

Snacking During Pregnancy and its Relationship with Gestational Weight Gain

By

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## Abstract

### Background

High-fiber diets are associated with weight management though data are lacking in pregnant women. Pregnant women consume half of the daily fiber recommendation (~15 grams/day) and 55% experience excessive gestational weight gain (GWG). Fiber from snacks in the general U.S. population is significant ( $\geq 20\%$ ) to total fiber intake (1). The purpose was to assess the relationships between snacking, energy, and fiber intake in participants from a 12-week RCT to study if a high fiber diet can prevent excessive GWG.

### Methods

Women were block-randomized (2:1 ratio) into either the intervention (n=12) or usual care (n=8) group. The intervention group was advised to consume  $\geq 30$  grams of fiber/day and met weekly in a group with a dietitian. High fiber snacks (10-12 grams/day) were given during the first 6 weeks of the study but were not provided from 6-12-weeks. Three 24-hour diet recalls were collected at 0-, 6-, and 12-weeks for nutrient analysis. Snacks were participant-identified during diet recalls. T-tests and a regression analysis were completed following an intent-to-treat analysis.

### Results

From 0-6-weeks, the intervention group increased fiber intake overall and from snacks (+10.8 grams and +4.5 grams, respectively;  $p < 0.05$ ), while decreasing snack calories by 25.4 kcals ( $p = 0.122$ ). However, from 6-12-weeks a decrease in fiber intake overall and from snacks occurred in the intervention group (-5.9 grams vs -4.7 grams;  $p = 0.122$  and  $p < 0.05$ , respectively). GWG in the intervention group was lower relative to the usual care group from baseline to 12-weeks with borderline significance (4.7 kg and 6.3 kg respectively;  $p = 0.149$ ). Percent energy

intake from snacks was not a significant predictor of GWG ( $p=0.508$ ).

### Conclusion

Giving high-fiber snacks to pregnant women increased fiber intake without significantly increasing energy intake. Though total fiber in the intervention group decreased when snacks were not provided, total fiber intake was 4.9 grams greater than baseline. In conclusion, increasing fiber intake during pregnancy may help prevent excessive GWG.

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## **Chapter 1: Introduction**

### Introduction

Maternal weight gain during pregnancy is also known as gestational weight gain (GWG). Recommendations for GWG were last updated in 2009 by the Institute of Medicine (IOM) and the National Research Council. These vary from woman to woman, as they depend on pre-pregnancy body mass index (BMI) (2). A majority of women are currently gaining outside recommended GWG parameters, with 20.9% of women gaining inadequately and 47.2% gaining excessively (3). Excess GWG puts pregnant women at a higher risk for maternal obesity, gestational diabetes mellitus, pregnancy-induced hypertension, and complications during labor or birth (4). Gaining excessively has also been associated with large-for-gestational age (LGA) offspring and moderate evidence has linked excess GWG to infant mortality in observational studies (2). Thus, it is important to give attention to factors that may influence a pregnant woman's weight gain, like dietary intake.

Prenatal nutrition is a topic of interest due to an increased need for calories and nutrients during pregnancy to aid in healthy fetal growth and development (5). Maternal intake is influenced by social, behavioral, and environmental factors. Included within environmental factors is access to healthy food, which can be a determinant in maternal diet quality (2). Research has shown that higher quality maternal diets are related to appropriate GWG, thus lower quality diets are related to weight gain outside the recommendations (6). Further, a cross-sectional study in 2014 concluded that, "inadequate dietary intake of total vegetables and oils below the MyPyramid recommendation was associated with higher odds of being in the excessive GWG status group than in the adequate GWG status group"(7). Thus, it is evident that

diet plays a role in GWG; though limited research exists that relates GWG to snacking.

