Effect of Single Goal Versus Multiple Goal Dietary Interventions on Diet Quality Measures During Pregnancy

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ABSTRACT

Background: During pregnancy, over 50% of women gain more than is recommended based on the National Academy of Medicine (NAM) guidelines. There is no consensus on dietary interventions to prevent excessive gestational weight gain (GWG). Excessive GWG is associated with development of gestational diabetes (GDM), hypertension, and can also result in high infant birth weight.

Objective: The purpose of this study was to evaluate the difference in the ability of a single goal (SG) vs multiple goal (MG) intervention to improve diet quality and maintain micronutrient status.

Design: Pregnant women were randomized within two pilot trials to an intervention**,** MG (n=21) and SG (n=16), or usual care (UC, n=18 combined). The MG intervention included traditional lifestyle counseling methods incorporating several nutrition topics, as well as physical activity. The SG intervention solely focused on increasing dietary fiber (>30gm/day). Both interventions included instruction by registered dietitians. Twenty-four-hour dietary recalls were collected for the three groups and three diet quality measures were calculated, including the AHEI-2010, AHEI- P (2005), and AHEI-P (2010).

Results: At study end, the SG group saw improvement in all three diet quality measures ($p<0.009$) and the MG group saw improvement in two diet quality measures (AHEI-2010 & AHEI-P-2010, $p<0.041$). The UC group saw no change in diet quality during the same time period ($p>0.05$). There was no significant difference in calcium, folate, or iron status between the groups.

Conclusions: A SG intervention focusing on fiber during pregnancy may be a simple approach to increasing diet quality. More research on SG interventions is needed.

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CHAPTER 1: INTRODUCTION

Gestational weight gain (GWG) above the Institute of Medicine's (IOM) recommendations is associated with complications such as gestational diabetes, high rates of cesarean-sections, high infant birth weight, greater levels of adiposity in newborns, and high rates of childhood obesity [1]. Excessive GWG is also associated with postpartum weight retention, which contributes to higher obesity rates [2]. Additionally, 57% of women entering pregnancy with a normal BMI that gain excessively will retain 10-20 pounds of body weight. [3] This is exacerbated in African Americans with 50% of women increasing their BMI by 10 points from the time of pregnancy to 12 years postdelivery [4].

Due to the potential negative health consequences, dietary interventions to prevent excessive weight gain during pregnancy have been studied. Many interventions have multiple dietary components, including caloric restriction. Other studies include both dietary components and physical activity. Common dietary interventions implemented during pregnancy include the American Heart Association diet (AHA diet), Mediterranean diet, and low-glycemic index diet. These diets all have multiple component interventions that could lead to low compliance rates [5]. Intervention compliance is the strongest predictor of success in weight management studies. During pregnancy women have a high medical burden with the amount of medical care that is required, and a complicated dietary intervention can add stress [5]. This is important because increased stress is a potential mechanism for increased GWG [6]. More feasible nutrition interventions are needed to prevent excessive GWG.

To best measure the effectiveness of dietary interventions, an appropriate and standardized way to measure diet quality during pregnancy is needed. The purpose of this study was to analyze how three diet quality measures are impacted by both a single goal (SG), high fiber (HF) approach, and a standard multiple goal (MG) approach.

1.1 Research Questions

1. During the intervention, is there a difference in diet quality using the three diet quality indices (AHEI-2010, AHEI-P-2005, AHEI-P-2010)?

2. During the intervention, is there a between group difference in diet quality using the three diet quality indices (AHEI-2010, AHEI-P-2005, AHEI-P-2010)?

1.2 Secondary Research Questions:

1. Does using a SG diet intervention during pregnancy result in a different **fruit and vegetables intake** compared to using a MG approach?

2. Does using a SG diet intervention during pregnancy result in a different **intake of iron, folate, and calcium** than when using a MG diet approach?

3. Does using a SG diet intervention during pregnancy results in a different **intake of saturated fat** than when using a MG diet approach?

1.3 Gaps in Current Research

There is little research regarding the dietary patterns that exist during pregnancy. A study of Australian women showed that out of 857 pregnant women, none met the recommendations for all five food groups. [7] A similar study looked at adherence to dietary guidelines in a population of Nordic women. Higher levels of adherence to the guidelines was associated with lower postpartum weight retention. [8] When compared to non-pregnant women of childbearing age, pregnant women had a higher diet quality. However, diet quality in both groups would be classified as low [9]. There is little guidance and consensus among healthcare providers

regarding maternal diet, therefore women are searching for nutrition information elsewhere. In a survey of 100 pregnant women, only 5.9% received nutrition information from a professional, while others received information from magazines, websites, friends, and family. [10]

CHAPTER 2: LITERATURE REVIEW

2.1 Interventions to prevent excessive GWG:

MG interventions are considered the gold standard for weight management. However, mixed results have been found for MG interventions to prevent excessive GWG. A meta-analysis of 44 clinical trials looked at MG nutrition interventions, MG physical activity interventions, and interventions that combined the two. The MG nutrition interventions were given an evidence rating of "moderate" for reducing gestational weight gain [11]. Another MG intervention that combined a community-based nutrition intervention and physical activity counseling was successful in reducing GWG in an urban population [12]. The Mediterranean diet was trialed as a MG intervention to prevent excessive GWG during pregnancy and was found to be successful at producing more appropriate GWG. However, the higher the Mediterranean diet score, the higher the risk of extremely low weight gain in pregnancy [13]. The Fit for Delivery Trial focused on decreasing calories and high fat foods, while increasing physical activity. This was also a successful MG intervention for preventing excessive GWG in women with a normal pre-pregnancy BMI. However, the same intervention was not successful in preventing excessive GWG in obese and overweight women [14]. Lacking is an intervention that is simple, easy to implement, and has potential for clinical translation.

2.2 Why did these interventions fail?

The benefits of goal setting have been well studied and found to be an effective way for promoting dietary behavior change [15]. Most interventions include multiple components or target multiple behaviors for change. However, adherence is reported to be the strongest predictor for intervention success [16] [17]. It is suggested that focus on one dietary component

(SG), versus multiple behaviors, may have greater adherence and equal or better intervention outcomes [18]. Limited studies have compared the effectiveness of SG versus MG interventions. Recommending multiple lifestyle changes is associated with lower compliance rates and overall poorer outcomes [18]. A 2004 study looked at compliance rates of adults when given five behavioral lifestyle modifications. Only 10.8% of adults were able to meet the recommendations in all five categories, which included physical activity, nonsmoking, diet quality, healthy weight, and moderate alcohol consumption [18]. The only indicators for improved compliance to multiple behavioral changes were having a college diploma and absence of chronic illness [18]. While pregnancy is not a chronic condition, one in five pregnant women have at least one chronic condition which could potentially lower compliance rates [19]. Further, pregnancy represents a time when multiple changes are occurring physically to a woman's body, emotionally, and in preparation for the baby to arrive. Therefore, a SG intervention may be a better option for pregnant women due to the simplistic approach and lower burden it places on the individual.

2.3 What is the one nutrient with the best evidence for weight management success?

Higher intake of fiber is associated with decreased risk for cardiovascular disease, improved gut health, improved glycemic control, and lower body weight [20]. A meta-analysis looking at the effect of HF diet versus a diet low in fiber was conducted in 2019 [21]. The study found that a diet high in fiber was associated with lower all-cause mortality risk in non-pregnant individuals. There is evidence to suggest the ability of fiber to potentially aid in the improvement of metabolic syndrome [22]. A longitudinal study that looked at 590 women and found that higher fiber intake was associated with a decreased risk for becoming overweight or obese [23].

For every one-gram increase in dietary fiber, weight was reduced by 0.25 kilograms over a 20-month period. Percent body fat also decreased by 0.25% for every one gram of fiber consumed. [24]. A meta-analysis of 50 fiber-related studies found that an increase in fiber intake by at least 14 grams per day, can lead to a 10% decrease in calories consumed [23].

Fiber also has many potential benefits for maternal health. One study found that an insoluble fiber intake greater than 13.8 grams per day was associated with a 67% decreased risk for developing preeclampsia in pregnancy. The same study also found that consuming 21.2 grams per day of total fiber was associated with triglyceride levels 11.9 mg/dl lower than individuals with lower fiber intake during pregnancy. [25]

A HF diet during pre-pregnancy and early in pregnancy can reduce the risk of developing GDM [21]. For every 10 grams of fiber consumed in the diet, the risk of developing GDM decreased by 26% [21]. For women diagnosed with GDM, a HF diet was related to lower rates of insulin initiation [21]. A study investigating dietary interventions during pregnancy in women with gestational diabetes (GDM) was completed in 2011 [26]. A HF diet was used as the SG approach and a low glycemic index diet as the MG intervention. The women in this study were observed for overall pregnancy outcomes and total glycemic index. Diet quality was not measured. A HF diet resulted in slightly lower glycemic index scores; however, there was not a significant difference between groups. Therefore, a HF diet may be an alternative way to decrease total glycemic index when working with a population that needs a more simplified approach [26].

2.4 Proposed mechanisms for fiber's impact on weight change

There are three proposed mechanisms for how fiber intake plays a role in weight control, which include hormonal effects, colonic effects, and intrinsic effects [23] [27]. The proposed mechanisms can be found in Figure 1. Both the hormonal and colonic impacts that fiber has on the body are related to the regulation of insulin, which is why HF diets are studied in individuals with gestational diabetes. As fiber intake increases, the incidence of insulin resistance decreases [27]. Insulin is indirectly impacted by fiber intake, due to the slowed gastric emptying that results from viscous fiber intake. Slowing the rate at which the stomach empties into the small intestine for absorption, slows the rate of carbohydrate uptake into the blood and therefore decreases the rate of insulin release [27]. Decreasing the rate of insulin being released prevents the development of insulin resistance. Increasing fiber is also suspected to impact satiety signaling. A randomized, double-blind crossover study used a HF muffin versus a low-fiber muffin to study the impact fiber had on blood glucose and insulin secretion in healthy adults [28]. After consuming a HF muffin, blood glucose levels were 33% lower when compared to consuming the low-fiber product. Postprandial insulin response was also decreased significantly in the HF muffin group [28].

The second proposed method for how fiber impacts weight change, is the colonic effect. Fiber acts as a prebiotic, which gets fermented by the gut microbes to produce short-chain fatty acids (SCFA). SCFA produced in the colon are used as energy by colonocytes or absorbed into the blood. The SCFA that are absorbed into the blood circulate and reduce the need for hepatic glucose production. Reducing this need for glucose production is how insulin sensitivity increases. It is the increase in insulin sensitivity and decrease in insulin secretion that is thought to impact body weight [27].

Lastly, it is proposed that higher fiber foods tend to take longer to chew, increasing gastric acid production [23]. The increase in gastric acid production leads to the stomach stretching and becoming distended. It is the distending of the stomach that triggers the vagal nerve and results in feelings of fullness. The more rapid feeling of fullness that comes with increased fiber intake is likely one reason caloric intake can be decreased, and therefore, weight loss may occur. As the food moves from the stomach to the small intestine, satiety hormones like polypeptide YY, ghrelin, and glucose-like peptide-1 are released and signal fullness [27]. A 9-week study looking at the dose-dependent relationship between fiber intake and reported hunger level found a significant relationship between the two variables [29]. Increasing fiber, in the form of wheat dextrin, increased short-term satiety measured on a visual analog scale. The groups receiving higher levels of wheat dextrin also reported going significantly longer without hunger between meals. The high wheat dextrin groups also decreased calories during the same time period [29]. A HF diet could potentially prevent overconsumption during pregnancy, and thereby, prevent excessive GWG.

2.5 Why could fiber be advantageous during pregnancy?

There is no recommended dietary intake (RDI) for fiber, however the adequate intake (AI) for fiber intake during pregnancy is 14 grams per 1000 calories, or 28 grams based on a 2,000-calorie diet. Despite the guidelines, the average American only consumes 15 grams per day and only 5% of the population is consuming the recommended 25 grams per day [30]. The recommend intake in pregnancy is 28 grams per day and a recent study found that pregnant women consume an average of 17.3 grams per day [31].

Pregnancy represents a transient excursion into metabolic syndrome like state. Many commonly prescribed diets are beneficial to the general population but are not effective during pregnancy. This could be a result of the 'metabolic syndrome-like' state of pregnancy [32]. During pregnancy, maternal metabolism of fat, protein, and carbohydrates change to meet the growing demands of the fetus [32]. Specifically, changes in glucose metabolism during pregnancy greatly impact basal metabolic rate [32]. Increased glucose utilization, as well as increased hepatic glucose production can impact insulin secretion [32]. With many metabolic changes occurring during pregnancy, interventions need to be designed to address this unique population. Though no studies have been completed during pregnancy, studies have compared MG vs SG in adults with metabolic syndrome.

