this report, we found that women who exceeded the weight gain guidelines had a significantly higher pre-pregnancy BMI than women who gained weight within the guidelines.

Dietary Intake of Women during Pregnancy

In the 2005-2006 National Health and Nutrition Examination Survey (NHANES) the average dietary intake of non-pregnant women 20 years of age and older was

reported. Average energy intake was 1785 kilocalories and macronutrient distribution was reported as 16.0%, 49.4%, and 33.8% for protein, carbohydrates, and fat, respectively (71). Average energy intake for our study (reported as an average of all trimesters) was 2041 ± 350. The energy intake of our study participants may have been higher than the women participating in the NHANES because of the increased energy needs of pregnancy (the United States Department of Agriculture recommends 300 additional calories during the 2nd and 3rd trimesters) (72). Though NHANES does sample pregnant women, to our knowledge, no accessible recent national statistics have been published on diet patterns during pregnancy.

Using the 2005-2006 NHANES data, the National Cancer Institute reported the average servings of fruit and vegetables consumed by women 20 years of age and older. The average (± SD) fruit intake was 1.0 ± 0.4 servings per day and average the vegetable intake in this population was 1.6 ± 0.3 servings per day (73). The average daily intake of fruit and vegetables in our study (reported as an average of all trimesters) was 1.9 ± 0.8 and 2.0 ± 0.8 servings, respectively. Thus, fruit and vegetable intake in PEN participants appears higher than average. This may be due in part to the higher educational level and higher socioeconomic status in PEN participants than the average US citizen.

Fruit and Vegetable Intake: Weight Gain During Pregnancy and Infant Birth Weight

The findings of this study show that the intervention group did not report a higher mean fruit and vegetable intake at the 2nd or 3rd trimesters of pregnancy and did not report increased fruit and vegetable intake from baseline compared to the control group. Additionally, the odds of gaining excessive weight during pregnancy and the odds of delivering a large for gestational age infant were not significantly lower in women who met the recommendations for fruit and vegetable intake. To our knowledge this is the

first study to evaluate the odds of excessive gestational weight gain when participants met the recommendations for fruit and vegetable intake compared to those who did not.

A study by Mikkelson et al. in 2006 used data from the Danish Birth Cohort (n=43,585) to determine if fruit and vegetable consumption in pregnancy was associated with birth weight in a well-nourished population. Fruit and vegetable intake was estimated using a fruit and vegetable questionnaire administered at the 25th week of gestation. Using data from the questionnaire, the researchers separated participants into quintiles of combined fruit and vegetable intake (measured in grams). The reported quintiles of fruit intake that ranged from 33g in the lowest quartile to 157g in the highest quintile. According the National Health Services of the United Kingdom, 1 serving of fruit is equivalent to 80g of fruit. Therefore, the lowest quintile represented a little less than half of a serving of fruit per day while the upper quintile represented about 2 servings of fruit per day. Significant positive relationships were found between combined fruit and vegetable intake and infant birth weight. The strongest association was found for fruit intake in which birth weight increased by 10.7 g (95% CI 7.3-14.2) per quintile of fruit and vegetable intake (74). This study differed from ours in that they engaged a large sample size, the study used a FFQ to obtain and analyze fruit and vegetable intake, and the analysis was completed by examining quartiles of intake instead of tertiles. Additionally, in the Danish sample, these women were younger with an average age of 29 ± 4 years, and 24% of women reported smoking during pregnancy (smoking was an exclusionary criteria for the PEN study).

Nutrition and Physical Activity Curriculum for Pregnancy

The primary aim of this study was to analyze differences in gestational weight gain and nutrient intake between control and intervention groups. No significant differences in maternal gestational weight gain between control and intervention groups

were observed. However, the energy intake of the intervention group was significantly lower from the 1st and the 3rd trimester compared to the control. Additionally, we observed that more intervention participants increased their fiber intake per 1000 kilocalories from the 1st to the 3rd trimester and more participants decreased their total sugar intake in the intervention compared to the control.

A study in 2007 by Kinnunen et al. provided counseling to improve diet and physical activity among 105 pregnant mothers during five routine visits to a public health nurse in six primary health clinics in Finland. Compared to the control group, counseling did not affect the number of primiparas exceeding weight gain recommendations. However, the intake of vegetables, fruit and berries increased by 0.8 portions/day (p=0.004) and dietary fiber increased by 3.6 g/day (p=0.007) more in the intervention group than in the control group (18). In 2012, an extension of this study that examined women with at least one risk factor for GDM (for example, participants with a pre-pregnancy BMI suggesting overweight status) but no pre-existing diabetes (n=399) found that women in the intervention group had a lower mean gestational weight gain (as indexed to week of gestation) by 0.11 kg per week than the usual care group (p=0.04) (75).

A similar study by Asbee et al provided participants (n=100) with one counseling session in the first trimester of pregnancy with a registered dietitian to address diet and moderate-intensity physical activity as well as the IOM weight gain guidelines. In addition, weight was measured at each appointment and the healthcare provider informed the intervention participants of their weight gain status (below, within, or above recommendations). If weight gain exceeded recommendations, the physician reviewed the participant's diet and exercise regimen. While the study found that the intervention group gained significantly less weight than the control group, this did not result in better adherence to IOM weight gain guidelines. Similar to our findings, women in the

overweight (OR: 0.08; 95% CI: 0.02-0.41) and obese (OR: 0.04; 95%CI: 0.008-0.20) pre-pregnancy BMI groups were less likely to adhere to the IOM weight gain guidelines compared to women in the normal weight pre-pregnancy BMI category. Still, 25% of women in the normal weight category did not adhere to IOM gestational weight gain recommendations (76). These results are similar to those of our study where 31% of women in the normal weight pre-pregnancy BMI group exceeded the recommendations. This study demonstrates that with a large sample size and involvement of critical clinicians (registered dietitians and obstetric physicians) gestational weight gain can be significantly reduced by encouraging healthy lifestyle habits early in pregnancy. Importantly, these other interventions were less intense than PEN as they provided five or fewer intervention visits throughout pregnancy. These studies show potential for reducing excessive maternal weight gain during pregnancy given a strong curriculum and appropriate presentation of information.

Diet Quality Scores During Pregnancy

Diet quality scoring was used to assess overall adequacy of the maternal diet during pregnancy. Both the Healthy Eating Index (HEI) and the Diet Quality Index for Pregnancy (DQI-P) scores were calculated and compared between control and intervention groups and evaluated against adherence to gestational weight gain recommendations. The findings of this study showed that the intervention group did not have higher HEI or DQI-P composite scores at the 2nd and 3rd trimesters of pregnancy and did not have more improvement in composite scores from baseline measurements compared to the control group. Furthermore, the odds of gaining excessive weight during pregnancy were not lower in women who had DQI-P and HEI scores in the upper tertile compared to those in the lower tertile .

The HEI may be appropriate for use during pregnancy because it indexes nutrient intake to energy intake, measuring nutrient density. Additionally, the HEI bases scoring on all MyPyramid food groups and can be calculated using output from the ASA-24 which has recently been used in NHANES data. Thus, the HEI may be able to efficiently assess diet quality in large sample sizes.

The Center for Nutrition Policy and Promotion reported that the average HEI composite score for the US adult population (including people of all ages and genders) was 53.5 points. This value was calculated using 1 day of dietary intake data provided by 8,529 participants in the 2007-1008 National Health and Nutrition Examination Survey (77). Our study calculated average (± SD) HEI scores of 62 ± 14 and 64 ± 8.2 in trimesters 1 and 3, respectively. Compared to the national average, the average HEI score was higher in our sample of pregnant women possibly related to the high level of education and socioeconomic status.

Using the HEI, Shin et al. investigated the relationship between diet quality and gestational weight gain. Using NHANES data from 490 pregnant women, the researchers determined the odds of exceeding the gestational weight gain recommendations based on total HEI score and the intake of each component. Mean HEI scores for women who had gained adequate weight and excessive weight were 58 ± 3.3 and 54 ± 1.6, respectively. The study concluded that while HEI scores were not a determinant of adequate gestational weight gain, inadequate intake of total vegetables (OR 3.8; 95% CI 1.1–13.2, p=0.03) and oils (OR 2.8; 95% CI 1.2–6.4, p =0.02) were associated with excessive gestational weight gain (78). This study differs from our study in that it used a larger sample size, the dietary intake information was obtained using a single interviewer-assisted 24-hour recall, and the HEI calculation utilized the HEI-2005. Additionally, this study calculated gestational weight gain at the time of 24-hour recall (which varied between 1-9 months of gestation) and indexed weight gain to month of

gestation. The sample population also differed from the PEN study as 39% of women reported an education level of high school or less, 62% were white, and 40% of participants were 25 years old or younger.