To date, there are few studies that focus on GWG in relation to maternal snacking behaviors (excluding diet quality). Pregnant women with “deliberate meal and snack planning” (6) were more likely to achieve appropriate GWG in a recent cross-sectional study (6), but this study failed to include their definition of a “snack.” In opposition, excess GWG was associated with eating snacks when they were defined as crisps, ice cream, sweets, cakes, biscuits, potato chips, and popcorn (8). Research shows that adult snacking patterns are comprised of a greater variety of foods, rather than energy-dense, nutrient poor foods exclusively. Adults have also chosen snack foods, such as, fruits, vegetables, and nuts/seeds (9). These food sources contain more fiber than foods mentioned previously, and consumption of these foods as snacks may lead to more controlled GWG due to fiber’s ability to increase satiety and improve digestive processes. Snacking is currently a controversial topic due to its many definitions (10, 11). However, with evidence that women are consuming snacks during pregnancy (6, 8) there should be more focus on investigating specific snacking behaviors that relate to appropriate GWG.

### Statement of Purpose

GWG within the recommended parameters is desirable for positive outcomes. In the United States, almost half of all women are gaining excess gestational weight, putting them and their babies at a higher risk for complications during and after pregnancy (4). A multitude of factors affect GWG, and diet quality has been recognized as one of them (2, 7, 8, 12). Yet, there is limited research specifically targeting snacking behaviors in relation to GWG. In this thesis study, I explored the relationships that exist between snacking during pregnancy and GWG. Additionally, the relationship between consumption of fiber-rich snacks (totaling  $\geq 10$  grams of fiber per day) and overall daily fiber intake was investigated as a secondary focus of this study.

## Research Questions

### *Primary Research Question:*

What is the relationship between percent energy (kcal) from snacks and GWG?

### *Secondary Research Question:*

What is the difference between the intervention and usual care groups for fiber intake from snacks and total daily fiber intake?

## **Chapter 2: Review of Literature**

### **Introduction**

The purpose of this review of literature is to analyze associations between snacking on gestational weight gain (GWG). Gestational weight gain is maternal weight gained during pregnancy. Recommendations for GWG are based on pre-pregnancy body mass index (BMI), and vary from woman to woman (2). The current trend in the United States is to gain excess weight during pregnancy (3). Dietary intake has been identified as one of many factors that affect whether or not GWG is appropriate (2). Consumption of snacks falls within overall dietary intake. Research surrounding snacking in relation to GWG is limited. Therefore, this review will focus on GWG in relation to maternal snacking during pregnancy.

### **Gestational Weight Gain Recommendations**

GWG recommendations issued by the Institute of Medicine (IOM) initially in 1990 were reviewed and edited in 2009 (2). These recommendations serve as guidelines for appropriate weight gain during pregnancy and focus on both short and long term outcomes. Appropriate GWG increases the likelihood of positive outcomes for the mother and her offspring. The GWG recommendations are based on pre-pregnancy BMI, using BMI cut-off points set by the World Health Organization. Thus, a woman with a pre-pregnancy BMI classified in the normal weight range is recommended to gain more weight (25-35 pounds total GWG) than a woman classified in the obese weight range (11-20 pounds total GWG) (2). Gaining gestational weight within these set parameters is beneficial to both the mother and her offspring.

*Benefits to mother.* Gaining gestational weight within the recommended range leads to lower risk for adverse outcomes for the mother (4). She has a decreased risk of complications,

such as, diabetes, obesity, and hypertension during and after pregnancy. Avoiding excess GWG will also make it easier for the mother to return to her pre-pregnancy weight. This will benefit her whether she is planning to have another child or not, since adult body weight increases with age. Research has also shown that mothers with a pre-pregnancy BMI in the normal weight range are less likely to gain excess gestational weight (3, 13). Thus, finding ways to help women achieve a normal BMI prior to pregnancy is important.

*Benefits to infant.* Appropriate GWG is associated with an infant born in a normal birth weight range for gestational age (2). An infant born in the normal range is at lower risk for growth and developmental complications. Additionally, the risk of childhood obesity may be lower in infants born in the normal weight range. It is also important to recognize that decreased adverse outcomes may lead to a shorter hospital stay for the infant and mother.