2.6 MG and SG interventions equally effective in non-pregnant adults

There are very few studies that have compared SG versus MG dietary interventions, especially using fiber as a SG intervention. A 2015 study by Ma et al., randomized adults diagnosed with metabolic syndrome to either a traditional MG behavioral lifestyle intervention (following the AHA dietary recommendations) or a SG, HF study. No between group difference for weight loss was found, though the HF group lost 1.7 kg less than the MG group [5]. However, the HF group had a lower participant dropout than the AHA group (12.6% vs 9.9%) [5]. Further, for AHEI scores, no significant between group difference was found [5]. The study concluded that a HF diet was a good option for populations that struggle with lower rates of compliance [5].

Another study also compared MG vs. SG in non-pregnant adults. Olendzki and colleagues compared differences in diet quality between a HF diet, a low-saturated fat diet, and a

combination of the two diets in non-pregnant women. All three interventions produced significant improvements in diet quality using AHEI scores [33]. The HF group had significant decreases in saturated fat intake without fat intake being addressed in their education. This study concluded that a simplified dietary intervention can produce similar results as more complex approaches, while also being a lower burden on individuals [33]. In pregnancy, no studies have compared the effectiveness of SG and MG interventions. Only one SG pilot study has been done during pregnancy.

2.7 SG high fiber intervention during pregnancy

While SG interventions have been studied outside of pregnancy, it is a novel approach to preventing excessive GWG. Hull and colleagues studied the impact of a HF diet as an approach for preventing excessive GWG during pregnancy. Data reported in this study are from the PreGnancy Intervention Revolving Around Goal-Focused Education (GIRAFE) pilot [34]. The GIRAFE pilot study used a HF intervention as a SG dietary approach, while Hull's GRUVE pilot study focused on an overall healthy eating pattern-- a MG intervention. Both interventions were effective at preventing excessive GWG. The intervention group from the GIRAFE study will be used as the SG group for this project, and the intervention group from the GRUVE study will be used as the MG group. An important outcome to understand the success of these interventions is assessment of dietary quality.

2.8 What is dietary quality and why is it important to measure?

Diet quality is typically defined by the level of compliance to a specific set of dietary guidelines. There are a wide variety of ways to quantify diet quality. Some of these methods also use food group servings, food variety, and micronutrient intake to score diet quality [35]. In non-pregnant women, studies show that a poor diet quality is strongly associated with increased weight gain [36]. A longitudinal study that spanned 16 years found that women with a poor diet quality had a significantly greater chance of becoming overweight [36]. An abstract published in 2018 found a potential mechanism for this relationship between diet quality and body weight. A higher diet quality score may result in the ability to mitigate genetic predisposition to obesity [37]. While the data are limited in pregnant populations, similar results are found. For every additional 5 kg/m^2 in pre-pregnancy BMI points, diet quality is found to be 0.9 points lower during pregnancy, using the AHEI-P-2005[38].

Despite the evidence in non-pregnant adults, the relationship between excessive weight gain and diet quality during pregnancy is limited in the United States. Interventions focused on improving diet quality in pregnancy could result in less GWG. A study of pregnant Norwegian women used a modified diet quality measure to assess compliance with Nordic nutrition guidelines for pregnancy. The researchers found that diet quality scores were inversely related to postpartum weight retention. However, GWG was not reported. [8] Dietary quality is important to measure during pregnancy. Next we will discuss the different indices available to measure diet quality.

2.9 Measures of diet quality during pregnancy

A gap in the literature is the lack of consensus for measuring diet quality outcomes during pregnancy. Often blood glucose control, calorie intake, and weight change are used as outcomes in dietary interventions without investigating a direct measure of diet quality. Restrictive dietary interventions could be impacting the overall diet quality during this critical time period. Outside of pregnancy, the USDA's Healthy Eating Index (HEI), Harvard's Alternative Healthy Eating Index (AHEI), and overall fruit and vegetable intake are commonly used diet quality measures [39]. Another tool, based off the Mediterranean diet, was developed and named the Mediterranean Diet Score (MDS). This tool was not developed for use in pregnancy, however a study found that higher MDS during pregnancy was protective against cardiometabolic risk in offspring. MDS during pregnancy has not been studied in relation to GWG. [40] The HEI has been used in pregnancy studies without being modified. One study found that HEI scores remained stable between all trimesters of pregnancy, with no significant change. This study did not report a statistical relationship between HEI and GWG among the pregnant women [41] .

Some studies modified these measures to be used during pregnancy. Most notably, the Alternative Healthy Eating Index for Pregnancy (AHEI-P-2005) was created [38]. The AHEI-P-2005 removes alcohol as a component of the equation and adds emphasis on specific nutrients of concern during pregnancy. The AHEI-P-2005 measure is based off the AHEI-2005, and both include measures of fiber. The AHEI-P-2005 also includes fruits, vegetables, white to red meat ratio, trans fat, unsaturated to saturated fat ratio, calcium, folate, iron, protein, and total energy intake.

Several updates were made to the AHEI-2005 to create the AHEI-2010. These updates included changes in how cereal fiber, legumes, red and processed meats, and polyunsaturated fats are scored. The updated measure also adds categories for scoring sodium intake and sugar sweetened beverage consumption [42]. Both versions of the AHEI are strong predicters of chronic disease risk [42]. The updates that were made to the AHEI-2005 to create the AHEI-2010, have also been applied to the pregnancy measure to create the AHEI-P-2010 [43].

2.10 Other measures of dietary quality during pregnancy

In addition to using diet quality tools, assessing intake of foods groups has been related to weight change and health outcomes surrounding pregnancy. In a longitudinal study of young women, greater intake of fruit and vegetables was associated with lower weight gains [44]. There are many additional positive health outcomes associated with fruit and vegetable intake, and several have been studied during pregnancy. Higher leafy-green vegetable intake is related to lower incidence of SGA births[45]. Consumption of fruits, vegetables, and vegetable oils are associated with decreased risk for preeclampsia [46]. A previous study also found that vegetable intake was directly correlated to fiber consumption, as well as folate, vitamin C, vitamin A, potassium, and magnesium [46]. Therefore, fruit and vegetable intake alone are relevant outcomes for comparing the diet impact of interventions during pregnancy. In addition to measuring overall dietary quality, assessment of specific micronutrients is important to measure during pregnancy.

2.11 *Important micronutrients during pregnancy*

While there are many micronutrients of interest during pregnancy such as vitamin A, vitamin C, iodine, choline and vitamin D; folate, iron, and calcium are of particular concern due to their high level of need and risk for deficiency during this critical time. Nutrient requirements increase during pregnancy due to the highly anabolic state. While the vast majority of women meet macronutrient needs, up to 20-30% of women world-wide are not meeting micronutrient needs during pregnancy [47].

Because of the importance of nutrition during pregnancy and the poor outcomes associated with certain nutrient deficiencies, many nutrients of concern are fortified into processed foods and/or supplemented. Throughout history, foods have been fortified with nutrients that are of concern during pregnancy, including: iodized salt and folate fortified cereals and grains. The Academy of Nutrition and Dietetics currently only has standards for increasing iron and folic acid during pregnancy, and other micronutrients follow the typical Dietary Reference Intake (DRI) for healthy adults [47]. This project is looking at diet quality, however dietary nutrients of interest will also be quantified and compared among intervention groups. The main purpose for measuring the intake of these nutrients of concern is to ensure that the interventions did not decrease consumption of these nutrients. The importance of these nutrients is also why the AHEI-P is one of the diet quality measures used in this project, because it emphasizes folate, iron, and calcium.

Folic acid is one of the most commonly studied micronutrients with regards to pregnancy. Folic acid is important during pregnancy due its role as a coenzyme for carbon transfers involved in DNA synthesis [47]. Folate recommendations for pregnancy are 600 mcg per day, which is usually met by a combination of prenatal vitamin consumption and intake of fortified foods. The

United States has mandatory folic acid fortification of grains, which prevents 1,300 babies from being born with a neural tube defect every year [48]. With proper folic acid supplementation, 70% of neural tube defects are prevented. [48]. Because of the role folic acid plays in fetal outcomes, this nutrient is emphasized in the AHEI-P and will be looked at individually as well.

While folic acid supplementation is well studied during pregnancy, iron remains the most common nutrient deficiency during pregnancy, with greater than 38% of women being globally anemic at some point during their pregnancy [47]. Upwards of 50,000 maternal deaths worldwide are attributed to iron deficiency anemia [49]. This is partially due to the increased demand during pregnancy, and therefore an increased recommended intake. The recommended intake for women is 18 mg/day, however during pregnancy the recommend intake is 27 mg/day [50]. It is vital that iron recommendations are met because iron functions as a coenzyme in hemoglobin and myoglobin synthesis and the blood volume is greatly increased throughout pregnancy [47]. Absorbed iron is also needed for the fetus. The need for iron gradually increases by 0.8 mg/day during the first trimester and up to 7.5 mg/day during the last trimester [50]. To meet the needs later in pregnancy, absorption of iron in the small intestine increases with the length of pregnancy [50]. The health outcomes associated with iron deficiency anemia in pregnancy include: preterm birth, low-birth weight infants, small for gestational age infants, immune dysfunction, and lower cognitive function in infancy [47].

Calcium plays an important role in regulating bone metabolism throughout the lifespan. Because of the rapid fetal skeletal growth, calcium needs during pregnancy increase from 1,000 mg/day to 1,300 mg/day. The World Health Organization recommends 500 mg of calcium carbonate given three times per day, for a total of 1,500 mg/day. The maternal recommendations are higher because the fetus is accumulating 250-300 mg/day during the third trimester alone

[51]. The hormones that fluctuate during pregnancy potentially interfere with typical calcium and bone metabolism, so meeting these calcium recommendations during pregnancy is important [51]. However, only 5% meet dairy food group recommendations, which impacts total calcium intake [10]. The AHEI-P considers the increased need for calcium during pregnancy, while the HEI and AHEI do not.

Saturated fat intake is a nutrient of interest for this project because increased levels of saturated fat in the diet are associated with increased weight gain, however this has not been studied during pregnancy [52]. While more is known about the need for essential fatty acids, especially omega-3s, due to the role they play in fetal neurodevelopment, there is little research on ideal intake of other fats, including saturated fat [53]. Although saturated fat intake is controversial, there is a strong correlation between saturated fat intake and fatty liver disease in women [53]. A HF diet decreases levels of saturated fat intake and this will be investigated in this project.

CHAPTER 3: METHODS

Pregnant women were randomized within two separate pilot trials to an intervention or usual care. Twenty-one participants were educated on an overall healthy diet for pregnancy, physical activity, and breastfeeding within the multiple goal (MG) intervention. Sixteen participants received education to increase fiber intake to 30 grams per day or more within the single goal (SG) intervention. The control groups from both studies received usual care (UC, n=18) and were combined for the purpose of this study.[54]

3.1 Multiple Goal Parent Study:

Women were recruited prior to reaching 20 weeks of pregnancy and were randomized into either a UC group or MG intervention. The study inclusion/exclusion criteria were the same for both groups and are outlined within the recruitment section below (see section 3.3). The MG group received weekly group-based phone counseling that was provided to participants for 18 weeks during weeks 16-18 to 28-34 of their pregnancy. Conference phone calls lasted 1 hour per week, and were led by a Registered Dietitian who covered a variety of nutrition and health related topics [54]. Some of the topics taught during these weekly sessions included: healthy eating, physical activity, and breastfeeding [54]. Twenty-four-hour dietary recalls were obtained at baseline (16-18 weeks pregnant), and at study end (28-34 weeks pregnancy).

3.2 Single Goal Parent Study:

Women were recruited between 9 to 15 weeks of pregnancy and block randomized into a SG intervention or a UC group. The study inclusion/exclusion criteria were the same for both groups and outlined within the Recruitment section (see section 3.3). A fiber screener was used at baseline and women already consuming greater than 20 grams of fiber per day were excluded

from the study. The SG group was encouraged to consume at least 30 grams of fiber per day, while the other women received UC as guided by the Obstetrician. The intervention was given in the form of weekly group-based phone counseling from week 14-16 to 26-28 of pregnancy. For the initial 6 weeks of the intervention, the participants were given two high fiber (HF) snacks per day to aid in compliance with the fiber goal. Daily intake and weight status were tracked via the LST Athome phone application. Three twenty-four-hour recalls were collected at baseline and at 6 weeks and 12 weeks after the initiation of the intervention. Twelve weeks post-intervention will be referred to as study end for this project.

3.3 Recruitment:

Participants were recruited at the University of Kansas Medical Center's Obstetrics and Gynecology Clinic. Participants were informed of the study either during their OBGYN clinic visit, or by a KUMC campus-wide email. To be recruited, women had to be pregnant and less than 18 weeks gestation, be a healthy pregnant woman with no known diseases that would complicate pregnancy, including diabetes, pre-eclampsia, hypertension, and any other metabolic abnormalities. Only English-speaking participants were recruited. Participants were eligible for the SG group if pre-pregnancy BMI was between 18.5-40 kg/m^2. The MG group was made up of women with a pre-pregnancy BMI of 18.5-45 kg/m^2. Both groups recruited women ages 18-45 years old. Consort diagrams for SG and MG groups can be seen in figure 2 and figure 3

3.4 Ethics:

The parent studies were approved by the University of Kansas Medical Center's Institutional Review Board (GIRAFE - HSC# 00004032, GRUVE - HSC#123749). All outlined

study procedures were conducted ethically and in accordance with the principles outlined in the Declaration of Helsinki. Subjects were given a written copy of the informed consent before any study procedures were performed. All pregnant women received standard prenatal care from their providers during the study. Women in the SG group received a total $305 throughout the study. The women in the UC group received $185 during the study. Lastly, the MG group received $240 for their participation.