As a tool developed by independent researchers (and not the USDA), the Diet Quality Index for Pregnancy (DQI-P) has not been extensively used in research to measure diet quality. To our knowledge, ours is the first study to analyze the relationship between DQI-P scores and gestational weight gain. However, Laraia et al. investigated the relationship between pre-pregnancy obesity status and diet quality using the DQI-P among 2,394 women in North Carolina. Dietary information was obtained by self-report at 26-28 weeks of gestation using a modified Block food-frequency questionnaire. The average DQI-P score for this population was 55 ± 11.6 points and pregravid obesity was associated with 76% higher odds of falling into the lowest diet quality score tertile (OR: 1.76; 95% CI: 1.24-2.49) (79). In an earlier analysis of the Pregnancy, Infection, and Nutrition (PIN) study, Bodnar and Siega-Riz reported an average DQI-P score of 56 ± 12 points (29). Our study found an average DQI-P score of 54 ± 8.9 points, which did not change significantly in any group throughout gestation. It is interesting that the DQI-P score in our study is comparable to that of previously reported studies because the PIN study recruited high-risk participants of low socioeconomic status and low education levels (49% of participants had less than a high school education). Additionally the PIN study differed from ours in that a food frequency questionnaire was used to collect usual dietary intake. The two previous studies show that the DQI-P may be a useful tool for determining diet quality patterns in a high-risk population. However, because it does not take into account important variables in weight management such as added sugar and refined grain intake, DQI-P may not be as useful for predicting excessive gestational weight gain.

Strengths of Study Design

The PEN study was a randomized, controlled feasibility study of an employee-wellness, team-based, peer-led, pregnancy-specific curriculum encouraging healthy eating and physical activity during pregnancy. It is important to keep this in mind when considering the strengths and limitations of the PEN study design.

A strength of the PEN program is that it made use of many different modalities to encourage healthy behaviors. The evidenced-based curriculum was developed by experts in the field including obstetricians, midwives, dietitians, and researchers. The curriculum utilized team-based, peer-led sessions, which used group accountability to foster individual accountability. Weekly goal-setting encouraged adoption of specific behaviors. Additionally, a web-based component encouraged participants to track their attendance and progress towards their behavior goals. The format of the PEN program (using peer-led, concise, weekly sessions) makes it ideal for the workplace. Because the PEN program was multi-modal, the curriculum was more intense than those of other programs used in the past to influence maternal diet habits and physical activity. Thus, a strength of the study was reinforcement of key material and promotion of healthy behaviors using several different modes of delivery.

This study tested the Automated, Self-Administered 24- Hour Dietary Recall (ASA-24), an innovative means of collecting dietary intake information. While participant feedback about the usability of the tool was mixed, the ASA-24 collected a 24-hour recall from all participants at 3 time points during pregnancy. This is a strength of the PEN study as many other studies use only one dietary recall, generally during the 2nd trimester of pregnancy.

Another strength of this study design was the calculation of gestational weight gain. Maternal weight gain was indexed to week of gestation at delivery to effectively allow inclusion of participants who delivered at 35 weeks gestation and those who did

not deliver until 42 weeks. Similarly, to compare birth weight of infants born before or at term (≥ 37 weeks gestation) the updated 2013 Fenton growth charts were used. The Fenton growth charts were developed from a meta-analysis of nearly four million births from countries including the United States, Germany, Italy, Australia, Scotland, and Canada making it a comprehensive, generalizable tool (63). Using this updated growth chart allowed us to more accurately and appropriately assess infant birth weight percentile.

Lastly, to improve the program for use in the future, the PEN study made use of surveys to receive participant feedback. Accessible feedback is a strength of the study as it allows for participant-recommended improvements, moving forward.

Limitations of Study Design

As previously mentioned, the PEN study was a feasibility study and was not powered to identify statistically significant differences between the control and intervention groups. With a small sample size (n=28), outliers have a large effect on group means and the statistical power of the analysis is low which reduces the ability to observe a true effect. Also, the sample in this study was comprised mainly employed, white women, of higher socioeconomic status and educational levels who were over the age of 30. Therefore, our findings may not be generalizable to other populations with different demographic characteristics.

Another limitation of this study was the use of self-reported pre-pregnancy weight in all participants and the use of self-reported latest weight before delivery (for 3 participants). Since many women do not plan their pregnancies or anticipate the precise time of conception, and do not visit their primary provider immediately prior to conception, pre-pregnancy body weight is generally not consistently measured and recorded in medical records. Furthermore, it is not practical to recruit women who are

expecting to become pregnant to obtain a pre-pregnancy weight. For these reasons, self-reported pre-pregnancy weight is commonly used in research to determine pre-pregnancy BMI and to calculate gestational weight gain recommendations. A study by Shin et al evaluated the validity of pre-pregnancy BMI weight status from self-reported pre-pregnancy height and weight in comparison to pre-pregnancy BMI calculated from measured data during the first trimester of pregnancy by NHANES (2003-2006). Self-reported pre-pregnancy weight of 504 women was compared to imputed data, a method of using multiple imputed values to infer the "true" value. The mean difference between self-reported versus imputed pre-pregnancy weight was -1.7 ± 0.1 kg and the measures were significantly correlated ($r = 0.98$; $p < 0.001$) which suggested agreement between the measures (80).

An additional limitation of this study was the week of gestation when some participants began the intervention. Ideally, participants should start the intervention early in the first trimester of pregnancy to extend the duration of positive behavior changes, but some participants initiated the intervention as late as the second trimester, and one participant, in particular, started sessions in her 20th week of gestation. Therefore, some participants did not receive any part of the curriculum during their first trimester of pregnancy. Since the curriculum includes behaviors that encourage a healthy weight gain, this is a limitation because early excessive gestational weight gain may predict excessive total gestational weight gain (5).

An additional limitation of our study was the use of only one 24-hr recall collected via the ASA-24 to estimate usual dietary intake at each trimester. The ASA-24 output was compared to the NCI Fruit and Vegetable Screener using a correlation and the r-squared value was 0.3, suggesting a relatively weak correlation between the methods. In addition, participant feedback showed that the ASA-24 was, at times, not user-friendly. Forty percent of the participants who completed the feedback survey (n=23) reported

that the recall took 30 minutes or longer to complete. On a scale of 0-100 (0 being very easy to navigate and 100 being very difficult to navigate) participants on average (± SD) rated the ASA-24 website at 49 ± 24. When asked how well the ASA-24 captured participants' usual intake on a scale of 0-100 (zero being very well and 100 being not well at all) the average (± SD) response was 37 ± 25. In addition, 65% of participants reported having difficulty finding some foods that they had consumed. Seventeen percent of participants commented on the tool's lack of compatibility with certain electronic devices such as Apple products and tablets. However, the most common complaint (mentioned by 48% of participants) was the inability to turn off the animated guide function which slowed participant response entry. It was not realized until completion of the study that the prompts sent to participants to complete the ASA-24 could have sent so that the animated guide could have been turned off. When asked if completing the ASA-24 would deter participants from participating in a similar study, 13% responded "Yes" and 30% responded "Maybe." Participant dissatisfaction with the ASA-24 or their difficulty in using this tool may have led to under- or misreporting of dietary intake.

A potential improvement to increase the reliability of the ASA-24 recall method would be to request multiple 24-hour recalls per trimester. A study by Frankenfeld et al compared the completion of two ASA-24 recalls to a 4-day food record in 93 adults affiliated with George Mason University. While mean nutrient intakes were similar between the recalls and record, Pearson correlations showed moderate associations among the nutrients and calculated HEI-2005 scores. Correlations ranged from 0.16 to 0.78 and most fell between 0.4 and 0.6. This suggests that the ASA-24 recalls might depict different information than a 4-day food record. The findings of this study indicate that it may require more than two ASA-24 recalls per time point to ensure diet recalls are similar to information obtained from a 4-day food record (81). However in our study,

given the participant feedback about the use of ASA-24, requesting that participants complete multiple recalls at each time point would add an increased time commitment and potentially additional participant burden. For future studies, the ASA-24 is being revised to address consumer feedback.

Future research using the ASA-24 will shed more light on its usability and accuracy of the recalled diet. An article about the ASA-24 by Subar et al. describes two studies that are underway which will assist in formally evaluating the ASA-24. Both studies will compare the output of one ASA-24 recall to the output of one Automated Multi-Pass Method interviewer-administered recall (82). However, for current or planned studies, it's important that researchers consider the benefits of an automated 24-hour recall (such as efficiency and cost) against the potential loss of food item detail and less accurate food intake data especially when conducting studies with large sample sizes.