*Limitations.* GWG guidelines do not provide recommendations specific to women of short stature, adolescents, or members of racial/ethnic minority groups (2). This is due to inadequate research surrounding these groups of women. Evidence related to GWG in short statured women is not fully developed. However, women in this category do tend to gain weight in the lower-end of the GWG parameters when using their pre-pregnancy BMI (2). As mentioned, the guidelines are also not validated for women less than 20 years of age, since weight is still measured using pediatric growth charts. These limitations may make setting goals for GWG challenging for mothers that fall within these groups.

*Predictors of gestational weight gain.* The IOM examined a multitude of factors that affect GWG, including “social/institutional, neighborhood/community, environmental, interpersonal/family, and individual levels” (2). Maternal dietary intake fits within most of these

categories. Sub-factors related to dietary intake include, but are not limited to: food availability, cultural traditions/beliefs, education level, and access to health professional services. Food insecurity refers to decreased access to healthy food for individuals. This may affect a mother's ability to eat consistent meals and may result in lower diet quality. Cultural beliefs and traditions may also influence decisions made about food consumption during pregnancy. A woman's culture may influence her decisions related to types of foods consumed, frequency of eating, and total daily energy intake needs. Actual total energy intake may be higher than recommended for women who believe they need to "eat for two." Pregnant women who reported this belief and did not set GWG goals gained excess gestational weight in a cross-sectional study by Chuang et al. (6). Additionally, pre-pregnancy overweight or obese status is linked with an increased risk of excess GWG (3, 8, 12, 13).

### Excessive Gestational Weight Gain

Gaining excess weight during pregnancy is a rising concern due to an overall increase in overweight and obese women (2). Many women are currently gaining outside recommended GWG parameters, with 20.9% of women gaining inadequately and 47.2% gaining excessively (3). As stated previously, women in the pre-pregnancy overweight or obese category are at a higher risk for excess GWG, when compared to normal weight women (3, 8, 12, 13). Gaining weight outside of these parameters is not ideal due to increased risks for poor health. Excess GWG puts both the pregnant woman and her offspring at a higher risk for complications before, during, and after pregnancy (2, 4). Avoidance of adverse outcomes may be possible with maternal lifestyle modifications, including dietary intake at meals and snacks.

## Defining a Snack

Current research lacks a standard definition of a snack, resulting in inconsistencies among research studies (10). Approaches used in research studies to classify snacks include: participant-identified, time of day, location of eating occasion, type of food consumed, or any combination of these (9, 10, 14-17). A cross-sectional study compared the participant-identified approach to the time-of-day approach finding advantages and limitations for each strategy (18). However, consensus is still needed to determine the most suitable approach to distinguish a snack.

*Time of day.* Food that is consumed during certain time frames may be considered a snack (10, 11). Some studies have established 4-hour time parameters for breakfast, lunch, and dinner (10, 11). Eating occasions that occur outside specified parameters are then considered snacks using this method. Classifying snacks in this manner may be more fitting for individuals that work traditional daytime jobs, than those who work odd hours (i.e. night shifts). The latter will likely consume foods outside of set time parameters due to non-traditional main meal times. A more appropriate method, used by Kant et al. (2015), may be to classify snacks as any eating occasion not identified by the participant as breakfast, brunch, lunch, or dinner (19).

*Type of food.* Specific types of foods (i.e. vending machine items, sweets, salty foods, etc.) may be considered a snack regardless of when or where they are consumed (10, 11). Snack foods have been identified as relatively cheap, pre-packaged, easy-to-access, and were perceived as unhealthy by survey participants at a university setting (20). One study (9) analyzed snacking and its effect on body composition by grouping similar foods consumed by participants into separate categories. Nicklas et al. used this method to distinguish 12 eating patterns and linked various snacking behaviors to changes in body composition (9). The researchers found many

snack patterns to be associated with better diet quality when compared to exclusion of snacks. Additionally, two snacking patterns (alcohol and milk desserts) were associated with lower BMI. However, there were no associations found between body composition and the remaining ten snack patterns. In another study, energy-dense snack foods were examined independently to associate intake of these foods with changes in body composition, finding that energy-dense snacks lead to an increase in annual weight gain (14).