3.5 Diet Recall Methods:

The 24-hour dietary recalls collected from the SG and MG groups were collected using the multiple pass method. The multiple pass method is a five-step method for collecting dietary intake to ensure that all food details are collected. Research staff that obtained the recalls were trained in 24-hour-recall interviewing. Recalls from two weekdays and one weekend day were obtained from the SG study at baseline, 6-weeks, and 12-weeks. The MG study had one recall taken at baseline and one at study end. All recalls were obtained over the phone. Dietary supplement data were collected from SG study using a questionnaire, which was given at baseline and end of study. For the MG group, dietary supplement intake information was gathered within the 24-hour recall.

Both parent studies entered all recalls into Nutrition Data System for Research Software (NDSR, version 16, University of Minnesota, Minneapolis, MN) for food group analysis. Food group data collected from NDSR was used to calculate the Alternative Healthy Eating Index (AHEI- 2010) and the Alternative Healthy Eating Index- Pregnancy (AHEI-P-2005), as well as an updated AHEI-P-2010. The updated AHEI-P-2010 is based on the changes that were made to

the AHEI-2005. All three measures were calculated to see if there were significant difference in diet quality scores between the MG group and the SG group.

3.6 Diet Quality Scoring Methods:

SG dietary data were averaged over three days for each participant at each time point. Because MG had one recall per time point, averages did not need to be calculated. Next, NDSR food group (File 09) and nutrient outputs (File 04) were put into the diet quality calculators that were created in Excel. The following food groups were needed from NDSR output File 09: total vegetables, fruit, nuts, nut butters legumes, whole grains, red meat, processed meat, and white meat. Saturated fat, trans fat, percent calories from polyunsaturated fatty acids, sodium, calcium, iron, and folate were taken directly from NDSR output file 04. Further breakdown of the categories can be seen in Table 1 of the appendices. Because NDSR and both the AHEI and AHEI-P use different serving size references, the diet quality calculator also converted serving size from NDSR servings to AHEI servings (see Table 2 for conversion table). Each category was given a score from 0-10 and added together for the total diet quality score. For all three diet quality measures, the higher the score the better the quality of the diet. The AHEI-P-2005 is measured on a 0 to 90 point scale with 90 being a perfect score, and the AHEI-2010 is on a scale of 0 to 100. [42] The updated version of the AHEI-P has a scoring range of 0 to 130. After calculations, the participants were given a diet quality score for each time point. Individuals in the MG group had a diet quality score at baseline and end of intervention (34-36 weeks), while the SG group had diet quality scores for baseline, 6 weeks, and end of intervention. In the SG intervention, the week in gestation for the end of intervention varied based on when women

entered the study. Once the scores were calculated, they were put into SPSS for statistical analysis.

Total fruit and vegetable intake were measured using servings per day from NDSR output file 09 and compared between groups. The conversion from NDSR servings to AHEI servings is found in Table 2. For all three indexes, fruit juice was not counted in the fruit servings, and potatoes and fried potatoes were not counted towards vegetable servings. Iron, calcium, and folate are the three nutrients of concern for this project. Daily intake of the three nutrients of concern was taken from NDSR output file 04 and analyzed separately, along with saturated fat. Micronutrient intake was compared to the EAR, and a percentage of participants meeting the EAR was calculated. The percentages are based on food intake alone without the prenatal vitamin dose.

3.7 Statistical Methods:

Means and standard deviations were calculated for descriptive characteristics. One-way ANOVA and Pearson Chi-Square compared between group differences for baseline characteristics. Diet quality scores were compared within groups (baseline to intervention end) using repeated measures analysis of co-variance (ANCOVA). Between group differences for the change in diet quality from baseline to intervention end was assessed using on-way ANCOVA. Covariates in the model included caloric intake at baseline and 12 weeks, as well as maternal education level. SPSS version 26 was used to complete statistical analysis for all data, and significance was set at a p-value ≤ 0.05.

CHAPTER 4: RESULTS

4.1 Subject Characteristics

Maternal characteristics of the UC, MG, and SG groups are presented in Table 3 of the appendices. The UC group had 17 women, the SG had 16, and the MG had 21. The average age of the UC group was 29.1 ± 4.2 years, while the SG average was 28.8 ± 3.9 years, and MG was 30.0 ± 4.7 years. Seventy nine percent of the UC group was White, 5.3% Asian, and 5.3% defined as other. The SG group had 81.3% of participants identify as White, 12.5% as Black, and 6.3% defined as other. The MG group was composed of 76.2% White, 19% Black, and 4.8 % other. Participants in the MG group started the study at an average of 17.2 weeks gestational age (GA), while the SG group started earlier with an average of 13.6 weeks gestational age (GA). Baseline BMI was similar between all three groups. The UC mean BMI was 27.9 kg/m^2, SG was 27.0 kg/m^2, and the MG was 28.3 kg/m^2. Fifty-eight percent of women in the UC group had excessive GWG by study end, while the 50% of the SG group, and 38.1% of the MG group gained excessively. Of all women combined, 57% gained excessively [55]. There was a significant difference in GWG between the three groups, with the UC gaining significantly more weight than the SG and MG groups ($p<0.036$). There was also a significant difference in GA at entry to study. The UC and MG studies started later in pregnancy than the SG group ($p<0.003$).

Table 4 presents baseline dietary quality scores for all groups. There were no significant differences in baseline diet quality scores between the groups.

4.2 Diet quality changes during the intervention and between group differences

Diet quality at baseline, at the end of intervention and the changes in diet quality during the intervention are presented in Table 5 and Figures 4a-c. No change in diet quality was detected in the UC group by any of the indices. An increase in diet quality was detected in the

SG group by the AHEI-2010 and AHEI-P-2010, by 9.6 and 11.6 points, respectively ($p<0.05$). An increase in diet quality was detected in the MG group by the AHEI-2010 and AHEI-P-2010, by 8.6 and 9.1 points, respectively ($p<0.05$). Also presented in Table 5 are the results for the between group differences for the change in diet quality. No between group difference for the SG and MG groups was found using the AHEI-2010 or AHEI-P-2010 index. A between group difference was detected between the UC and both MG and SG for both indices ($p<0.05$). Lastly, the AHEI-P-2005 did not detect a difference for the change in diet quality between any of the groups.

4.3 Between group differences for vegetable, fruit, and legume intake

Table 6 presents the number of food group servings at baseline, study end, and the change in food servings during the study. No difference was found for the change in intake of fruit or vegetable servings per day. Differences were found for intake of legumes. The SG group consumed significantly more servings of legumes per day by study end than UC group ($p=0.012$). The SG group also significantly increased their legume intake by 0.74 servings per day from baseline to study end ($p=0.026$). The SG group averaged 1.7 servings of legumes per day at study end. The MG increased legume intake by 0.32 servings per day ($p=0.197$), for an average of 0.7 servings per day at study end. The UC group decreased legume servings by 0.27 servings per day ($p=0.36$) and averaged 0.39 servings per day at study end.

4.4 Between group differences for folate, iron, and calcium and saturated fat

Table 7 presents the mean intake for iron, calcium, folate, and saturated fat at baseline, study end, and the change in intake during the study. No change in intake from baseline to study end for any nutrients of concern was found, and no between group differences were detected.

CHAPTER 5: DISCUSSION

An increase in diet quality was detected for both the MG and SG interventions by the AHEI-2010 and AHEI-P-2010 indices ($p<0.05$). No change in diet quality was detected for the MG and SG interventions by the AHEI-P-2005. For the control group, no change in diet quality was detected by any index. Lastly, no change in micronutrients was found during the study and no between group difference was found for the micronutrients studied.

A study by Ma et al. is the only clinical trial to compare a MG vs. a SG high fiber intervention. This study was in middle-aged non-pregnant adults diagnosed with metabolic syndrome. Our results mirror the findings from Ma et al. [5]. Both studies found that both the SG and MG interventions increased diet quality during the intervention. This suggests that there is no difference for the change in diet quality resulting from a SG high fiber or MG intervention [5].

Many dietary interventions are restrictive, requiring reducing overall intake and/or reducing intake of certain foods or food groups. One benefit of a SG high fiber intervention is that the intervention focuses on increasing consumption of foods that are rich in dietary fiber. Therefore, the intervention does not put a limit on any food group, but instead focuses on high fiber foods. The mindset is not restriction as in most other interventions. A pilot study used a non-restrictive dietary intervention approach and focused on only increasing foods rich in fiber and protein. They found an increased overall diet quality and participants reported a high satisfaction with the non-restrictive intervention [56]. Calorie levels were not prescribed, however individuals randomized to the intervention reduced their total calorie consumption. Since both protein and fiber are known to promote satiety, it is not clear whether fiber or protein, or a combination of both was the mechanism for a reduction in caloric intake [56].

Despite changes being detected in the SG and MG groups by the AHEI-2010 and AHEI-P-2010, the AHEI-P-2005 did not detect a change in diet quality. The AHEI-P-2005 includes a category for fiber intake and the AHEI-P-2010 does not count fiber but instead scores total gram per day of whole grains. Because the AHEI-P-2005 did not change from baseline to study end in the SG group, it is possible that one of the other components of the diet quality measure that differed between the measures was mitigating the change in total fiber consumed.

Though the SG intervention focused only on increasing fiber intake, no decline in intake of important micronutrients related to pregnancy was found. No change in folate or iron intake during the intervention was found in the SG or MG groups. This confirms that focusing on one nutrient (increasing fiber) did not result in a decrease in the intake of essential vitamins and minerals. Although the intake of micronutrients was not decreased, the impact of a HF diet on blood levels of iron, calcium, and folate is unknown. Some high fiber foods are high in oxalates and phytates, which could decrease the bioavailability of iron and calcium [57].

Overall iron intake was low in all groups with the average intake for all three groups being 16.7 mg of iron per day with the Estimated Average Requirement (EAR) for pregnancy being 22 mg/day. The MG group had 19% of participants meet the EAR for iron, the SG group had 31%, and the UC group had 11%. This is consistent with the literature that emphasizes the need for a prenatal vitamin with adequate amounts of iron and folic acid due to women not getting enough through the diet [48]. The percent of women from each group meeting the EAR for pregnancy for calcium, iron, and folate can be seen in Table 8. The greater intake in calcium consumption in the SG versus MG group is possibly due to the higher intake of leafy greens in the SG group. In the SG group, increasing fruits and vegetables was encouraged and leafy greens could provide additional calcium. However, fruit and vegetable intake was not significantly

higher in the SG at study end. The reason for the significant difference in calcium between groups is unknown.

Previous studies found that increased fiber intake was partially driven by increased vegetable intake, however, the SG group saw no significant increase in vegetable intake from baseline to study end [46]. While fruit and vegetable intake were encouraged in the SG group's nutrition lessons, HF snacks were also provided and were likely the source of the increased fiber. There was also no significant difference for vegetable intake between the two intervention groups or the UC group.

No benefit from focusing on a HF diet was found for saturated fat intake. This is not consistent with the decrease in saturated fat that the HF group in Olendzki's study experienced [33]. Diet quality and saturated fat have not previously been reported, and the results from this study may indicate focusing on increasing fiber may not decrease saturated fat intake. While both the SG and UC groups had a mean decrease between 2 to 3 grams from baseline to study end, the change was not significant. The reason for a decrease in saturated fat intake in the UC group during pregnancy, without an intervention, is unknown.

5.1 Limitations:

This study examined previously collected data. Additionally, the parent studies were completed in different years, with different numbers of participants, and different intervention lengths. Both intervention studies were pilot studies, and therefore included smaller sample sizes. Ideally, the groups would have been randomized before the study started to prevent the between group differences in diet quality. Another noted limitation in comparing these two studies, is that the MG group had one 24-recall per time point for each participant and SG group had three 24-

hour recalls per participant at each time point. Because of the method differences, MG group's dietary data describes participant actual intake and SG group's data is capturing the average intake over three days. A larger randomized control trial is needed to make stronger conclusions.

Diet quality measures come with limitations. The diet quality measures used do not count vitamin and mineral supplements towards the overall diet quality score. Because of this, most pregnant women had relatively low scores for the iron and folate categories. However, almost all women were taking a prenatal multivitamin to make up for the relatively low intake.

5.2 Considerations for Future Research:

Further research is needed to understand how focusing on one nutrient, increasing fiber, impacts diet quality. There is also need for more randomized control trials to study the relationship between diet quality and GWG during pregnancy. Future studies should consider collecting maternal blood samples, to see how a HF diet impacts the blood nutrient status during pregnancy.