Conclusion

Based on the findings in this study we conclude that in our study sample there is no relationship between maternal fruit and vegetable intake and gestational weight gain or infant birth weight. Additionally, we found no significant differences in gestational weight gain, fruit and vegetable intake, or diet quality scores between control and intervention groups. However, some significant differences were seen in pre-pregnancy weight and BMI between groups who met and exceeded the 2009 IOM gestational weight gain guidelines as well as differences in improvement of dietary habits from the 1st to the 3rd trimester between control and intervention groups.

Future Research

Future directions in this area of research with a larger, more diverse participant group should focus on interventions that start in and promote appropriate weight gain

early during the 1st trimester as excessive early weight gain is associated with exceeding total gestational weight gain recommendations (5). This may be accomplished by including a strong curriculum on weight gain recommendations and the importance of fruit and vegetable intake early in pregnancy (before 12 weeks gestation). Furthermore, it would be beneficial to continue the use of diet quality scoring in the pregnant population and develop a scoring system that controls for energy intake while accounting for current, pregnancy-specific nutrient recommendations. Although the results of this study did not confirm our hypotheses and are by no means conclusive, these novel questions merit further study.

OREGON HEALTH & SCIENCE UNIVERSITY

Protocol Approval Date: 11/19/2012

Clinical Research Consent Summary

You are being invited to join a research study because you are pregnant, and are an employee of Oregon Health & Science University (OHSU) or a spouse of an OHSU employee. The purpose of this research study is to develop and evaluate a health behavior curriculum for OHSU employees called The OHSU Pregnancy Exercise & Nutrition Program (PEN). You do not have to join the study. Even if you decide to join now, you can change your mind at a later date.

If you decide to join, you will be asked to sign a consent form, which shows you give permission to be in the study, your doctor agrees you can participate in the study, and an authorization form, which shows you give permission for us to use your health information for the study.

In this study, we will develop and learn about a wellness program for pregnant women called The OHSU Pregnancy Exercise & Nutrition Program (PEN). **This program will be called "PEN Program" throughout this form.**

We want to:

1. Study a 20-session curriculum used by pregnant women, designed to prevent gestational diabetes (a condition resulting in elevated blood sugar levels during pregnancy), and excessive pregnancy weight gain.
2. Learn if the PEN Program can influence diet and physical activity behaviors among pregnant women to reduce their risk factors of developing gestational diabetes.
3. Measure body weight, diet, physical activity, other health behaviors, markers of gestational diabetes, including Hemoglobin A1C, blood glucose, urinalysis, and insulin, as well as cholesterol and triglycerides, Vitamin D levels, and information about your newborn, including height, weight, and APGAR score. There will be a brief questionnaire about breastfeeding approximately 12 weeks after delivery.
4. The PEN Program was developed by researchers at OHSU, and the OHSU Moore Institute is funding this research study.
5. We do not yet know if the PEN Program will prevent gestational diabetes and excessive pregnancy weight gain.
6. Participation in this study will last throughout your pregnancy with follow-up approximately 12 weeks after your delivery, for a total of about 10 months. There will be 4 study visits to collect data, which includes blood and urine testing. If you are randomized to be in the intervention group, you will also attend a 1-hour introduction session and nineteen 30-minute PEN Program group weekly meetings, consisting of 5 participants per group.
7. There are a few risks involved in participating in the study, none of which are serious.

OREGON HEALTH & SCIENCE UNIVERSITY

Clinical Research Consent

Form TITLE: The OHSU Pregnancy Exercise & Nutrition Program

PRINCIPAL INVESTIGATOR: Linn Goldberg, M.D. (503) 494-6559

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SPONSOR: Oregon Health & Science University Moore Institute

PURPOSE: You are being invited to join this research study because you are pregnant and are an employee of Oregon Health & Science University (OHSU) or are a spouse of an OHSU employee. The purpose of this research study is to develop and evaluate a health behavior change curriculum for pregnant OHSU employees or their spouses called The OHSU Pregnancy Exercise & Nutrition Program (PEN Program). The goals of the PEN Program are to promote healthy behaviors among women who are pregnant and to reduce their risk factors for development of gestational diabetes.

If you choose to participate in this study, you will be required to make 4 visits to OHSU for collection of data: a study visit during each trimester of your pregnancy and a follow-up visit 12 weeks after you give birth. If you are randomized to the intervention arm of the study, you will be in the PEN Program which requires 20 weekly meetings for approximately 30 minutes of group curriculum sessions.

Thirty OHSU employees or their spouses will be enrolled in this study.

PROCEDURES: A screening phone call or brief in-person visit will be conducted to determine if you are interested and eligible to participate in the study. Your personal physician must also approve of your participation.

If eligible for the study, we will schedule a baseline study visit. At this visit, we will collect your demographic characteristics (age, education level, employment status, socioeconomic status), and a medical history including medication use, smoking status, alcohol intake, prior pregnancies, birth weight of previous children, and history of diabetes and hypertension and cholesterol and triglyceride levels. We will also ask questions about your prior exercise practices and your ability to exercise safely

The purpose of the baseline visit is to assess physical health and obtain baseline health assessments, physical health evaluation, and measurements of height, weight, blood pressure and heart rate. This visit will include a brief physical examination conducted by a study physician to examine your heart, lungs and peripheral vascular

system to check for possible heart and/or lung and blood vessel disease and assess readiness for physical activity. A blood draw will assess lipid and lipoprotein (cholesterol and triglyceride) levels, and glucose in the urine. The visit will take approximately 1 hour. Several surveys to assess diet and physical activity behaviors will be completed. These can be completed at the time of your baseline visit, or at your convenience using a computer with an internet connection. At the completion of your baseline visit, you will be provided a physical activity monitor (accelerometer) and asked to wear it for 7 days to record your physical activity level. Accelerometers assess the amount and intensity of physical activity. You will be asked to wear an accelerometer for one week after each of the data collection visits to determine your physical activity level and complete a pregnancy physical activity questionnaire online. Information about what symptoms participants should watch for indicating when they should stop exercising and contact their health care provider will be provided to the intervention group in the curriculum materials and to the control group through an informational handout.

The device is small, lightweight, and attached to a waist belt or wrist band. The device records body motion and measures your physical activity during the day. You can take the belt and device off at night during your sleep, and when taking a bath, shower or when swimming.

Measurements and data collection visit will occur four times. There will be four total study visits. One will occur at baseline, during the first trimester of your pregnancy, and two during the second and third trimester of your pregnancy. The fourth study visit will be a follow-up visit approximately 12 weeks after you give birth. The second, third, and follow-up visits will take approximately 30 minutes, with approximately another hour of completing questionnaires which can be done at your convenience within 48 hours of the visit. Each of the study visits will include measurement of weight, blood pressure and heart rate, along with a blood draw to assess lipid levels, glucose, and other markers for gestational diabetes. Surveys will assess diet and physical activity.

Diet surveys will use an automated, self-administered 24-hour recall system (ASA-24) to estimate dietary intake. In addition, three web-based dietary screeners, the NHANES/NCI Diet Screener Questionnaire (the DSQ), the NCI Fat Screener, and the NCI Fruit and Vegetable Screener, will be used to measure dietary components and diet changes. These dietary surveys will be obtained each trimester, and again at the 3-month follow-up visit. At the 3-month follow- up visit, you will be asked to complete a survey about infant feeding practices. You will also be asked to complete the Edinburgh Depression Scale. Each of these surveys can be completed online.

The study visits will take place at the Human Performance Laboratory at the OHSU main campus in the Hatfield Research Center (11th floor). Most appointments will be scheduled in the morning because there will be a fasting blood draw, with exceptions made for employees working non-traditional shifts. The surveys will be completed during the study visit or at your convenience within 48 hours of your study visit.

The data collected and schedule of visits is provided in the table below:

	Baseline Visit 1 First Trimester	Visit 2 Second Trimester	Visit 3 Third Trimester	Birth Information	Visit 4 3-Month post birth
Consent discussion,	X				
Physical Exam and medical history collected by	X				
Fasting Blood draw (3-4	X	X	X		X
Urine Collection checking	X	X	X		X
Blood Pressure	X	X	X		X
Height, weight	X	X	X		X
24-hour Dietary recall, NCI Diet Screener Questionnaire, NCI Fat Screener, NCI Fruit &	X	X	X		X
Accelerometry and Pregnancy Physical Activity	X	X	X		X
Edinburgh Depression	X	X	X		X
Information about birth (duration of labor, delivery mode, APGAR Score of baby, newborn's length and weight, breast feeding				X	
Infant feeding survey					X
Total time	2 hours	1.5 hours	1.5 hours	0 hours; medical record review only	1.5 hours

Blood will be drawn during each of the four visits, and we will collect three to four tablespoons of blood for the lab work. A urine sample will be collected to assess protein in the urine.