Eating location. The location in which an individual consumes food may dictate whether a person considers it a snack or not (10, 11, 20). Wansink and colleagues used structured interviews to explore environmental cues that differentiated a meal versus snack in a university setting. Cues included items, such as, sitting vs. standing, type of dishware used, eating for 10 minutes vs. 30 minutes, and eating with family vs. eating alone. Participants described snacking as “eating alone for 10 min while standing, using paper plates and napkins,” (20) but concluded that “eating with family is the strongest indicator of a meal” (20). Using these cues independently to determine a snack may be problematic because an individual may consume a very similar amount of food regardless.

Combination of methods. Any combination of the previously mentioned factors may also characterize an eating occasion as a snack (10, 11). For instance, standing while eating using disposable paper ware is oftentimes associated with snacking behaviors. However, if an entire family is eating while standing at a social event, then it may be considered a meal based on the type and amount of food consumed. Due to the many factors that go into classifying meals versus snacks, it can be hard for researchers to distinguish between the two.

## Adult Snacking Behaviors

Adult eating behaviors vary widely and can have positive, negative, or null effects on weight status (15). Current eating pattern trends include consuming a higher percentage of energy (kcal) as snacks, resulting in less energy (kcal) intake at breakfast, lunch, and dinner (19). This trend was found when comparing dietary data from National Health and Nutrition Examination Surveys (NHANES) results from 1971-74 and 2009-2010 (19). A cross-sectional study (n=233) in the United States found that adults on average are consuming 2.1 snacks per day, amounting to 404 calories per day on average (15).

Snack frequency. The number of snacks consumed per day and its effect on adult weight status has varied in cross-sectional studies (15, 16, 21). Barnes and colleagues (2015) found no associations with snacking frequency in relation to BMI and diet quality (15). Another cross-sectional study found snacking frequency in normal weight individuals to be inversely associated with adiposity. However, the opposite was true with individuals in the overweight and obese categories (16).

Snack patterns associated with weight gain. Consumption of calorie-dense foods as snacks have led to an increased weight status (14-16, 22). Hendriksen et al. (2011) studied 9,383 normal weight and overweight Dutch adults consuming energy-dense snack foods (cakes, sweets, savory snacks, fried foods, etc.) and found positive associations between consumption of these foods and higher annual weight gain (14). Another cross-sectional study linked eating snacks with >210 kilojoules (about 50 kcal) to increased BMI and waist circumference in women (21). Similarities exist in snacking patterns that are linked with weight gain – they involve high calorie foods.

*Snack patterns associated with weight maintenance.* Eating less energy-dense snacks that have a higher nutrient content, like vegetables, is common among individuals with a lower BMI status (15). This association was found in a cross-sectional study by Barnes et al. (2015) using a sample of 233 adults. A snack was defined as any eating occasion that was not identified as a meal (breakfast, brunch, lunch, and dinner/supper) or beverage. Barnes et al. found no associations between total energy intake or snacking frequency when relating these factors to BMI (15). Nicklas et al. identified 12 snacking patterns in a cross-sectional study using data from NHANES: 2001-2008. This study found that 5 of the 12 snack patterns ranked higher for diet quality using the 2005 Healthy Eating Index, when compared to consuming no snacks. The 5 snacking patterns included: fruits, vegetables, legumes, grains, salty snacks and/or other miscellaneous food items (9). These studies make it evident that snacking patterns vary from person to person, so it is likely that these variations in snacking patterns also exist among pregnant women.

### Snacking During Pregnancy

Limited research exists discussing snacking during pregnancy. An observational study by Barebring et al. linked snacking to excess GWG. Snacks were defined in this study as “sweets, cakes, ice cream, biscuits, potato chips, popcorn, but excluding nuts and seeds” (8). Thus, snacks were assumed to be energy-dense, nutrient-poor foods.