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Appendixes

Table 1: Comparison of Diet Quality Measures

Component	AHEI-2010*	AHEI-P-2005	AHEI-P-2010[1]
Vegetables	Total vegetable (servings/day)[2]	Total vegetables + legumes + soy products (servings/day)	Total vegetable (servings/day)[2]
Fruit	Total fruit (servings/day)[2]	Total fruit (servings/day)[2]	Total fruit (servings/day)[2]
Nuts & Legumes	Nuts + nuts butters + legumes + meat alternatives (servings/day)	-	Nuts + nuts butters + legumes + meat alternatives (servings/day)
Bread Grains	Whole grains (oz equivalents/day)	Fiber (g/day)	Whole grains (oz equivalents/day)
Protein	Read meat + processed Meat (servings/day)	Red to white meat ratio (ratio of servings/day)	Read meat + processed Meat (servings/day)
Fat	PUFA (% total energy) Total fat (% of total energy) Long chain N3s (mg/day)	Trans fat (% of total energy) Ratio of PUFAs to Saturated Fat (ratio of g/day)	PUFA (% total energy) Total fat (% of total energy) Long chain N3s (mg/day)
Sodium	Total sodium intake (mg/day)	-	Total sodium intake (mg/day)
Alcohol	Total alcohol intake (servings/day)[4]	-	-
Micronutrients	-	Calcium (mg/d), Folate (mcg/d), Iron (mg/d)	Calcium (mg/d), Folate (mcg/d), Iron (mg/d)
Other	Sugar sweetened beverages + fruit juices	-	Sugar sweetened beverages + fruit juices

[1]Created for use in this study
[2]Vegetable servings exclude white potatoes, fried potatoes, and other fried vegetables
[3]Total fruit servings excludes fruit juices
[4]Removed from scoring when used during pregnancy [58] [42]

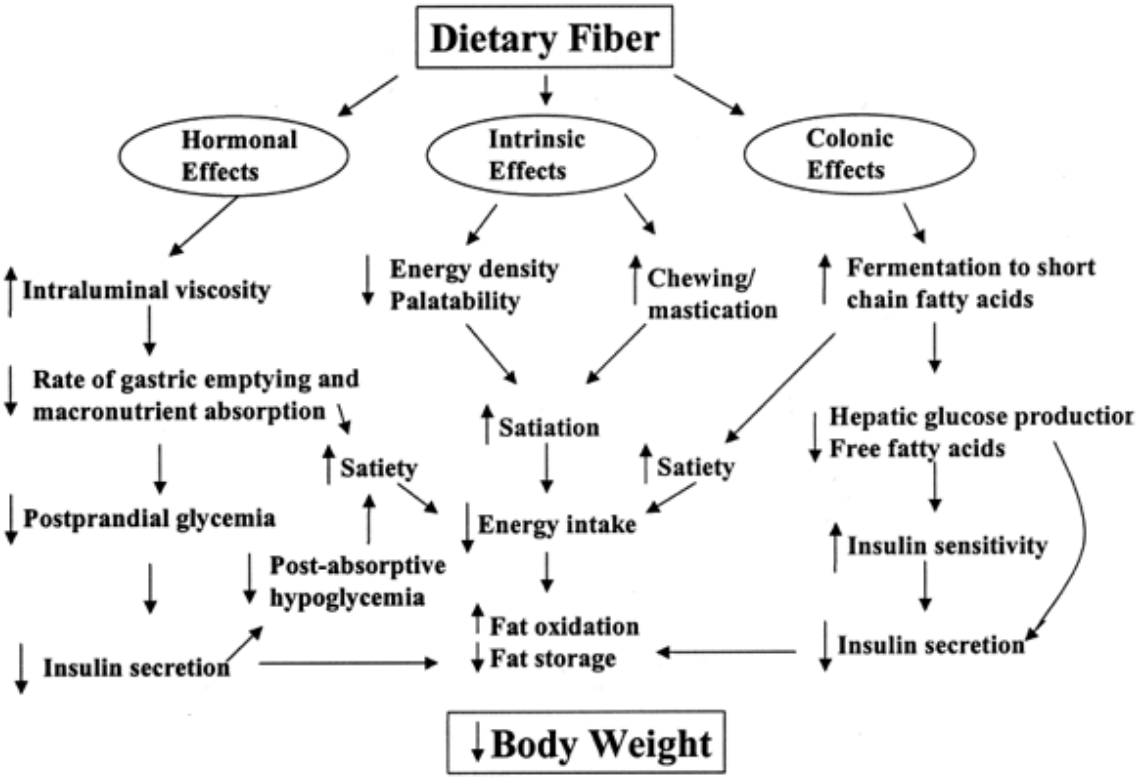


Figure 1: Mechanisms of Fiber and Weight Change [27]

Table 2: Converting NDSR Servings to AHEI Servings

Food item	NDSR Serving	aHEI Serving	Conversion of NDSR serving to aHEI serving
Fruit Juice	4 fl oz	8 fl oz	/2
Sugar-sweetened beverages	8 fl oz	8 fl oz	None
Fruit	½ cup fresh, frozen canned, 1 med, ½ grapefruit, ¼ cup dried	1 medium piece whole fruit, .5 cup of berries	None
Vegetable	Raw, cooked or canned=0.5 Raw leafy=1 cup	.5 cup or 1 cup leafy greens	None, take out potatoes from count
Whole Grains	Whole grain oz equivalents	Recommendation is 90g/d for men (6 servings	1 oz equivalent = 1 serving
Nuts/legumes/vegetable protein	½ cup beans/legumes, ½ oz nuts, 1 TB nut butter, meat alternative=1 oz Isoflavones in aglycon mg	1 oz (28.35g) of nuts, 1 TB nut butter	/2 for nuts, none for rest Isoflavone total/1.2/7
Red/processed meat	1 oz all meat	4 oz unprocessed meat; 1.5 oz processed	/4 for unprocessed meat /1.5 for processed meat
Alcohol	5 oz wine, 12 fl oz beer, 1.5 fl oz liquor	4 oz wine, 12 oz beer, 1.5 oz of liquor	None unless wine.
Sodium		Percentiles of population	Use the percentiles given by Hoy, et al in the "Sodium Intake of the US Population" flyer
Trans fats	Total G	% of energy	Use total g and total calories to calculate % of energy
Long chain n-3	Mg/day	g/day	Add EPA and DHA, multiply by 1000

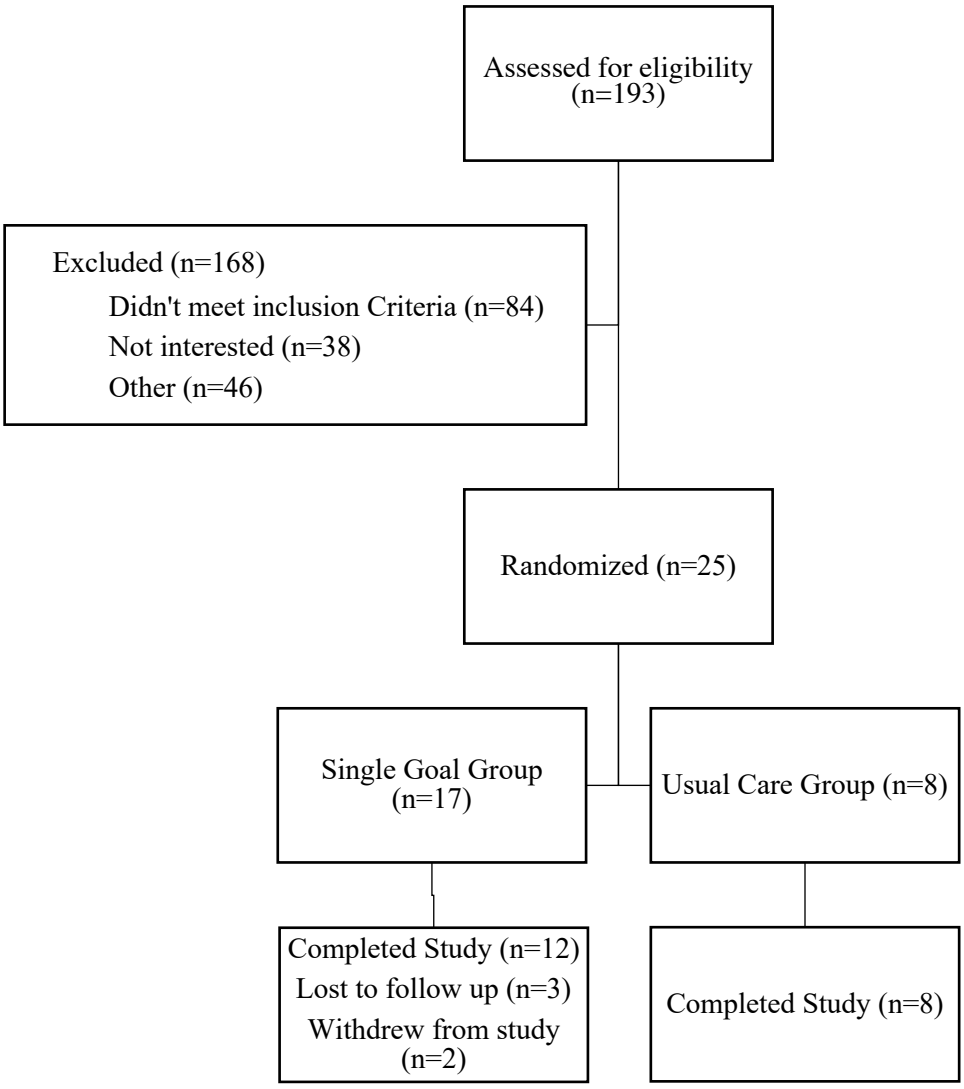


Figure 2: Consort Diagram for SG Study

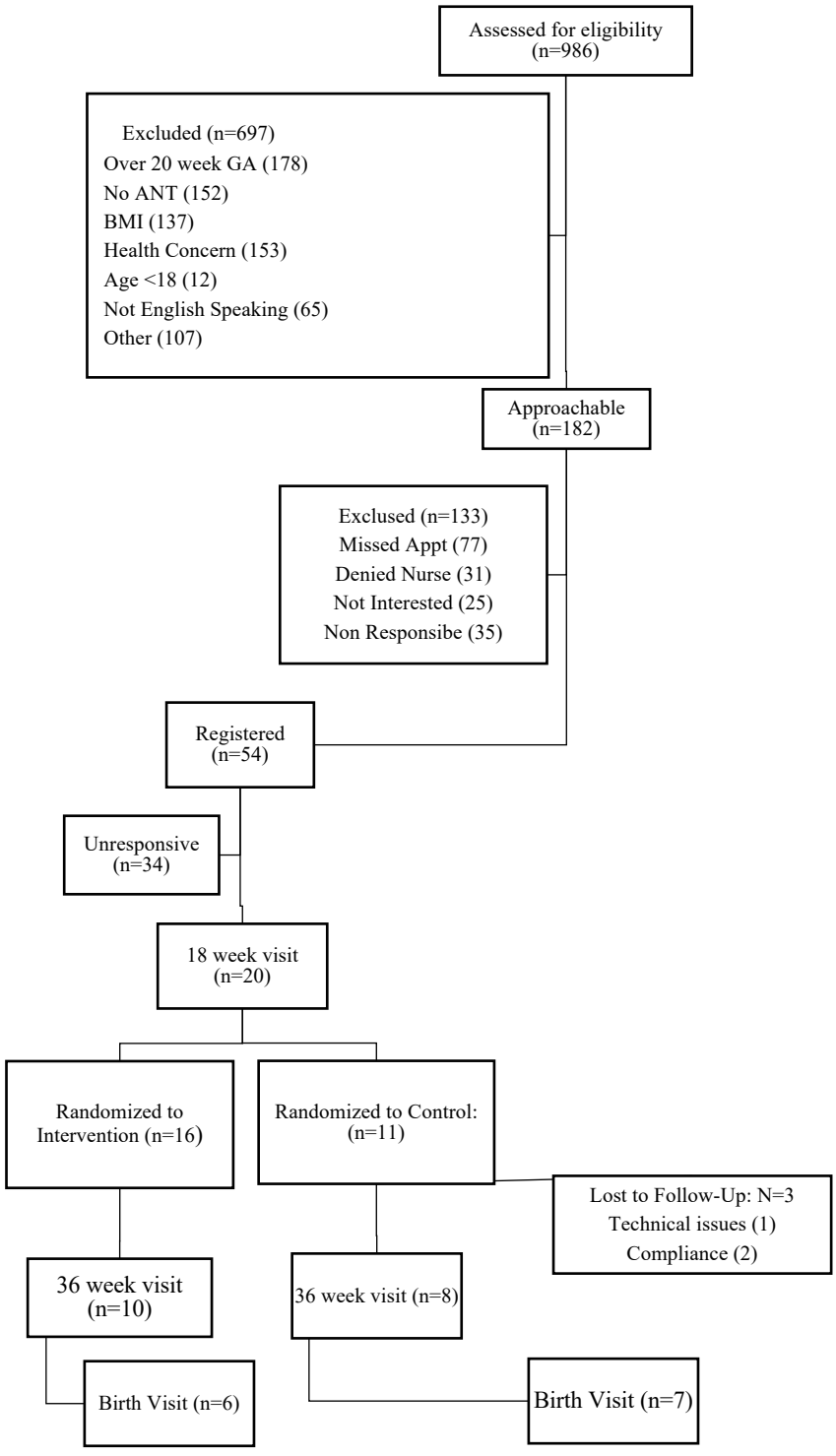


Figure 3: Consort Diagram for SG Study

Table 3: Descriptive statistics for usual care, single goal, and multiple goal.