We will collect information about your delivery from the medical records of you and/or your baby. Specifically, we will obtain the lab results from the research-specific blood draws, duration of labor, delivery mode, any delivery complications, and to obtain results of glucose tolerance tests and other clinical information about your pregnancy (weight, blood pressure, and physical or laboratory measures) if conducted by your health care provider. Your baby's medical record will be reviewed to obtain your newborn's APGAR score and length and weight.

If you do not deliver at OHSU, we will ask you to sign a request for release of those medical records from your health care provider. If you do not have an OHSU medical record number, one will be established for you so we can obtain the results from the lab tests that will be conducted at the OHSU central laboratory.

This is a randomized study. Neither you nor the investigator can choose whether you get the intervention arm or the control arm. One-half of the subjects in this study will be randomized to the intervention arm, and one-half will get the control arm of the study.

If you are randomized to the intervention arm of the study, you will participate in the PEN Program sessions.

- Group curriculum sessions will meet once per week for 20 sessions. The first session will last about 1 hour, with the remaining lasting about 30 minutes. Weekly sessions take place outside of work time (either before work, during a break, or after work).
- Weekly sessions will be held at convenient OHSU locations.
- You will be scheduled for a time and location of your team's choice.
- During each session, you will work with your team to complete learning activities designed to help you make healthy changes to your eating and exercise habits.
- You will also have opportunities to complete additional online activities, set and monitor weekly goals, view cooking videos, and join a gym.
- You will receive e-mail and text message reminders to keep you on track.

At the end of each session, we will ask you to provide us with brief written feedback about the study and the PEN Program. In addition, a session facilitator will contact all intervention participants during in-person sessions or by email to participate in a focus group (group interview with other participants). Focus group participation is voluntary. Up to 5 participants will be selected for each focus group on a first come, first serve basis. You may be asked about your experience in doing the PEN Program, make suggestions to improve the PEN Program, and to discuss aspects of the program and other experiences that affected your health habits. Each focus group will take about 30-45 minutes.

Research staff conducting the interviews and focus groups will take notes in order to get all the information. The information is confidential, and names and other specific identifying information will be excluded from the notes. Notes will be identified by code number, not by name. The code number will not contain your initials, birth date, or other items that could identify you. Notes will be stored in password protected personal computer files in restricted-access directories, with the password known only to staff that need to access the data.

We may ask to videotape and/or photograph you as part of your participation in this study. . You may also choose not to be videotaped or photographed.

Being in this study will not affect any care that you might receive at OHSU.

If you have any questions regarding this study now or in the future, contact Dr. Linn Goldberg, at (503) 494-6559.

RISKS AND DISCOMFORTS: During study visits, we will draw blood from your arm. You may feel some pain when your blood is drawn. There is a small chance the needle will cause bleeding, a bruise, or an infection.

By measuring your blood pressure and having a physical exam by a study physician, we may find you have a health condition that needs treatment. If treatment is necessary, you will be responsible for the costs of follow-up care and any missed workdays. The Principal Investigator can help you find follow-up care if you request his help.

We will ask you to complete questionnaires about your health and behaviors. Some of these questions may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions that you do not wish to answer.

You will be asked to complete the Edinburgh Depression Scale online. This survey asks 10 questions about your emotional well being. Some of the questions may seem very personal or embarrassing and may upset you. You may refuse to answer any of the questions that you do not wish to answer. If the questions upset you or if your score suggests that you may be depressed, we will help you find a counselor.

You will be asked to wear a physical activity monitor for 7 days after each study visit to record your physical activity level. There are no known risks or discomforts from wearing this device.

Those individuals randomized to the intervention group of the study will be encouraged to participate in physical activity. There are safety considerations to be aware of when exercising, along with when to stop exercising and when to consult your health care provider. This information and these considerations will be provided in the curriculum sessions and reviewed during the baseline screening visit. If the following symptoms occur, stop exercise and consult your health care provider: excessive shortness of breath, chest pain, uterine contractions causing discomfort (more than 6-8 per hour), vaginal bleeding, any “gush” of fluid from vagina (suggesting premature rupture of the membranes), dizziness or faintness. Also, women diagnosed with pregnancy-induced hypertension, heart or lung problems, placenta previa or certain cervical abnormalities may need to stop exercising.

Read more: http://www.livestrong.com/article/423988-when-do-you-stop-exercising- when-pregnant/#ixzz2CPTgAbbq

Efforts will be made to keep your personal information confidential as described in the CONFIDENTIALITY section, but we cannot guarantee total privacy. There is a small chance that your information could be accidentally released.

BENEFITS: You may or may not personally benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

ALTERNATIVES: You may choose not to be in this study. If you do choose to be in the study, you can decide not to participate in focus groups and optional curriculum activities. You can also miss curriculum sessions due to occasional scheduling conflicts.

CONFIDENTIALITY: We will not use your name or your identity for publication or publicity purposes. A code number will be assigned to you to collect your data and personal information. Only the investigators named on this consent form will be authorized to link the code number to you. All identifying information about you will be removed from the data before they are released to any other investigators.

Study data will be collected and managed using REDCap (Research Electronic Data Capture). REDCap is a secure, web application designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks), audit trails and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). The system was developed by a multi-institutional consortium, which includes Oregon Health & Science University and was initiated at Vanderbilt University. The database is hosted at the Oregon Health & Science University Datacenter. The system is protected behind a login and Secure Sockets Layer (SSL) encryption. Technical IT support is provided by the OCTRI Biomedical Informatics Program.

Data collection is customized for each study or clinical trial based on a study-specific data dictionary defined by the research team.

Research records may be reviewed and copied by people involved in conducting or overseeing research including the OHSU Institutional Review Board, and the Office for Human Research Protections (OHRP)**.**

All other parties including employers, insurance companies, and relatives will be refused access to your information unless you provide written permission or unless we are required by law to release it.

We may request your social security number in order to process any payments for participation.

COSTS: There will be no cost to you or your insurance company to participate in this study.

Participants will receive $100 after completing the first study visit, and $100 after completing the follow-up study visits. Participants who are randomized to the intervention arm of the study will also receive up to $50 per month for 5 months to pay for a commercial gym membership.

LIABILITY: If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact Dr. Linn Goldberg, at his office (503) 494-6559 or mobile phone number (503) 936-7014.

You have not waived your legal rights by signing this form. If you are harmed by the study procedures, you will be treated. Oregon Health & Science University does not offer to pay for the cost of the treatment. Any claim you make against Oregon Health & Science University may be limited by the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

PARTICIPATION: If you have any questions regarding your rights as a research subject, you may contact the OHSU Research Integrity Office at (503) 494-7887.

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

If in the future you decide you no longer want to participate in this research, we will destroy all your blood and other data collected. However, if your samples are already being used in an ongoing research project and if their withdrawal jeopardizes the success of the entire project, we may ask to continue to use them until the project is completed.

You may be removed from the study if you do not complete the required study visits.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

The participation of OHSU students or employees in OHSU research is completely voluntary and you are free to choose not to serve as a research subject in this protocol for any reason. If you do elect to participate in this study, you may withdraw from the study at any time without affecting your relationship with OHSU, the investigator, the investigator's department, or your grade in any course. If you would like to report a concern with regard to participation of OHSU students or employees in OHSU research, please call the OHSU Integrity Hotline at 1-877-733- 8313 (toll free and anonymous

SIGNATURES

OPTIONAL STUDY PROCEDURES

The optional portion of this study are described in detail throughout this consent form and listed here as a summary. Please read the options and place your initials next to your choice below. You can still participate in the main part of the study if you choose not to participate in the optional part.

Option:

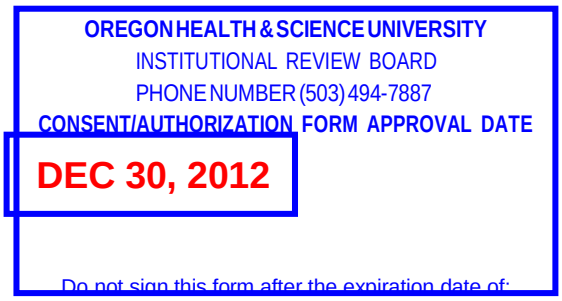
_____ I give my consent to participate in the main part of this study, and give my consent for to videotape and/or photograph me as part of my participation in this study.

or

_____ I give my consent to participate in the main part of this study, but I do not give my consent for to videotape and/or photograph me as part of my participation in this study.