On the contrary, researchers found that women with planned eating occasions were more likely to achieve appropriate GWG (6). A cross-sectional study by Shin et al. found that pregnant women who consumed vegetables and oils (fish oils, nut/seed oils, and non-hydrogenated

vegetable oils) daily were more likely to have appropriate GWG (7). It is important to note that vegetables contain fiber, which is helpful in increasing satiety and digestive processes.

Reviewing these studies makes it evident that fiber has an important role during pregnancy.

### Benefits of Fiber

Dietary fiber is found in plant foods, is indigestible, and ferments in the lower part of the gastrointestinal tract (23, 24). Inclusion of dietary fiber is associated with a variety of health benefits. Fiber aids in regulation of cholesterol and has been associated with higher levels of HDL cholesterol, which is a protective factor for cardiovascular disease (25). Additionally, fiber has been associated with lowering blood pressure (25), increasing satiety (23, 26, 27), lowering BMI, maintaining blood glucose levels (28), and decreasing the risk for metabolic syndrome (24). Metabolic syndrome leads to an increased risk for chronic diseases. Despite this strong association, many adults are presently not meeting the recommendations for daily fiber intake.

Current fiber intake. Americans consistently consume about half of the daily dietary fiber recommendations (25, 29, 30). Recommendations for fiber intake are 25 grams per day for women, 28 grams per day for pregnant women, and 38 grams per day for men (23, 26, 27, 29, 30). Fiber intake is highest at the dinner meal (38% of total daily fiber intake) and snacks also include high amounts ( $\geq 20\%$  of total fiber intake), when compared to other meals (1).

Fiber intake during pregnancy. A maternal diet high in fiber has been associated with desirable health outcomes. Research suggests that maternal fat mass changes late in gestation have been inversely associated with fiber intake (31). A prospective cohort study (n= 813 Hispanic pregnant women) found that higher dietary fiber intake has been associated with

decreased risk of having abnormal blood glucose levels during pregnancy (32). Additionally, an observational study (n=495 healthy pregnant Icelandic women) found an inverse association between fiber intake and GWG in overweight pregnant women (12).

## Conclusions

There is a need for more research surrounding GWG and eating patterns in pregnant women. GWG recommendations have been established and serve as a guide for appropriate weight gain. However, research relating GWG to snacking and fiber intake is very limited. Studies (6-8, 12) that do exist on this topic are either cross-sectional or observational, and are therefore unable to prove causal effects. Conclusions and suggestions for advancement in research on topics previously discussed are as follows.

Gestational weight gain. Recommendations for GWG were last issued in 2009 by the IOM. Gaining within set weight ranges using pre-pregnancy BMI results in a lower risk for adverse outcomes for both the mother and her offspring. The current trend is for women to gain outside the parameters set for GWG. A higher percentage of women gaining outside these set ranges tend to gain excess weight, rather than inadequate weight (3). Many factors exist in the literature that serve as predictors of GWG. One of particular interest in this review is dietary intake, and specifically snacking behaviors (2).

Consistently defining a snack. Hess et al. (2016) and Leech et al. (2015) published review articles discussing snacking and its various definitions. The researchers made it evident that there is a need for a standard definition of a snack (10, 11). Studies related to snacking revealed that snacks were either not defined (6), were participant-identified (15, 16, 18), were classified as

energy-dense, nutrient-poor foods (8), or used a combination of methods (9). These inconsistencies pose a challenge for research surrounding snacking behaviors.

*Snacking during pregnancy.* There are a multitude of factors that affect GWG and snacking has been recognized as one of them (2, 7, 8). Snacking has not been clearly defined within all studies making the results difficult to interpret. Researchers typically classify snacks as “unhealthy” foods. However, available literature shows that adults are also snacking on foods that provide more nutritional benefits and are less associated with annual weight gain, such as fruits, vegetables, and nuts/seeds (15). These foods contain dietary fiber and high intakes of fiber have an inverse relationship with many health risks. With snacking contributing to  $\geq 20\%$  of total fiber intake (1), it can be hypothesized that increasing snacking frequency may lead to a higher intake of fiber. Thus, more research is warranted in this area.