	N	UC	N	SG	N	MG
Maternal Age (years)	19	29.1 ± 4.3	16	28.81 ± 3.9	21	30.0 ± 4.7
GA at Entry (weeks)	19	16.7 ± 3.3	16	13.7 ± 3.6*+	21	17.2 ± 1.6+
Pre-pregnancy Weight (kg)	19	74.4 ± 12.7	16	72.4 ± 18.4	20	74.7 ± 23.6
Pre-Pregnancy BMI (kg/m^2) **Normal (%)** **Overweight (%)** **Obese (%)**	19	27.9 ± 5.5 7 (36.8) 7 (36.8) 9 (26.3)	16	27.0 ± 5.2 7 (43.8) 4 (25.0) 5 (31.2)	21	28.3 ± 8.4 10 (47.6) 5 (23.8) 6 (28.6)
Total GWG (kg) **Not excessive (%)** **Excessive (%)**	16	17.7 ± 7.2* 4 (21.1) 11 (57.9)	16	13.4 ± 4.2*+ 8 (50.0) 8 (50.0)	15	12.6 ± 5.0*+ 7 (33.3) 8 (38.1)
BL Energy Intake (kcals)	18	1994 ± 779	16	1958 ± 372	21	1892 ± 792
BL %Calories from fat	18	32.6 ± 7.4	16	37.4 ± 7.6	21	34.4 ± 10.9
BL %Calories from carbs	18	51.4 ± 9.1	16	46.5 ± 8.0	21	49.7 ± 14.0
BL %Calories from Protein	18	16.0 ± 4.2	16	16.1 ± 3.0	21	15.8 ± 6.7
Race (%) **White** **Black** **Asian** **Other**	17	15 (78.9) - 1 (5.3) 1 (5.3)	16	13 (81.3) 2 (12.5) - 1 (6.3)	21	16 (76.2) 4 (19.0) 1 (4.8) -

Annual Income (%) **25K-50K** **50K-75K** **75K-100K** **100K -125K** **>125K**	19	5 (26.3) 3 (15.8) 4 (21.1) 5 (26.3) 2 (10.5)	16	3 (18.8) 6 (37.5) 2 (12.5) 4 (25.0) 1 (6.3)	21	7 (33.3) 5 (23.8) 1 (4.8) 2 (9.5) 6 (28.6)
Education Level (%) **High School or Less** **Post-Secondary** **Graduate Degree +**	19	5 (26.3) 5 (26.3) 9 (47.4)	16	4 (25.0) 8 (50.0) 4 (25.0	21	5 (23.8) 6 (28.6) 10 (47.6)

***Significant difference between control group and intervention (UC vs SG, UC vs MG)**

[+] Significant difference between intervention groups (SG vs MG)

Table 4: Change in diet quality scores from baseline to study end and between group differences

				Repeated Measures[a]		Change[b]		
Diet Quality Measure	Study Group	Mean Diet Quality Score (Baseline)	Mean Diet Quality Score (Study End)	Mean Change in Diet Quality	P-value for the interaction	Within group P-value for the change in diet quality during the intervention	P value for the main effect of group difference	Group Comparison	P-value
AHEI-2010	UC	50.6[a]	48.9[a]	-1.7	0.028*	0.59	0.066	UC vs SG	0.022*
	SG	48.6[a]	58.2[a]	9.6		0.009*		UC vs MG	0.017*
	MG	40.0[a]	48.8[a]	8.6		0.002*		SG vs MG	0.849
AHEI-P-2005	UC	57.5[a]	57.7[a]	0.13	0.39	NS	0.35	UC vs SG	NS
	SG	57.6[a]	63.5[a]	5.9		NS		UC vs MG	NS
	MG	50.7[a]	55.3[a]	4.5		NS		SG vs MG	NS
AHEI-P-2010	UC	71.2[a]	71.1[a]	-0.10	0.051	0.977	0.060	UC vs SG	0.025*
	SG	70.8[a]	82.4[a]	11.6		0.003*		UC vs MG	0.045*
	MG	60.8[a]	70.0[a]	9.1		0.002*		SG vs MG	0.590

a. Repeated measures ANCOVA: Covariates appearing in the model are evaluated for the following: maternal education level, baseline calories, baseline
b. ANCOVA: Covariates appearing in the model include maternal education, BL Energy level, study end kcals, and BL dietary quality index

*Denotes significant difference ($p<0.05$)

Table 6: Change in food group servings per day from baseline to study end and between group differences

Food Group	Study Group	Mean Food Group Servings/day (Baseline)	Mean Food Group Servings/day (Study End)	Mean Change in Food Group Servings	Repeated Measures[a] P-value for the interaction	Repeated Measures[a] Within group P-value for the change in food groups during the intervention	Change[b] P value for the main effect of group difference	Change[b] Group Comparison	Change[b] P-value
Fruit	UC	1.4[a]	1.1[a]	-0.31[a]	0.22	NS	0.19	UC vs SG	NS
	SG	0.58[a]	1.5[a]	0.87[a]		NS		UC vs MG	NS
	MG	.81[a]	0.82[a]	0.01[a]		NS		SG vs MG	NS
Vegetables	UC	2.4[a]	2.1[a]	-0.30[a]	0.24	NS	0.76	UC vs SG	NS
	SG	2.9[a]	2.4[a]	-3.8[a]		NS		UC vs MG	NS
	MG	1.6[a]	2.4[a]	0.75[a]		NS		SG vs MG	NS
Legumes	UC	0.67[a]	0.39[a]	-0.27[a]	0.021*	0.36	0.040*	UC vs SG	0.012*
	SG	0.92[a]	1.7[a]	0.74[a]		0.026*		UC vs MG	0.233
	MG	0.38[a]	0.70[a]	0.32[a]		0.20		SG vs MG	0.111

a. Repeated measures ANCOVA: Covariates appearing in the model are evaluated for the following: maternal education level, baseline calories, baseline
b. ANCOVA: Covariates appearing in the model include maternal education, BL Energy level, study end kcals, and BL dietary quality index

Table 6: Change in micronutrient intake per day from baseline to study end and between group differences

Nutrient	Study Group	Mean nutrient intake/day (Baseline)	Mean nutrient intake/day (Study End)	Mean Change in nutrient intake	Repeated Measures[a] P-value for the interaction	Repeated Measures[a] Within group P-value for the change nutrient intake during the intervention	Change[b] P value for the main effect of group difference	Change[b] Group Comparison	P-value
Iron (mg)	UC	14.9[a]	15.4[a]	0.49	0.39	NS	0.40	UC vs SG	NS
	SG	14.6[a]	18.3[a]	3.7		NS		UC vs MG	NS
	MG	14.4[a]	16.9[a]	2.6		NS		SG vs MG	NS
Calcium (mg)	UC	1032.5[a]	1101.3[a]	68.8	0.42	NS	0.16	UC vs SG	NS
	SG	1072.5[a]	1278.9[a]	206.4		NS		UC vs MG	NS
	MG	1008.3[a]	984.4[a]	-23.4		NS		SG vs MG	NS
Folate (mcg)	UC	475.6[a]	609.2[a]	133.5	0.58	NS	0.75	UC vs SG	NS
	SG	528.0[a]	668.2[a]	140.2		NS		UC vs MG	NS
	MG	588.9[a]	634.9[a]	46.0		NS		SG vs MG	NS
Saturated Fat (g)	UC	24.9[a]	21.8[a]	-3.1	0.78	NS	0.44	UC vs SG	NS
	SG	26.7[a]	24.6[a]	-2.1		NS		UC vs MG	NS
	MG	25.1[a]	23.7[a]	-1.3		NS		SG vs MG	NS

a. Repeated measures ANCOVA: Covariates appearing in the model are evaluated for the following: maternal education level, baseline calories, baseline
b. ANCOVA: Covariates appearing in the model include maternal education, BL Energy level, study end kcals, and BL dietary quality index