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this form.



_____

Name of Subject, Printed

_____

Signature of Subject Date

_____

Name of Person Obtaining Consent, Printed

_____

Signature of Person Obtaining Consent Date

OREGON HEALTH & SCIENCE UNIVERSITY

MED. REC. NO. ___
NAME ___

IRB#:

HIPAA CLINICAL RESEARCH AUTHORIZATION

Title of Study: The OHSU Pregnancy Exercise & Nutrition Program.
Name of Principal Investigator: Linn Goldberg, M.D.
Phone Number: 503-494-6559

We have already asked you for your consent to be in the research study. We are also required to seek separate permission to use your health information for the study. The Health Insurance Portability and Accountability Act (HIPAA) is a federal law designed to help protect the privacy of health information.

During this study, OHSU will use and disclose (release) health information about you. Under federal law, we may not use or disclose it unless you authorize us to do so by signing this form. This authorization is voluntary. You do not have to sign this form. If you choose not to sign it, you cannot join this study.

The health information we will collect, use, and disclose is described in the attached consent form. The consent form also describes why we will use the health information. Investigators, study staff, and others at OHSU who are involved in the research or overseeing the research may use and disclose your health information.

We may send your health information to others outside OHSU who are involved in the research or overseeing the research, including The Office for Human Research Protections, which oversees research involving humans.

When we send information outside of OHSU, it may no longer be protected under federal law. In this case, your information could be used and re-released without your authorization.

We may continue to use and disclose your health information indefinitely.

Some of the information collected and created in this study may be useful for your future health care and will be placed in your OHSU medical record. While the research is in progress, you may not have access to this information. After the study is complete, you will be able to access any study information that was added to your OHSU medical record.

You have the right to withdraw this authorization at any time. To withdraw your permission for us to use information that identifies you, please send a written request or email to:

Linn Goldberg, M.D.
Division of Health Promotion and Sports Medicine
Oregon Health & Science University
3181 SW Sam Jackson Park Road
Portland, OR, 97239

The use and disclosure of your health information for this research will stop as of the date the principal investigator receives your request. However, the use and disclosure of information collected in good faith before your request arrives will continue. Withdrawing this authorization will not affect your health care or your relationship with OHSU.

Please ask the investigator or study staff if you have any questions about this HIPAA authorization.

We will give you a copy of this signed form.

Name of Subject, Printed

Signature of Subject Date

Name of Person Obtaining Consent, Printed

Appendix 2. Pregnancy Health Care Provider

Pregnancy Health Care Provider Approval to Participate

OREGON HEALTH & SCIENCE UNIVERSITY
Linn Goldberg, M.D., Principal Investigator
tel: 503 494-6559 | email: goldberl@ohsu.edu

The OHSU Pregnancy Exercise & Nutrition Program

The purpose of this study, the OHSU Pregnancy Exercise & Nutrition Program, is to develop and evaluate a wellness program to improve the nutrition and physical activity practices among pregnant women to prevent their risk of developing gestational diabetes mellitus. Participants will be thirty OHSU employees or employee spouses. Employees or employee spouses who wish to participate need approval from their pregnancy health care provider, will be prescreened by study staff for eligibility (able to exercise), and will sign an informed study consent and authorization.

Once enrolled, employee participants will be scheduled for baseline health assessments: surveys of diet and exercise behaviors, measured height, weight, and blood pressure, along with a medical history and cardiopulmonary physical examination. All participants will be assessed four times; once during each trimester of pregnancy and again 12 weeks after delivery for a total study involvement time of about 10 months. Health assessment information collected before, during, and after the program will be used to determine if the PEN Program curriculum is effective in improving dietary intake, increasing or maintaining physical activity on most days of the week by objective and subjective (survey) methods, whether measurements changed over the 10 month period, assess weight gain occurred during pregnancy, and to evaluate onset and markers for gestational diabetes and pregnancy outcomes for the infant, including APGAR score, method of delivery and maternal health.
All participants will be asked to wear an accelerometer for seven days to determine their level of physical activity and also complete an assessment of physical activity levels for that seven day period. Study physicians will perform the physical examinations and assess potential participant's ability to safely exercise.

For participants randomized to the intervention group, there will also be an approximate 30-minute long PEN Program group meeting each week for 20 week where they will learn about a healthy lifestyle and information about health during pregnancy by using the PEN program self-administered curriculum. Intervention participants will be requested to be physically active on a regular basis, and will be provided a gym membership. Women randomized to the control condition will receive a pregnancy handout and standard care by her health care provider during pregnancy. Data analysis will assess participant's baseline, during the pregnancy and after birth, to measure their

diet and exercise behaviors, pregnancy weight gain, overall health and whether gestational diabetes mellitus was detected.

I have discussed my plans to participate in The OHSU Pregnancy Exercise & Nutrition Program. If I am randomized to the intervention arm, I will be asked to increase my physical activity during my current pregnancy.

I have obtained his/her approval to participate in the study and be physically active.

Participant:

_____

(Participant Name Printed) *Signature*

Date

Health Care Provider:

_____

(Health Care Provider Name Printed) *Signature*

Date

Health Care Provider Telephone:

_____

Appendix 3. First Trimester Visit Check List

Name: _____ Study ID: _____

Screening Form: Date: _____Completed By: ___ REDCap Entry: ____ REDCap Verify: ____

Schedule Baseline Appt: Date: _____ Completed By: ___

Email consent: Date: _____Completed By: ___

MRN – if no MRN, request one Date: _____Completed By: ___

Update Screening Spreadsheet: Date: _____Completed By: ___

Consent Signed: Date: _____Completed By: ___

Print MRN Labels: Date: _____Completed By: ___

Initial Paperwork: Date: _____Completed By: ___ REDCap Entry: ____ REDCap Verify: ____

Health Thermometer: Date: _____Completed By: ___ REDCap Entry: ____ REDCap Verify: ____

PAR-Q: Date: _____Completed By: ___ REDCap Entry: ____ REDCap Verify: ____

BP: Date: _____Completed By: ___ REDCap Entry: ____ REDCap Verify: ____

Height: Date: _____Completed By: ___ REDCap Entry: ____ REDCap Verify: ____

Weight: Date: _____Completed By: ___ REDCap Entry: ____ REDCap Verify: ____

Physical Exam: Date: _____ Completed By: ___ REDCap Entry: ____ REDCap Verify: ____

Urine Sample: Date: _____Completed By: ___ REDCap Entry: ____ REDCap Verify: ____

Blood Draw: Date: _____Completed By: ___

Deliver Blood to Lab: Date: _____Completed By: ___

Fax or email forms: Date: _____Completed By: ___

Enter Lab Results into REDCap: REDCap Entry: ____ REDCap Verify: ____

DSQ: Date: _____Completed By: ____ REDCap Entry: ____ REDCap Entry: ____

Initialize ActiGraph: Date: _____Completed By: ____

Actigraph Distributed: Date: _____Completed By: ____

Notify Angela for Surveys: Date: _____Completed By: ____

ASA 24 Completed: Date Completed: _____

Actigraph Returned: Date: _____Completed By: ____

OB Approval Signed by OB/Health Care Provider: Date: _____Completed By: ____

Notes:

Appendix 4. Second and Third Trimester Visit Check List

Name: _____ **Study ID: _____**

Print MRN Labels: Date: _____Completed By: ___

Medications: Date: _____Completed By: ___ REDCap Entry: ____
REDCap Verify: ____

Nutrition Update Questions: Date: _____Completed By: ___ REDCap Entry: ____
REDCap Verify: ____

Health Thermometer: Date: _____Completed By: ___ REDCap Entry: ____
REDCap Verify: ____

DSQ: Date: _____Completed By: ____ REDCap Entry: ____
REDCap Entry: ____

BP: Date: _____Completed By: ___ REDCap Entry: ____
REDCap Verify: ____

Weight: Date: _____Completed By: ___ REDCap Entry: ____
REDCap Verify: ____

Urine Sample: Date: _____Completed By: ___ REDCap Entry: ____
REDCap Verify: ____

Blood Draw: Date: _____Completed By: ___

Deliver Blood to Lab: Date: _____Completed By: ___

Initialize Autograph Date: _____Completed By: ____

Actigraph Distributed: Date: _____Completed By: ____

Notify Angela for Surveys: Date: _____Completed By: ____

ASA 24: Date Completed: _____

Actigraph Returned: Date: _____Completed By: ____

Notes:

_____
_____
_____
_____

Appendix 5: Outline of PEN Curriculum Objectives and Goals

Session	Topic	Objectives	Goal
1	Introduction to PEN	• Get to know your team members • Learn about the PEN Program and point set • Learn benefits of physical activity and healthy eating during pregnancy • Receive pedometers and resistance bands • Learn about your gym membership	Be physically active for 30 minutes a day at least 4 days this week
2	Nutrient Needs During Pregnancy	• Learn about nutrient needs during pregnancy • Determine how to meet our calcium needs • Learn about how our body changes during pregnancy and how to achieve a healthy weight gain	Wear your pedometer and record your daily steps online at least 4 days this week.
3	Aerobic Exercise During Pregnancy	• Understand how pregnancy affects physical activity • Learn to measure aerobic intensity • Begin our aerobic exercise plan	Perform your aerobic exercise plan at least 4 days this week.
4	Fruits and Vegetables	• Learn the serving sizes of fruits and vegetables and the number of servings we should eat each day • Learn the health benefits of eating fruits and vegetables • Learn how to increase our fruit and vegetable intake	Choose at least one recipe from the website to help you eat 3 servings of fruits and 3 or more servings of vegetables per day at least 4 days this week.
5	Strength Training	• Learn benefits of strength training during pregnancy • Review strength training definitions • Learn strength training precautions • Create a strength training plan • Review the Strength Training Challenge	Use your gym membership to help you strength train at least 2 days this week.
6	Healthy Meal Planning	• Review the 3X5 Plan nutrition goals • Plan 2 healthy meals • Learn nutritious snack options • Learn high protein food options	Prepare and eat healthy meals meeting the 3X5 Plan goals at least 2 days this week.

7	Maintaining a Healthy Back	• Learn basic back anatomy and ergonomics • Practice how to maintain a neutral spine posture and back stretches • Review the muscles and exercises involved in core strength	Perform 4 stretches and 3 or more cores exercises per day at least 4 days this week.
8	Figuring Out Fat	• Learn the difference between saturated, unsaturated, and trans fats • Identify common sources of dietary fat • Identify and select healthy breakfast options	Eat a low-fat breakfast (less than 30% of calories from fat) at least 4 days this week.
9	Stress and Coping	• Determine our current stress level • Understand the major causes and signs of stress • Recognize the difference between “healthy” and “unhealthy” stress • Learn healthy ways to cope with stress	Practice a positive coping technique you find helpful at least 4 days a week.
10	So Far, So Good	• Review non-starchy and starchy vegetables • Practice strength training exercises • Learn about the glycemic index • Review or progress with the PEN program goals	Work on the goal of your choice from the Midpoint Review this week.
11	Portion Distortion	• Learn the difference between a portion size and a serving size • Learn how portion sizes have changed over the past 20 years • Learn how portion size impacts energy balance	Reduce the portion size of a food or beverage at least once a day for four or more days this week.
12	Your Beverage IQ	• Learn how calories from beverages affect our overall calorie intake • Identify high calorie drinks and low calorie alternatives	Drink 8 (8 oz) cups of water each day for at least 4 days this week.
13	Sugar Decoded	• Learn the added sugar content of common foods • Learn the other names for sugar • Learn where healthier ingredients can be found in grocery stores	Reduce the amount of added sugar you consume at least 4 days this week.
14	Cardiovascular	• Understand the risk factors for	Research your

	Health	cardiovascular disease in women • Learn the signs and symptoms of cardiovascular disease in women • Learn what we can do to reduce our cardiovascular disease risk	recommended values or “levels” for blood pressure, cholesterol, triglycerides, and blood sugar. Below are some resources you can use in your search. Then use your research to answer the “Session Goal” questions on the website.
15	Understanding Depression	• Learn about the types of depression, including postpartum depression • Learn how depression affects our health • Learn strategies to improve our mood and help prevent depression and anxiety	Be engaged in one or more activities you enjoy, at least 4 days this week.
16	Nutrition Jeopardy	• Learn facts about nutrients • Review the benefits of eating whole grain foods	Eat 3 or more servings of whole grains per day at least 4 days this week.
17	Breastfeeding	• Learn the benefits of breastfeeding for mothers and babies • Learn the differences between colostrum, breast milk and formula • Learn about your nutritional needs during lactation • Learn how to overcome breastfeeding challenges	Watch the breastfeeding video included in this week’s online activity and to write a list of any questions we have about breastfeeding to discuss with our health care provider at our next visit.
18	Campaign Planning	• Create a campaign to encourage others to make healthy behavior changes	Post the most useful health strategy we have learned during the PEN Program on our Team wall this week.
19	Energy Balance after Pregnancy	• Present our Team’s campaign • Learn about energy balance after pregnancy • Review healthy foods to meet our nutrition needs • Learn the importance of physical activity after pregnancy	Write our plan for physical activity and a healthy diet for after we deliver.

20	Staying Connected	• Review the PEN program session goals • Determine a way to stay connected with our Team	Choose a previous goal from the PEN Program that you would like to continue working on this week. Review all goals in the Goal Checklist in the back of your Workbook.

Appendix 6: Evidence-based Table Summarizing Fruit and Vegetable Intake During Pregnancy, Gestational Weight Gain, and Diet Quality Scoring

	Study Identification	Participants	Design	Outcomes
1	Simas TA, Liao X, Garrison A, Sullivan GM, Howard AE, Hardy JR. Impact of updated Institute of Medicine guidelines on prepregnancy body mass index categorization, gestational weight gain recommendations, and needed counseling. J Womens Health (Larchmt) 2011;20:837-44.	11,688 women who delivered singleton births at a hospital in Massachusetts between April 2006-September 2009	A retrospective review of labor and delivery records. Objective was to quantify how 2009 revisions of the IOM recommendations of weight gain guidelines change women's adherence to GWG.. BMI groups and GWG were categorized according to IOM 1990 and 2009 recommendations.	Significant differences between BMI categorization and GWG adherence. Compared to 1990 guidelines, 16.7% of women were classified differently using 2009 guidelines with more classified as overweight. 17.1% of the 1990 appropriate gainers would be classified as overgainers according to new guidelines.
2	Butte N, Ellis K, Wong W, Hopkinson J, Smith E. Composition of gestational weight gain impacts maternal fat rentention and infant birth weight. Am J Obstet Gynecol 2003;189:1423.	63 women with ranging BMI	Assessed pre-pregnancy body composition and at 9, 22, and 36 weeks gestation as well as at 2, 6, and 27 weeks after delivery using DXA. Body composition of newborn was also determined at 2 and 27 weeks old.	Postpartum fat retention correlated positively with gestational weight gain
3	Young T, Woodmansee B. Factors that are associated with cesarean delivery in a large private practice: the importance of prepregnancy body mass index and weight gain. Am J Obstet Gynecol 2002;187:312.	Primiparous deliveries in Florida private practice between Feb 1993 and July 2001	Retrospective study examining BMI and GWG as risk factors for cesarean section	Excessive pregnancy weight gain (>35 lb) associated with cephalopelvic disproportion/failure to progress in non-obese patients

	Study Identification	Participants	Design	Outcomes
4	Carreno C, Clifton R, Hauth J, et al. Excessive early gestational weight gain and risk of gestational diabetes mellitus in nulliparous women. Obstet Gynecol 2012;119:1227.	7,985 pregnant nulliparous women attending 16 clinical centers between 2003-2008	Secondary analysis of a randomized trial. Early gestational weight gain was estimated using pre-pregnancy self-reported weight and weight at 15-18 weeks and compared to IOM 2009 guidelines Rates of GDM, birth weight greater than 4,000 g, and large for gestational age were determined.	Excessive early gestational weight gain is associated with GDM
5	Josefsson J, Hoffman J, Metzger B. Excessive weight gain in women with a normal pre-pregnancy BMI is associated with increased neonatal adiposity. Pediatr Obes 2013;	38 pregnant women attedning a Chicago clinic	Evaluated differences in adiposity from neonates born to mothers with a normal pre-pregnancy BMI who either gained within or above IOM guidelines. Neonatal adiposity was measured within 72 h of birth by the method of air displacement plethysmography.	Mothers with excessive gestational weight gain gave birth to neonates with 50% more fat mass
6	Catalano PM, Thomas A, Huston-Presley L, Amini SB. Increased fetal adiposity: a very sensitive marker of abnormal in utero development. Am J Obstet Gynecol 2003;189:1698-704.	195 infants of women with GDM and 220 infants of women with normal glucose tolerance	Characterize body composition at birth in infants of women with gestational diabetes mellitus and normal GTT. Anthropometric measurements and total body electrical	There was no significant difference in birth weight or fat-free mass between groups. However, infants of women with gestational diabetes mellitus had significantly greater skinfold measures and fat mass than women with normal GTT.