Available evidence that relates snacking behaviors to GWG remains controversial, since studies have shown both excessive (6, 8, 12) and appropriate (6, 7) GWG. To build on existing literature, the association between maternal snacking and its relation to GWG should be further examined. Additionally, providing a clear definition of a snack in research studies is essential to interpret results.

## **Chapter 3: Methods**

### **Overview**

Data for this thesis were collected from its parent study titled, “Pregnancy **I**ntervention **R**evolving **A**round **G**oal-**F**ocused **E**ducation (GIRAFE study),” a non-blinded RCT. The parent study was a 12-week pilot study that block-randomized women into either the single goal (SG) high dietary fiber intervention group or the usual care (UC) group. The intervention group participated in group based phone counseling lessons (12 sessions; 60 minutes each) focusing on strategies that lead to a high fiber diet and appropriate GWG using IOM recommendations (2). The single goal in the parent study was for women to consume  $\geq 30$  grams of fiber per day. The UC group did not receive dietary counseling and received standard treatment from their obstetrician.

My thesis project primarily focused on GWG in relation to snacking behaviors. The secondary focus was on total fiber intake in relation to fiber intake from snacks. Data collected from the 24-hour dietary recalls and anthropometric measurements were used for statistical analysis to answer these questions.

### **Sample**

The GIRAFE study recruited women that were 9 to 15 weeks pregnant, between the ages of 18 to 45 years old, and with a BMI of 22.0-40.0 kg/m<sup>2</sup>. Women were recruited from The University of Kansas Medical Center (KUMC) Obstetrics (OB) Clinic, KUMC Intranet, by contacting prior participants of Pregnancy Health studies (when permission was given to contact), by posting on Facebook, and through word of mouth. At the OB clinic, recruiters had access to the daily patient schedule to screen for potential participants. Recruiters met with

potential participants to explain the study and ask them if they would like to be a part of the study. Those who were interested filled out a questionnaire to assess their fiber intake over the past year and gave further information about their health status to determine if they met GIRAFE research criteria. Women were excluded if their baseline intake of fiber exceeded 20 grams per day. Other exclusion criteria included: current or pre-pregnancy diabetes, hypertension, pre-eclampsia, other metabolic abnormalities, drug abuse, smoking, asthma, heart disease, and women with pregnancies of multiples. The GIRAFE study recruited 25 participants for its non-blinded RCT. Women were block randomized (2:1 ratio) into one of two groups: SG high dietary fiber intervention (n=17) or a UC group (n=8). Groups of 5-10 participants were ideal for this study to promote optimal group interactions via phone. All participants enrolled in the GIRAFE study were included in this thesis study.

### Setting

Assessments at baseline and 12-week visits were conducted in-person with research staff at KUMC. Diet recalls were obtained during in-person appointments (1 at baseline; 1 at twelve-weeks) and via phone (2 at baseline; 3 at six-weeks; 2 at twelve-weeks). Participants reported their weekly body weight to researchers via text or email using provided body weight scales. For the intervention group, group based phone counseling conducted by a Registered Dietitian took place weekly via phone for the length of the 12-week study.

### Ethics

This study was approved by the University of Kansas Medical Center Human Subjects Committee under the parent study (STUDY00004032). The research consent form (appendix A) was signed by participants prior to the study. Incentives were given for completed activities by using a ClinCard system, which works like a debit card. Women were paid for their baseline

visit, reported behaviors, group based phone counseling lessons attended, and stool and urine samples collected. The intervention group and UC group could potentially earn a total of \$280 and \$160, respectively, dependent upon research activities completed.

### Funding

The parent study received an unrestricted gift to the department from Roberts Family Foundation and this research was also supported in part by a grant from the KUMC Research Institute at the University of Kansas Medical Center (STUDY00004032).