Figure 4a: Mean AHEI-2010 scores from baseline to study end

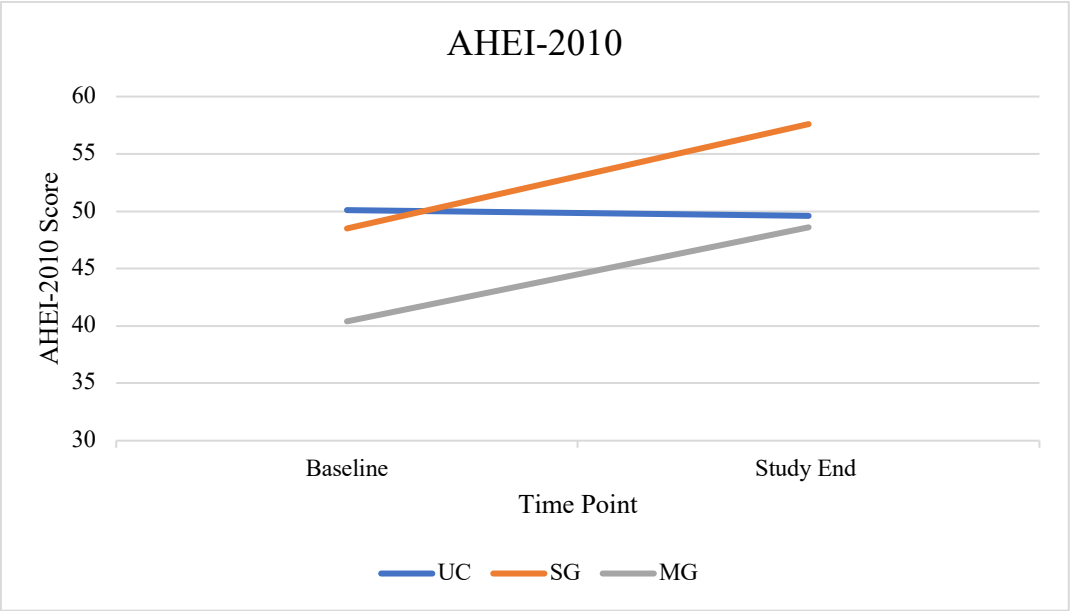


Figure 4b: Mean AHEI-P-2005 scores from baseline to study end

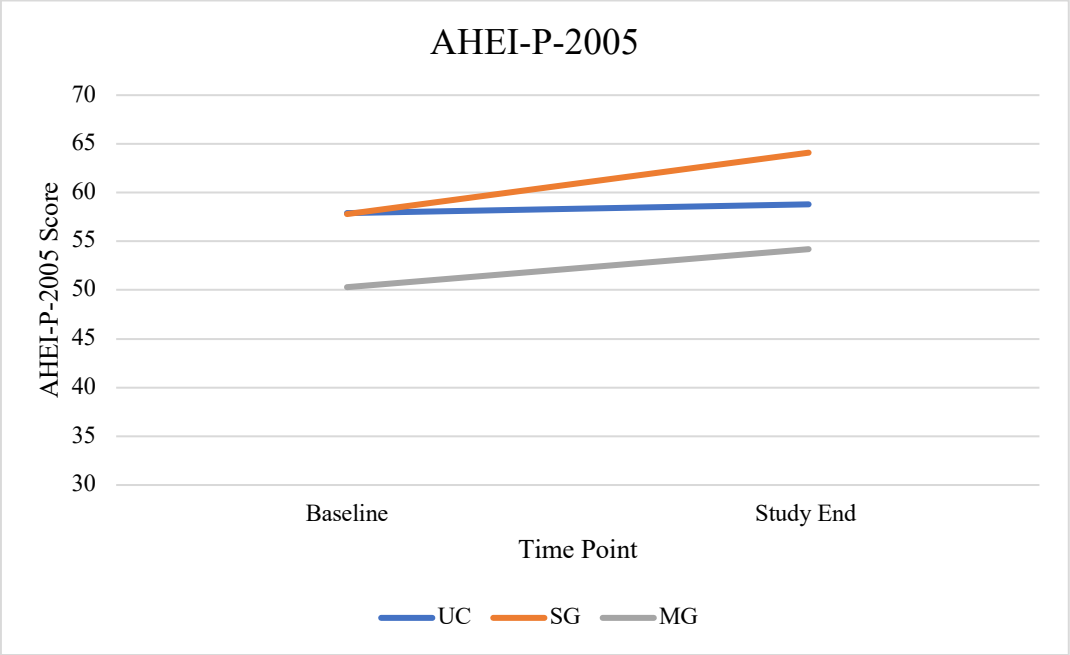


Figure 4c: Mean AHEI-P-2010 scores from baseline to study end

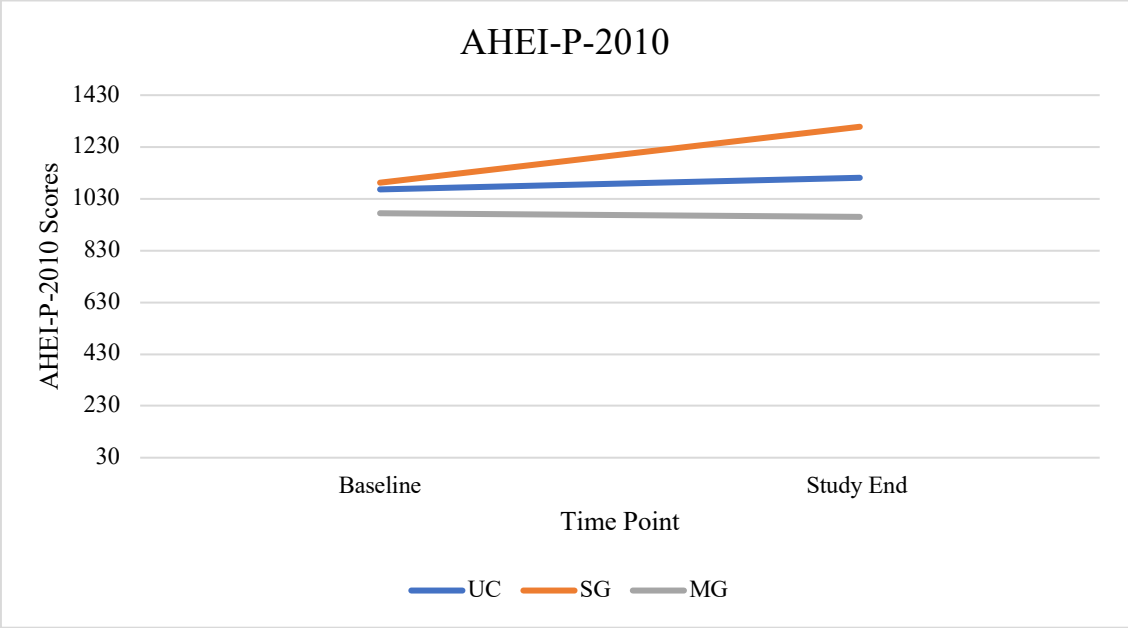
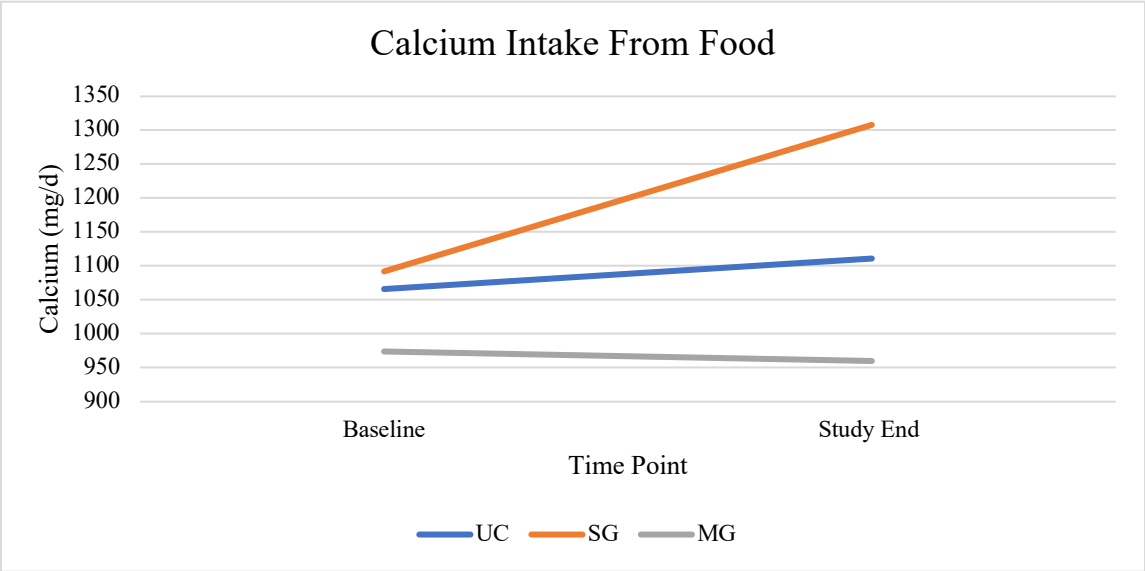
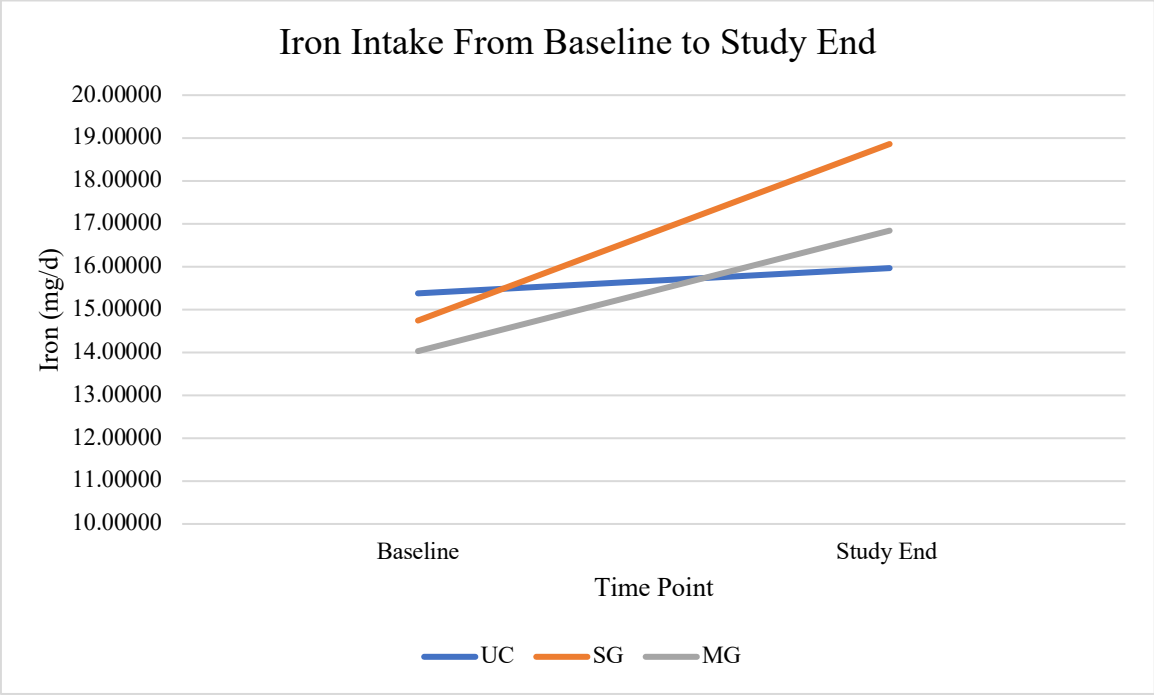


Figure 5: Change in daily calcium intake from baseline to study end



*Calcium intake is not considering supplemental calcium included in prenatal supplements

Figure 6: Change in daily iron intake from baseline to study end



*Iron intake is not considering supplemental calcium included in prenatal supplements

Figure 7: Change in legume servings per day from baseline to study end

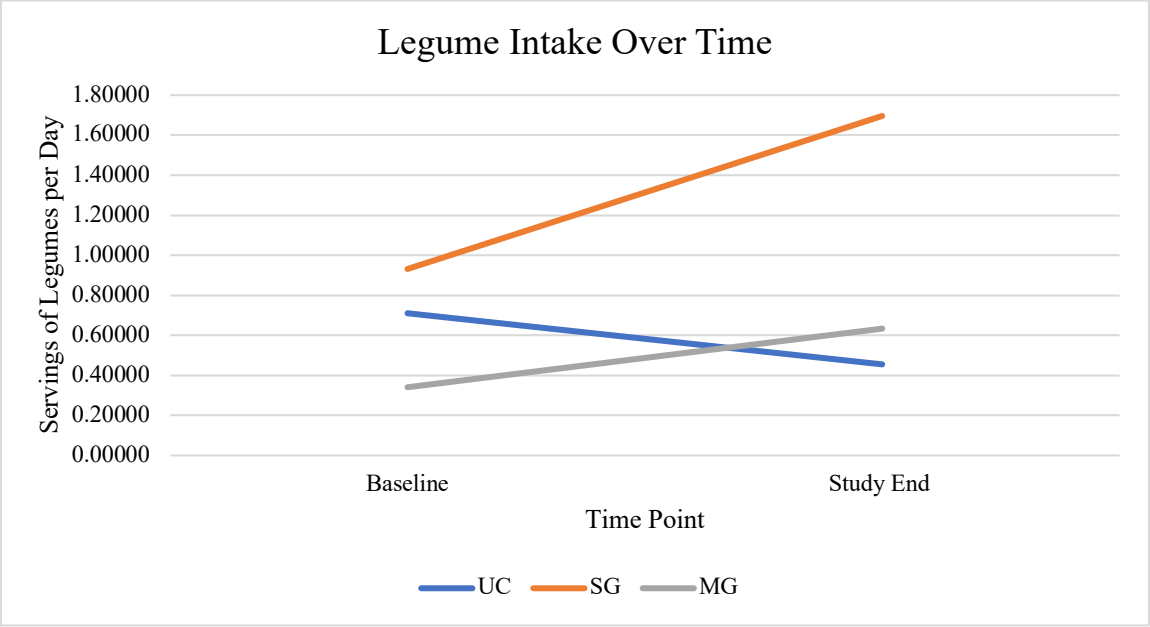


Table 7: Mean intake of nutrients of concern in MG, SG, and UC group at study end compared to the EAR for pregnant women

		Mean Intake (±SD)	% of Participants Meeting EAR	RDA During Pregnancy
Calcium (mg)	**MG**	960 (±506)	62%	800 mg
	SG	1308 (±358)	69%	
	UC	1111 (±326)	56%	
Iron (mg)	**MG**	16.27 (±8.55)	19%	22 mg
	SG	18.86 (±7.27)	31%	
	UC	15.96 (±6.12)	11%	
Folate	**MG**	606 (±346)	57%	520 mg
	SG	686 (±378)	44%	
	UC	635 (±348)	33%`	

RESEARCH CONSENT FORM

Feasibility of a single goal intervention to promote appropriate gestational weight gain Funding sources: Department of Dietetics and Nutrition, the National Institutes of Health, and the University of Kansas Research Institute

You are being asked to join a research study. You are being asked to take part in this study because you are pregnant. You do not have to participate in this research study. The main purpose of research is to create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate.

Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you and your infant can still get medical care and services at the University of Kansas Medical Center (KUMC).

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read the form carefully and ask as many questions as you need to, before deciding about this research.

You can ask questions now or at any time during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating.

This research study will take place at the University of Kansas Medical Center (KUMC) with Holly Hull, PhD as the researcher. About 90 people will be in the study at KUMC.

BACKGROUND

Over 50% of women gain excessive weight during pregnancy. Excessive gestational weight gain (GWG) is associated with high infant birth weight and maternal conditions including hypertension and gestational diabetes (GDM). Research shows a strong relationship between GWG and their children's development of obesity, diabetes and cardiovascular disease later in life.

It is important for women to gain an appropriate amount of weight during pregnancy, and have healthy eating habits for health of the mother and child. Pregnant women are encouraged to consume a healthy diet that includes ≥30 grams of fiber per day. Research has shown that most women fall well below this recommendation. A healthy diet with ≥30 grams of fiber per day is recommended and may prevent excessive GWG. Many women have poor eating habits during pregnancy and gain an excessive amount of weight.

In this study, the investigator is researching whether consuming ≥30 grams or more of fiber per day can help pregnant women gain an appropriate amount of weight during their pregnancy.

PURPOSE

By doing this study, researchers hope to learn if consuming a diet of ≥30 grams of fiber per day can prevent gaining too much weight.

PROCEDURES

If you are eligible and decide to participate in this study, your participation will last up to 12 weeks. This study will follow you during your pregnancy. You will be asked to track how much fiber you consume daily, track your weekly body weight, and attend weekly group based phone calls.

You will continue to have your routine prenatal care with your regular doctor.

You will be assigned to one of the following study treatment groups:

- Group 1: Subjects will participate in the group based phone counseling weekly from week 16 to 28 of pregnancy.
- Group 2: Subjects will continue with their usual activity. Participants in this group will not be advised on their diet but will report their body weight weekly.

You will be recruited between 9 to 15 weeks and enrolled in the study between 10 and 16 weeks of pregnancy, and will start the intervention after you are enrolled. You will be asked to read and sign this consent form before any tests or procedures can be completed. Table 1 describes study activities at visit 1 and visit 2.