	Study Identification	Participants	Design	Outcomes
			conductivity body composition evaluations at birth.	
7	Chen X, Scholl T. Association of elevated free fatty acids druing late pregnancy with preterm delivery. Obstet Gynecol 2008;112:297.	523 pregnant women at a health center in Camden, NJ	To examine the association between moderately elevated maternal plasma free fatty acids (FFAs) during late pregnancy and preterm delivery. Fasting plasma FFAs were measured during the 3rd trimester	Elevated maternal FFAs measured in early 3rd trimester associated with a doubled risk of preterm delivery
8	Bunt JC, Tataranni PA, Salbe AD. Intrauterine exposure to diabetes is a determinant of hemoglobin A(1)c and systolic blood pressure in pima Indian children. J Clin Endocrinol Metab 2005;90:3225-9.	42 Pima Indians aged 7-11 yrs	20 children were born to mothers with GDM during pregnancy and 22 were born to mothers who later developed diabetes.	Those children exposed to diabetes in the womb (via GDM) had higher HbA1C levels, higher systolic blood pressure, and lower HDL levels independent of age, gender, and adiposity.
9	Hinkle S, Sharma A, Swan D, Schieve L, Ramakrishnan U, stein A. Excess gestational weight gain is associated with child adiposty among mothers with normal and overweight prepregnancy weight status. J Nutr 2012;142:1851.	3600 American children born in 2001	Examined pre-pregnancy BMI-specific associations between GWG and child BMI Z-scoreat age 5.	Excessive gestational weight gain is associated with an increase in child BMI among normal and overweight mothers
10	Schack-Nielson L, Michaelson K, Gamborg M, Mortenson E, Sorenson T. Gestational weight gain in relation to offspring body	4234 subjects from the Copenhagen perinatal cohort	Examined pre-pregnancy BMI and GWG association with offspring BMI at 42 years of age.	Positive correlation of gestational weight gain with high offspring BMI in adulthood (at 42 yrs old). Greater GWG was associated

	Study Identification	Participants	Design	Outcomes
	mass index and obesity from infancy through adulthood. Int J Obes 2010;34:67.	(born 1959-1961)		with greater risk of obesity.
11	Knudsen VK, Heitmann BL, Halldorsson TI, Sorensen TI, Olsen SF. Maternal dietary glycaemic load during pregnancy and gestational weight gain, birth weight and postpartum weight retention: a study within the Danish National Birth Cohort. Br J Nutr 2012;1-8.	47,003 women in the Danish National Birth Cohort between 1996-2002	Examine the associations between maternal dietary GL and gestational weight gain, birth weight, the risk of giving birth to a child LGA or small-for-gestational age and postpartum weight retention (PPWR).	Birth weight increased by 36 g from the lowest to highest GL quintile. Increased risk of LGA of was detected in the for highest GL quintile compared with the lowest GL quintile. higher gestational weight gain rates were detected in the highest GL quintile.
12	Evenson K, Wen F. Prevalence and correlates of objectively measured physical activity and sedentary behavior among US pregnant women. Prev Med 2011;53:39.	359 pregnant women from NHANES data	Pregnant women ≥16 years wore an accelerometer for 1 week	Women participated in a mean of 12.0 minutes/day (standard error (SE) 0.86) of moderate activity and 0.3 minutes/day (SE 0.08) of vigorous activity. Most pregnant women spend more than half the day doing sedentary behaviors and don't meet physical activity recommendations
13	McCurdy C, Bishop J, Williams S, et al. Maternal high-fat diet triggers lipotoxicity in the fetal livers of non-human primates. J Clin Invest 2009;119:323.	Adult female Japanese Macaques between 5-7 years of age	Livers were examined from offspring from both lean and obese mothers chronically consuming a high fat diet	All fetal offspring of high-fat diet mothers showed signs of NAFLD regardless of maternal obesity/insulin resistance
14	Kinnunen TI, Pasanen M, Aittasalo M, et al. Preventing excessive weight gain during	132 pregnant women from six maternity clinics	Intervention included individual counseling on diet and leisure time	Counseling did not affect the proportion of primiparas exceeding the weight gain

	Study Identification	Participants	Design	Outcomes
	pregnancy - a controlled trial in primary health care. Eur J Clin Nutr 2007;61:884-91.	in primary health care in Finland	physical activity during five routine visits to a public health nurse until 37 weeks' gestation	recommendations or total leisure time physical activity
15	Wilkinson S, McIntyre H. Evaluation of the 'healthy start to pregnancy' early antenatal health promotion workshop: a randomized controlled trial. BMC Pregnancy Childbirth 2012;19:131.	360 maternity hospital patients in Austrailia	Intervention women also attended a one-hour 'Healthy Start to Pregnancy' workshop (n = 178)	Fruit and vegetable intake increased in women who attended the HSP workshop by about a half serving per day. There was a clinically-relevant increase in physical activity (+27 minutes/week) and had a higher diet quality score than women receiving normal care.
16	Nascimento SL, Surita FG, Parpinelli MA, Siani S, Pinto e Silva JL. The effect of an antenatal physical exercise programme on maternal/perinatal outcomes and quality of life in overweight and obese pregnant women: a randomised clinical trial. BJOG 2011;118:1455-63.	82 pregnant women with a BMI >26 between 12-24 weeks gestation attending a prenatal healthcare center in Brazil	Women were randomized into 2 groups. One group received home exercise counseling and performed supervised exercises. The control group followed routine prenantal care only.	There was no difference in gestational weight gain between the two groups. Overweight women who exercised gained significantly less weight during the pregnancy. No differences were observed in blood pressure or quality of life between groups.
17	Thangaratinam S, Rogozinska E, Jolly K, et al. Effects of interventions in pregnancy on maternal weight and obstetric outcomes: meta-analysis of randomised evidence. BMJ 2012;344:e2088.	44 randomized controlled trials (7278 women)	Studies included 3 types of interventions during pregnancy on maternal and fetal weight: diet, physical activity, and a mixed approach.	Observed a 1.42 kg reduction in GWG with any intervention as compared to control. No significant differences in birth weight, LGA, or SGA between groups. Interventions were associated with reduced risk of pre-eclampsia and shoulder dystocia. Dietary intervention resulted in the largest reduction

	Study Identification	Participants	Design	Outcomes
				in maternal GWG.
18	Champagne CM, Broyles ST, Moran LD, et al. Dietary intakes associated with successful weight loss and maintenance during the Weight Loss Maintenance trial. J Am Diet Assoc 2011;111:1826-35.	828 successful weight loss participants	Successful weight loss participants who completed Phase I of the trial and lost 4 kg were randomized to one of three maintenance intervention arms in Phase II and followed for an additional 30 months. Intervention used the Dietary Approaches to Hypertension diet.	Increased intake of fruits and vegetables was associated with weight loss in Phases I and II
19	Canfi A, Gepner Y, Schwarzfuchs D, et al. Effect of changes in the intake of weight of specific food groups on successful body weight loss during a multi-dietary strategy intervention trial. J Am Coll Nutr 2011;30:491-501.	322 participants in a 2-year low-fat, Mediterranean, low-carbohydrate intervention trial (DIREC	Assessed changes in the intake of 12 food groups among participants using a validated electronic food frequency questionnaire.	Leading predictors for weight loss included increased vegetable intake and legume intake while predictors for weight gain included increased sweets. Overall, two-year weight loss is associated with a decrease of ~1 kg of total food consumed.
20	Gawade P, Markenson G, Bsat F, Healy A, Pekow P, Plevyak M. Association of gestational weight gain with cesarean delivery rate after labor induction. J Reprod Med 2011;56:95.	2495 induced labor patients at a medical center in Springfield, MA between 37 and 42 weeks gestation.	Retrospective cohort study. Weight gain during pregnancy was calculated by subtracting pre-pregnancy weight from weight recorded at delivery. Maternal and obstetric characteristics were examined as predictors of cesarean delivery.	For every 5kg increase in gestational weight gain, the risk for cesarian delivery in women undergoing labor induction increased by 13%