Table 1. An outline of study visits and procedures.

Study procedure	Baseline	6 weeks after starting study	Visit 2
Questionnaires	•		•
Urine	•		•
Stool	•		•
Maternal body weight	•		•
Maternal body composition (Bod Pod)	•		•
Maternal total body water	•		•
Maternal diet recalls	•	•	•
Satisfaction survey (group 1 only)			•
Process evaluation (group 1 only)			•

Group 1 activities only: If you are assigned to Group 1, you will have weekly hour long conference calls with a Registered Dietitian. You will be asked to call in to a toll free phone number during group session times for one hour, once a week. This will happen after you are enrolled and last for up to 12 weeks. You will be given a binder with weekly lessons that will be discussed during your group session. During the call, you will participate in structured educational lessons on a variety of topics related to healthy eating focused on fiber. At the first visit, the fiber diet will be described. You will be given instruction on how to download and use an app to track your fiber intake and body weight. You will be given a body weight scale and asked to report your weight each week. You will be asked to enter the food that you eat daily and enter your body weight weekly. You will enter this information into the app (LifeScience Technologies, LST) or their companion website.

If you are in group 1, at the end of the study you will be asked to complete a questionnaire and structured interview by telephone and should only take 20-30 min to complete. These questions

are to assess how you feel about your involvement in the study at the end of their pregnancy or after completing the intervention.

Diet intervention (weeks 1-12)

- You will start the high fiber diet the Monday of the week you start the weekly group phone calls. This date will be assigned to you once group enrollment is reached.

- You will receive a call from the dietitian if you are not meeting your fiber goals to discuss barriers and give advice. The phone call will last about 10 – 15 minutes depending on how many questions you may have for the dietitian.

- You will pick up your free high fiber snacks at Visit 1. You will be advised to eat two snacks per day.

Group 2 activities: Group 2 will not participate in the diet intervention or education lessons and will not use the app. If you are assigned to Group 2, you will continue with your usual activity levels. You will be given a body weight scale and asked to report your weight each week by phone, email, or text message. At 6 weeks after the baseline visit, you will receive a call to assess your diet.

Listed below are descriptions of what will occur at each visit. Both group 1 and group 2 will participate in visit 1 and visit 2.

<u>Visit 1 (after enrollment between 10-15 weeks)</u>

This visit will occur in the basement of the Child Development Unit, located at 3901 Rainbow Blvd, Kansas City, KS, 66160. The following procedures will occur:

- Your body weight, total body water, and body fat will be measured using the Bod Pod. Total body water will be measured using a platform bioelectrical impedance scale that you stand on. It sends a very low frequency signal from one foot to the other that you cannot feel and is not harmful. The Bod Pod is a computerized, egg-shaped chamber and it measures a person's mass and volume, from which their body density is determined. Using these data, body fat and lean muscle mass can then be calculated. The procedure will take about 5 minutes and you will need to change into a tight-fitting garment like a swimsuit or spandex shorts before the test. You will have a private place to change clothes and enter the chamber.
- You will be asked questions about your health, including your medical and obstetric history, pre-pregnancy weight, and smoking history.
- You will complete a questionnaire to assess your nutrition knowledge and asked to report what personal care products you use.
- You will be asked to complete questionnaires about the stress you have experienced during you pregnancy and questions on your diet. The questionnaires will ask you about the types and amounts of foods you eat. You will be asked about any vitamin or supplement use.
- You will be provided instructions on how to collect and store a stool sample. We will examine if there are differences between group 1 and group 2 for bacteria found in the stool.

- You will provide a urine sample. We will examine if there are differences in weight gain based on the levels of metabolites found in the urine.
- You will be assigned to one of the treatment groups.
- On two days after your visit, you will be called and ask about your diet. This should take between 15-20 minutes.
- This visit will last approximately 60 minutes.

At 6 weeks after you enroll in the study, you will receive a call to assess your diet. This will take approximately 20-30 minutes.

Visit 2 (at the completion of the 12 week intervention)
This visit will occur in the basement of the Child Development Unit, located at 3901 Rainbow Blvd, Kansas City, KS, 66160. The following procedures will occur:

- Your body weight and body fat will be measured using the bioelectrical impedance scale and the Bod Pod.
- You will complete a questionnaire to assess your nutrition knowledge and asked to report what personal care products you use.
- You will be asked to provide a urine sample and bring in your stool sample.
- This visit will last approximately 45 minutes.
- On two days after your visit, you will be called and ask about your diet. This should take between 15-20 minutes.

RISKS
Any risks associated with your child's standard care medical treatment will be addressed in separate hospital consent forms.

There are not expected to be any major health risks associated with taking part in this study. Although every reasonable effort has been taken, confidentiality during Internet communication procedures cannot be guaranteed. The risk associated with communication over the internet for this study would be similar to risk associated with internet communication used every day. You may want to include a passcode on your mobile device to prevent unauthorized access to the research data. You may also want to add the ability to perform a remote wipe of your mobile device if the device is lost or stolen. The Bod Pod procedure used to measure body density is not invasive. It does require entering a chamber and you might be stressed if you have a tendency to be claustrophobic. The investigators would be happy to show you the chamber so that you could decide.

Questionnaires
There is a risk of feeling uncomfortable while answering some of the questions in the questionnaires. If you feel uncomfortable at any time, you may skip a question or stop answering questions all together.

Possibility of Unknown Risks
There may be other risks of the study that are not yet known.

NEW FINDINGS STATEMENT

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS

You and your infant will not benefit from this study. We hope that the information learned from this study will benefit other babies in the future.

ALTERNATIVES

Participation in this study is voluntary. Deciding not to participate will have no effect on the care or services you or your infant receives at the University of Kansas Medical Center.

COSTS

The study will pay for all study-related medical services provided during this study. These services include the study visits, study-related tests and procedures such as the as listed in this consent form.

Any other medical visits and procedures you have outside of the study due to other standard of care treatments for your pregnancy or other health issues are billable to you or your insurance through normal hospital billing practices. Standard of care means necessary for the care of a medical issue as determined by your doctor and not necessary for this study.

FINANCIAL DISCLOSURE

The investigator and the KUMC Research Institute, Inc. will receive payment from the funding agency, the Department of Dietetics and Nutrition, for conducting this study. Payments will be used for research purposes only.

PAYMENT TO SUBJECTS

If you are in group 1 and complete all study visits, you will receive up to $305. You will receive $60 for the baseline visit after completion of the 24 hour diet recalls and collecting the urine and stool sample, $5 for completion of the 6 week diet recall, and collection of the urine and stool samples and $60 for visit 2 after completion of the 24 hour diet recalls and collection of the urine and stool samples. In addition, you will receive $5 for each time you report your body weight weekly, $5 each time you report your daily fiber intake weekly, and $5 for each time you attend the weekly lessons by phone (12 reports and 12 classes).

If you are in the group 2 and complete all study visits, you will receive up to $185. You will receive $60 for the baseline visit after you complete the 24 hour diet recalls and collecting the urine and stool sample and $60 for visit 2 after completion of the 24 hour diet recalls and collecting the urine

and stool sample. In addition, you will receive $5 for each body weight report you text to the study coordinator. If your participation in this study ends early, you will be paid only for the visits and reports/class attendance you have completed.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one will know where you spent the money.

You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

IN THE EVENT OF INJURY

If you or your infant has any problem during this study, you should immediately contact your treating physician first and later contact Holly Hull, PhD at 913-588-5358.

INSTITUTIONAL DISCLAIMER STATEMENT

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow for payment to persons who are injured in research at KUMC.

CONFIDENTIALITY AND PRIVACY AUTHORIZATION

The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. Your health information is protected by a federal privacy law called HIPAA. By signing this consent form, you are giving permission for KUMC to use and share your health information. If you decide not to sign the form, you cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities and from your medical record. You may be identified by information such as name, address, phone number, date of birth, or other identifiers. Your health information will be used at KUMC by Dr. Hull, members of the research team, the University of Kansas Hospital Medical Record Department, the KUMC Research Institute, and officials at KUMC who oversee research, including members of the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies. By signing this form, you are giving Dr. Hull and the research team permission

to share information about you with persons or groups outside KUMC. Your information will be shared with LifeScience Technologies and U.S. agencies that oversee human research (if a study audit is performed). These groups or agencies may make copies of study records for auditing purposes. The purpose for using and sharing your information is to make sure the study is done properly and to evaluate the safety and effectiveness of the intervention.

The HIPAA privacy law may not apply to everyone who receives your health information. Your information might not be protected by HIPAA if persons outside KUMC disclose it. In some cases, there may be other laws that protect your information from improper use.

Your permission to use and share your health information will not expire unless you cancel it. Any research information that is placed in your medical record will be kept indefinitely.

While you are participating in this study, you may see and copy any study information that is placed in your KUMC medical record. However, some study information is kept only by the researcher. The records kept only by the researcher may not be available to you until the end of the study.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

QUESTIONS

Before you sign this form, Holly Hull, PhD or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

SUBJECT RIGHTS AND WITHDRAWAL FROM THE STUDY

You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC. The entire study may be discontinued for any reason without your consent by the investigator conducting the study.

You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Holly Hull, PhD. The mailing address is Holly Hull, PhD, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The research team will stop collecting any additional information about you. The research team may use and share information that was gathered before they received your cancellation.

CONSENT

Dr. Holly Hull or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

Permission to be contacted about future studies

I give permission to be contacted about future studies that might require more information:

	YES	NO
About my child's growth and development	☐	☐
About any other health issues my child may experience	☐	☐
About my pregnancy and its after effects	☐	☐
About any other health issues I may experience	☐	☐

_____	_____	_____
Participant – Print Name	Signature	Date
_____	_____	_____
Person Obtaining Consent – Print Name	Person Obtaining Consent Signature	Date

RESEARCH CONSENT FORM
Promoting appropriate weight gain pregnant women
Funding sources: University of Kansas School of Health Professions, Kansas City Area Life Sciences Institute

You are being asked to join a research study. You are being asked to take part in this study because you are pregnant. You do not have to participate in this research study. The main purpose of research is to create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate.

Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you and your infant can still get medical care and services at the University of Kansas Medical Center (KUMC).

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read the form carefully and ask as many questions as you need to, before deciding about this research.
You can ask questions now or at any time during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating.

This research study will take place at the University of Kansas Medical Center (KUMC) with Holly Hull, PhD as the researcher. About 90 people will be in the study at KUMC.

BACKGROUND
Over 30% of women who become pregnant are overweight and approximately 70% of overweight women gain excessive weight during pregnancy. Maternal overweight and excessive gestational weight gain (GWG) are associated with high infant birth weight and maternal conditions including hypertension and gestational diabetes (GDM). Research shows a strong relationship between maternal obesity and GWG and their children's development of obesity, diabetes and cardiovascular disease later in life.

It is important for women to gain an appropriate amount of weight during pregnancy, have healthy eating habits and get regular physical activity for health of the mother and child. Pregnant women are encouraged to accumulate ≥30 minutes of physical activity on most days of the week. Research has shown that most women fall well below this recommendation Regular physical activity during pregnancy is recommended and shown to prevent excessive GWG. Many women have poor eating habits during pregnancy and gain an excessive amount of weight.

Group based phone counseling is a new way provide counseling and education. Participants "meet" during a conference call with fellow participants and a Health Educator. Each week a different educational topic is covered.

Protocol:
Gruve® study accelerometer, which is a device that can measure activity intensity and duration, and can be used to calculate how many calories are burned. The Gruve® gives real-time feedback

to the user by vibrating when the user has been sedentary for too long and by displaying a color coded bar that shows how close the user is to achieving their daily activity goal.

In this study, the investigator is researching group based phone counseling and the Gruve® to determine if they can help overweight pregnant women gain an appropriate amount of weight during their pregnancy. PURPOSE By doing this study, researchers hope to learn if the use of group based phone counseling and the Gruve® help prevent excessive GWG. PROCEDURES If you are eligible and decide to participate in this study, your participation will last up to 20 weeks. This study will follow you during your pregnancy and for 1 week after you give birth. You will be asked to come to the clinic about 3 times during this study. You must have computer and internet access in order to participate in this study.

You will continue to have your routine prenatal care with your regular doctor.
You will be assigned to one of the following study treatment groups: Group 1: Subjects will participate in the group based phone counseling weekly and wear the Gruve® from week 18 to 36 of pregnancy. Group 2: Subjects will use the Gruve® from week 18 to week 36 of pregnancy. Group 3: Subjects will continue with their usual activity levels.

You will be enrolled in the study between 12 and 16 weeks of pregnancy, but will not start the intervention until 18 weeks of pregnancy. You will be asked to read and sign this consent form before any tests or procedures can be completed.

If you are assigned to Group 1, you will have weekly hour long conference calls with a health educator. During the call, you will participate in structured educational lessons on a variety of topics including healthy eating, physical activity, meal preparation, and breastfeeding.

If you are assigned to Group 1 or 2, you will use the Gruve® device from 18 to 36 weeks of pregnancy. The Gruve® records how active you are on a daily basis and based on your activity levels, develops a program to slowly increase your activity over 16 weeks. Each day you have an activity amount goal, and a bar on top of the Gruve® tracks how close you are to meeting that goal. Once the bar turns green, you have reached your goal for the day. This repeats each day. If you have been sitting for too long, the Gruve® vibrates to alert you to move around. The Gruve® plugs into a USB port in your computer and your data is uploaded to the companion Gruve® website. Here you can see your daily activity levels to track your progress.

Visit 1 (18-20 weeks of pregnancy) You will need to fast (don't eat or drink anything) for 12 hours before this visit.

This visit will occur in the Hoglund Brain Imaging Center, located at 2021 W. 38th Ave., Kansas City, KS 66103. The following procedures will occur:

 You will be asked questions about your health, including your medical and obstetric history, pre-pregnancy weight, and smoking history.
 Your blood pressure will be measured.
 You will have an ultrasound performed, which is a test that uses the reflections of high-frequency sound waves to make an image of your baby. This test will estimate the size and weight

of your baby.
 Your weight, height, and wrist circumference will be measured. Circumference will be measured with a tape measure at the wrist.
 Skin fold measurements will be taken by pinching the skin and measuring the thickness with an instrument called a caliper. Measurements will be taken on the arm, back, hip, thigh, and calf.
 You will be asked to complete questionnaires about the stress you have experienced during you pregnancy and questions on your diet and physical activity. The questionnaires will ask you about the types and amounts of foods you eat and your degree of physical activity at home and at work during your pregnancy. You will be asked about any vitamin or supplement use.
 You will complete questionnaires about your motivation, goal setting, and the kinds of things that encourage you to reach your goals. Approximately 4 teaspoons of blood will be drawn from a vein in your arm for laboratory tests. Factors related to pregnancy, health and nutrition will be explored. Some examples, but not a complete list of factors we will study include fatty acids, lipids, glucose, insulin and hormones related to pregnancy and growth.
 You will be assigned to one of the treatment groups. If you are assigned to the group using the Gruve®, you will be given the device and instructions on how to use it. This visit will last approximately 1 hour.

If you are assigned to Group 1, you will be asked to call in to a toll free phone number during group session times for one hour, once a week. This will start at week 18 and end at week 36 of pregnancy. You will be given a binder with weekly lessons that will be discussed during your group session, led by a Health Educator.

If you are assigned to Groups 1 or 2, you will be asked to use the device through 36 weeks of your pregnancy. During the first week of wearing the Gruve®, you will be asked to go about your normal routine. This is called the assessment period. The Gruve® will determine your current physical activity level and calculate your physical activity goals that are appropriate for your pregnancy. You will be given a body weight scale and asked to report your weight each week. Your weight will be used to make adjustments to your daily physical activity goals.

If you are assigned to Group 3, you will continue with your usual activity levels. You will be given a body weight scale and asked to report your weight each week.
Visit 2 (34-38 weeks of pregnancy) You will need to fast (don't eat or drink anything) for 12 hours before this visit.

This visit will occur in the Hoglund Brain Imaging Center, located at 2021 W. 38th Ave., Kansas City, KS 66103.

The following procedures will occur:
 You will be asked questions about your health and how your pregnancy is progressing. If you are assigned to the group using the Gruve®, information about your usage of the device and your physical activity will be collected from the Gruve® website.
 You will have an ultrasound performed to estimate the size and weight of your baby. Your weight and wrist circumference will be measured. Skin fold measurements will be taken.
 You will be asked to complete questionnaires on your diet and physical activity. Approximately 4 teaspoons of blood will be drawn from a vein in your arm for laboratory tests.

 Your heart rate and your baby's heart rate will be recorded using a special device called biomagnetometer (MCG). The heart naturally creates a magnetic field, which can be detected by the MCG.

You will be asked to do the following before and during the MCG measurement:
o Drink at least 8 oz of water before testing begins in the clinic. Your body weight, heart rate, and blood pressure will be recorded before the MCG recording.

o Wear a sports bra or something similar with no underwire, change into scrubs (a cotton pullover top and slacks with a loose waistband), and remove any jewelry prior to testing. o Sit in an adjustable, reclining chair designed to support pregnant women. Every effort will be made to make you comfortable in the chair. You should not proceed with testing if you are uncomfortable. The biomagnetometer will be positioned to lightly touch your abdomen. Prior to starting the MCG, an ultrasound examination will be performed to help position the MCG.

After completing the ultrasound, the study team will leave the room and close the door. Someone may stay in the room with you if you like. The study team will be able to communicate with you through a sound system. The study team will come in at any time if you become tired or uncomfortable. o Hold still for a few minutes when the testing begins. The study team will first try to find the signals coming from your baby's heart.

 This visit will last approximately 1 hour.
Visit 3 (1-3 days after delivery) You will be asked to bring your infant with you to this visit. This visit will occur in the basement of the Child Development Unit, located at 3901 Rainbow Blvd., Kansas City, KS 66160. The following procedures will occur: You will be asked questions about your health.

 Information about your delivery will be collected from your medical record. If you deliver your baby at a hospital other than KU, the study team will request your delivery record and your newborn's record from that institution. You may be asked to sign an additional form for the other hospital to release this information.
 Your weight and wrist circumference will be measured.
 Skin fold measurements will be taken.

At this visit, measurements of your infant will be taken to assess his/her growth. The following procedures will occur:

 Your infant's weight, length, head circumference, and abdominal circumference will be measured. Circumference measurements will be taken with a tape measure.
 Your infant's skin fold measurements will be taken by pinching the skin and measuring the thickness with an instrument called a caliper. Measurements will be taken on your infant's arm, back, hip, thigh, side, and abdomen.
 Your infant's body composition will be determined using a machine called the Pea Pod®. Your child will lie on their back on a flat tray that slides into a transparent plastic chamber. The amount of volume (space) occupied by your infant will be measured. This measurement takes 2 minutes. The baby will be undressed during this procedure, except for a standard hat. The temperature of

the Pea Pod® chamber is about 880F, which is comfortable for an undressed newborn. You will be able to monitor your child during the test through the transparent top.
 This visit will last approximately 45 minutes.

RISKS

Any risks associated with your child's standard care medical treatment will be addressed in separate hospital consent forms.There are not expected to be any major health risks associated with taking part in this study. There are no known risks associated with the MCG measurement. However, the following are potential unexpected risks.

Blood Draws During the study, you will have blood drawn for laboratory tests.
The risks of drawing blood from a vein may include:
 bleeding
 faintness
 swelling of the vein
 pain
 bruising
 infection
 discomfort

This will be minimized by careful and clean techniques
Infant Body Composition Testing (Pea Pod®) Your infant may cry upon being placed in the Pea Pod® due to physical separation from you.

Skin Fold Measurements You may feel a pinch when the calipers are used to measure your skin folds. Your infant may feel a pinch when the calipers are used and may cry during the procedure. Questionnaires There is a risk of feeling uncomfortable while answering some of the questions in the questionnaires. If you feel uncomfortable at any time, you may skip a question or stop answering questions all together.

Exercise Risks There are certain risks and discomforts that may be associated with exercise that include temporary shortness of breath, muscle fatigue, sweating, and physical discomfort. Muscles may be sore up to three days after performing the exercise. Also, there exists the possibility of an undiagnosed medical problem that may surface during exercise. These include abnormal blood pressure response, fainting, irregular, fast, or slow heart rate, and in rare instances, heart attack, stroke, or death. If you experience one of these symptoms, please contact your OB for advisement. Possibility of Unknown Risks There may be other risks of the study that are not yet known.

NEW FINDINGS STATEMENT

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs. BENEFITS You and your infant will not benefit from this study. We hope that the information learned from this study will benefit other babies in the future. ALTERNATIVES Participation in this study is voluntary. Deciding not to participate will have no effect on the care or services you or your infant receives at the University of Kansas Medical Center. COSTS The study will pay for all study-related medical services provided during this study. These services include the study visits, the Gruve® and access to the

Gruve® website, study-related tests and procedures such as the blood draws, MCG, and infant body composition test as listed in this consent form.

Any other medical visits and procedures you have outside of the study due to other standard of care treatments for your pregnancy or other health issues are billable to you or your insurance through normal hospital billing practices. Standard of care means necessary for the care of a medical issue as determined by your doctor and not necessary for this study. FINANCIAL DISCLOSURE The investigator and the KUMC Research Institute, Inc. will receive payments from the funding agencies, the University of Kansas School of Health Professions and the Kansas City Area Life Sciences Institute, for conducting this study. Payments will be used for research purposes only. PAYMENT TO SUBJECTS If you complete all study visits, you will receive up to $240. You will receive $50 for Visits 1, 2 and 3 and $5 for each body weight report/class attendance (18 reports/classes). If your participation in this study ends early, you will be paid only for KUMC IRB # 13749 | Approval Period 6/6/2014 – 6/2/2015 | FWA# 00003411
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You will be given a ClinCard, which works like a debit card. After a study visit, payment will added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one will know where you spent the money.
You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795. The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential. IN THE EVENT OF INJURY If you or your infant has any problem during this study, you should immediately contact Holly Hull, PhD at 913-588-5358. INSTITUTIONAL DISCLAIMER STATEMENT If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow for payment to persons who are injured in research at KUMC.

CONFIDENTIALITY AND PRIVACY AUTHORIZATION The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Your health information is protected by a federal privacy law called HIPAA. By signing this consent form, you are giving permission for KUMC to use and share your health information. If you decide not to sign the form, you cannot be in the study.

Page 9 of 12 Protocol: Gruve® study The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities and from your medical record and your infant's medical record. You may be identified by information such as name, address, phone, date of birth, social security number, or other identifiers. Your health information will be used at KU Medical Center by Dr. Holly Hull, Dr. Debra Sullivan, Dr. Kathleen Gustafson, Dr. Susan Carlson, members of the research team, the University of Kansas Hospital Medical Record Department, the KUMC Research Institute, the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies. Study records might be reviewed by government officials who oversee research, if a regulatory review takes place.

The research team's conduct with you will be professional and every measure to ensure privacy will be taken. Conducting of the consenting process will be done in a private room along with the collection of any questionnaires.

All study information that is sent outside KU Medical Center will have your name and other identifying characteristics removed, so that your identity will not be known. Because identifiers will be removed, your health information will not be re-disclosed by outside persons or groups and will not lose its federal privacy protection. Your permission to use and share your health information will not expire unless you cancel it. QUESTIONS Before you sign this form, Holly Hull, PhD or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. SUBJECT RIGHTS AND WITHDRAWAL FROM THE STUDY You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC. The entire study may be discontinued for any reason without your consent by the investigator conducting the study.

You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Holly Hull, PhD. The mailing address is Holly Hull, PhD, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The research team will stop collecting any additional information about you. The research team may use and share information that was gathered before they received your cancellation.
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CONSENT
Dr. Holly Hull or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered. You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____
Signature of Participant Time Date

Print Name of Person Obtaining Consent
_____ _____

_____
Signature of Person Obtaining Consent

Date

Permission to be contacted about future studies I give permission to be contacted about future studies that might require more information:

YES NO

About my child's growth and development
□ □
About any other health issues my child may experience
□ □
About my pregnancy and its after effects
□ □
About any other health issues I may experience
□ □
Person Obtaining Consent – Print Name Person Obtaining Consent Signature Date
OPTIONAL SAMPLE STORAGE AND FUTURE USE You are being asked to allow left-over blood samples to be stored for future research. If you agree, your samples will be used for future research studies involving pregnancy, genes, or nutrition. The samples will be stored at Dr. Hull's research laboratory at KUMC. Your samples will be stored by a unique code and no personal identifying information will be included with them. Your samples will be stored indefinitely.
Some of the future research might include genetic testing. There is a small risk that if people other than the researchers were given your genetic facts, they could misuse them. If genetic information was given to employers or insurers it could affect your ability to get a job or be insured. Misuse

could cause problems for family members. In order to minimize these risks, your genetic information will be kept confidential.

Genetic Information Nondiscrimination Act (GINA) A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: Health insurance companies and group health plans may not request your genetic information that we get from this research. Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that we get from this research when making decisions to hire, promote, or fire you or when setting the terms of your employment. The GINA protections do not help you if you work for a company with less than 15 employees.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.
The information about the uses and disclosures of your health information for the main study also apply to this additional testing. You may choose not to participate in optional sample storage and future use, while still participating in the main study. You may also withdraw your consent to store your samples for future research at any time.

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You and your doctor will not get the results of any future testing. The results of your future testing will not be put in your medical record.

Please mark your choice “Yes” or “No” below. If you have any questions you can talk to the investigator or the study team. Yes, I agree to allow the investigator to store my left-over blood for future research No, I do not agree to allow the investigator to store my left-over blood samples for future research

_____ Print Participant’s Name
_____ _____ _____ Signature of Participant Time Date
_____ Print Name of Person Obtaining Consent
_____ _____ Signature of Person Obtaining Consent Date
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