	Study Identification	Participants	Design	Outcomes
21	Vesco K, Dietz P, Rizzo J, et al. Excessive gestational weight gain and postpartum weight retention among obese women. Obstet Gynecol 2009;114:1069.	1656 obese women at Kasier Permanente NorthWest between 2000-2005	Pregnancy weight gain was categorized as 0, 0-15, 15-25, 25-35, and 35+. Postpartum weight change was determined (weight at one year postpartum minus weight at pregnancy onset).	Incremental increase in risk of one-year postpartum weight retention of 10# with increased gestational weight gain (4x more likely with 25-35 lb gain and 8x more likely with> 35# weight gain)
22	Orbach H, Matok I, Gorodischer R, et al. Hypertension and antihypertensive drugs in pregnancy and perinatal outcomes. Am J Obstet Gynecol 2012;	100,029 deliveries between 1998 and 2008 in southern Isreal	Retrospecitve cohort study comparing pregnancies of women with hypertension (exposed or unexposed to medication) to those without hypertension.	Chronic hypertension during pregnancy with or without medical intervention is a significant risk factor for adverse perinatal outcomes like intrauterine growth restriction, small for gestational age, and preterm delivery.
23	Gibson K, Waters T, Catalano P. Maternal weight gain in women who develop gestational diabetes mellitus. Obstet Gynecol 2012;119:560.	652 women (163 in the GDM group and 489 controls)	Compared maternal weight gain before 24 weeks in women developing gestational diabetes mellitus (GDM) compared with controls with normal glucose tolerance	Overweight and obese GDM participants gained significantly more weight by 24 weeks
24	Hedderson M, Gunderson E, Ferrara A. Gestational weight gain and risk of gestational diabetes mellitus. Obstet Gynecol 2010;115:597.	341 GDM patients at Kaiser Permanante in Northern California	Estimated rate of weight gain before 24-28 weeks OGTT and subsequent risk for GDM	Increased gestational weight gain (especially in the first trimester is associated with increased risk of GDM. Rate of weight gain from 0.27-0.40 kg/wk and 0.41 kg/wk or more, were associated with increased risks of GDM

	Study Identification	Participants	Design	Outcomes
25	Chearskul S, Kooptiwut S, Pummoung S, et al. Obesity and appetite-related hormones. J Med Assoc Thai 2012;95:1472-9.	53 non-obese and 33 obese Thai women aged 25 to 45 years	Saliva and fasting blood samples were collected for hormone measurements and compared to participants' fat mass.	Plasma leptin related positively to fat mass and insulin resistance but negatively to acylated ghrelin level.
26	Te Morenga LA, Levers MT, Williams SM, Brown RC, Mann J. Comparison of high protein and high fiber weight-loss diets in women with risk factors for the metabolic syndrome: a randomized trial. Nutr J 2011;10:40,2891-10-40.	83 overweight women 18-65 years old	Women were randomized to either a moderately high protein diet or to a high fiber, relatively high carbohydrate,(> 35 g total dietary fiber) diet for 8 weeks	Participants on both diets lost weight as well as total and LDL cholesterol, triglycerides, fasting plasma glucose and blood pressure. However participants on the high protein diet lost significantly more body weight.
27	Tucker LA, Thomas KS. Increasing total fiber intake reduces risk of weight and fat gains in women. J Nutr 2009;139:576-81.	252 women in Utah with a mean age of 40	Prospective cohort assessing fiber intake using 7-day weighed food records at baseline and again after 20 months. Body fat was assessed at baseline and 20 mo.	Over the 20 months, ~50% of women gained weight and fat. For each 1g/1000kcal increase in total fiber, weight gain decreased by 0.25 kg and body fat gain decreased by 0.25 percent. Increasing dietary fiber significantly decreases the risk of gaining weight and fat in women perhaps by reducing total kcal intake.
28	Collins CE, Morgan PJ, Jones P, et al. A 12-week commercial web-based weight-loss program for overweight and obese adults:	309 adults in New South Wales, Australia with a BMI 25-40	12-week web-based weight loss program. Divided participants into three groups: basic web	Both groups, those with feedback and those without it, lost similar amounts of body weight, both significantly more than the control

	Study Identification	Participants	Design	Outcomes
	randomized controlled trial comparing basic versus enhanced features. J Med Internet Res 2012;14:e57.		program, enhanced web program (feedback was provided), or control. Programs targeted self-efficacy, goal setting, and self-monitoring.	group.
29	Brindal E, Freyne J, Saunders I, Berkovsky S, Smith G, Noakes M. Features predicting weight loss in overweight or obese participants in a web-based intervention: randomized trial. J Med Internet Res 2012;14:e173.	8112 Australian adults with a BMI greater than 25	Three web-based programs including two supportive sites (weight tracker and meal plan options) and one information-based site	No significant difference in weight loss between sites. Participants lost an average of 2.76% body weight. Participants of all sites lost more weight than the control (no website usage).
30	Sercekus P, Mete S. Turkish women's perceptions of antenatal education. Int Nurs Rev 2010;57:395-401.	15 Turkish primipara women between 24-28 weeks gestation	Eight participants received group education and 7 received individual education. All material was the same and included nutrition, lactation, what to expect, breathing and relaxation, and infant care.	Finding were qualitative. Most women believed the education had a positive effect on the pregnancy. Group education was preferred to individual.
31	Ranby KW, Aiken LS, Mackinnon DP, et al. A mediation analysis of the ATHENA intervention for female athletes: prevention of athletic-enhancing substance use and unhealthy weight loss behaviors. J Pediatr Psychol 2009;34:1069-83.	1668 female, high school athletes in the Pacific Northwest	Intervention consisted of 8 weekly, coach- and peer-led session with groups of 6 members and one peer leader. Curriculum consisted of sports nutrition, eating disorders, diet pills, and unhealthy weight loss.	Intervention group showed decreased intentions to use diet pills and increased knowledge of negative effects from unhealthy weight loss. Intervention did not reduce negative behaviors or modify peer norms.
32	Elliot DL, Goldberg L, Kuehl KS,	599 firefighters in	Intervention consisted of	Compared to the control, the

	Study Identification	Participants	Design	Outcomes
	Moe EL, Breger RK, Pickering MA. The PHLAME (Promoting Healthy Lifestyles: Alternative Models' Effects) firefighter study: outcomes of two models of behavior change. J Occup Environ Med 2007;49:204-13.	close proximity to OHSU	team-centered, peer-led, scripted curriculum about nutrition and physical activity. There were eleven sessions each 45-minutes long. Participants developed personal goals and evaluated them throughout the program.	intervention group increased fruit and vegetable intake, gained less weight, increased dietary understanding, and reported greater dietary social support
33	Shin D, Chung H, Weatherspoon L, Song WO. Validity of Prepregnancy Weight Status Estimated from Self-reported Height and Weight. Matern Child Health J. 2013 Dec 14.	2947 NHANES subjects consist-ing of 2,443 non-pregnant women and 504 pregnant women	Pearson's correlation was determined between self-reported versus measured weight in non-pregnant women. Pearson's correlations were also calculated between self-reported prepregnancy weight and measured weight in the first trimester	In pregnant women, the mean weight difference was -2.3 (0.7) kg, indicating that self-reported weight was lower by an average of 2.3 kg. The agreement in prepregnancy weight status determined by calculated prepregnancy weight (the standard) versus that determined by self-reported prepregnancy weight was substantiated by K=0.78. While weight was reported lower, it did not significantly change prepregnancy BMI status. Prepregnancy weight status classified based on self-reported prepregnancy height and weight was valid.

	Study Identification	Participants	Design	Outcomes
34	Subar AF, Kipnis V, Troiano RP. Using intake biomarkers to evaluate the extent of dietary misreporting in a large sample of adults: the OPEN study. Am J Epidemiol. 2003 Jul 1;158(1):1-13.	261 male and 223 female participants aged 40–69 years from the OPEN Study was conducted by the NCI from September 1999 to March 2000.	Evaluate absolute protein intake and total energy and energy-adjusted protein intakes via urinary nitrogen and doubly labeled water as compared to two averaged FFQs and two averaged 24-hr recalls	Women underreported energy intake on 24HRs by 16–20% and on FFQs by 34–38% and underreported protein intake by 11–15% on 24HRs and 27–32% on FFQs
35	Guenther PM, Kirkpatrick SI, Reedy J, Krebs-Smith SM, Buckman DW, Dodd KW, Casavale KO, Carroll RJ. The healthy eating index-2010 is a valid and reliable measure of diet quality according to the 2010 dietary guidelines for americans. J Nutr 2014;144:399-407.	2003-2004 NHANES (n=8262)	2 24-h dietary recalls from individuals aged ≥2 y from the 2003-2004 NHANES were used to estimate multivariate usual intake distributions and assess whether the HEI-2010	The distribution of scores among the population was wide (5th percentile = 31.7; 95th percentile = 70.4). As predicted, men's diet quality was poorer than women's, younger adults' diet quality, was poorer than older adults', and smokers' diet quality, was poorer than nonsmokers' ($P < 0.01$). This study supports the validity and the reliability of both versions of the HEI.

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