### Procedures

*Baseline.* At baseline, participants met in-person with trained research staff to learn more about the GIRAFE study, to receive study materials, to sign their consent form, to complete questionnaires (demographics and supplement use), to measure body composition, and to complete a 24-hour dietary recall. Women also reported pre-pregnancy weight and height, which were used to calculate pre-pregnancy BMI. All participants received a body weight scale to weigh themselves at home and were instructed to report weekly weight status via email or text. The UC group was asked to continue with standard treatment offered by their obstetrician. Women in the intervention group were asked to increase their fiber intake to 30 grams per day, were given a supply of high fiber study snacks and a binder with weekly lessons that focused on increasing daily fiber intake.

The intervention group received a 6-week supply of fiber-rich snacks. Participants were instructed to eat 2 paired snacks per day to improve adherence to their high fiber diet. For example, one of the paired snacks given included one Kind Bar and 1-ounce of Snapea Crisps, providing 10-12 grams of fiber combined. Proposed snacks were pre-portioned, shelf stable, and

labeled with the name of the snack, quantity, and fiber content. Individual snacks contained 3 to 7 grams of fiber. Snacks of lower fiber content were paired with those with higher fiber content to ensure that participants would consume  $\geq 10$  grams of fiber per day from snacks.

Women in the intervention group attended 12 weekly sessions of 1-hour long group based phone counseling led by a Registered Dietitian. These lessons were centered around the single goal of consuming  $\geq 30$  grams of daily fiber. Women were instructed to complete assignments, set individualized goals, and were encouraged to have discussions with other participants during these sessions.

*Midpoint.* At midpoint (6 weeks), all participants were contacted via phone to complete three dietary recalls.

*End of study.* During the 12-week visit, each participant returned to KUMC and met with research staff to measure body composition and complete an in-person 24-hour dietary recall. Both groups were called on two additional days to complete their remaining 2 dietary recalls.

### Data Collection

*Diet Recalls.* Interviewers for diet recalls were trained and tested on reliability in delivering standardized dietary interviews with an error rate less than 10%. Trained interviewers collected 24-hour dietary recalls using the multiple pass method (2 weekdays and 1 weekend day) for the GIRAFE study. Researchers used diet recall forms to record subject intakes (appendix B). Dietary recalls were collected at baseline, mid-point, and at the end of the study. The recalls were performed both in person and via phone. Two 24-hour diet recalls were completed in-person during baseline (1) and 12-week (1) visits and the remaining diet recalls (7) occurred via phone.

Research staff used food models during in-person diet recalls to assist participants in identifying portion sizes. At baseline, participants were given a Food Amounts Booklet to use at home for phone diet recalls. This was a pictorial booklet that helped participants identify portion sizes. Interviewers also had a more detailed copy of the Food Amounts Booklet. Food portions in the participant booklet were labeled with numbers or letters to identify food portion size to decrease likelihood of misreporting. The interviewer's booklet contained both the numbers/letters seen in the participant booklet, but also included detailed sizing information (inches, centimeters, etc.) that corresponded with those numbers/letters. For instance, a participant reporting that she ate a cookie would be asked to identify its diameter. The participant may have selected the letter "E" as the size of her cookie, whereas the interviewer's booklet indicates that the letter "E" is equivalent to a 4-inch diameter. All meals and snacks were identified by the participant during each diet recall. Options for labeling meals included: breakfast, brunch, lunch, dinner/supper, snack, or beverage only.

NDSR. After dietary intake was collected, the meal information was entered by trained research staff in the Nutrition Data System for Research (NDSR, version 2016, Minneapolis, MN) for meal, energy, and nutrient analysis, which included fiber intake. All NDSR diet recall entries were cross-checked for accuracy by a trained research member that did not enter the recalls. Quality Assurance reports were used to flag potential outliers and flagged entries were reviewed for possible elimination. Possible reasons for elimination of recalls included those coded as unreliable, those marked as a non-typical intake, and/or those with very high (>3500 kcals) or low (<600 kcals) total energy intake. Individual baseline recalls from subjects in the intervention group were excluded if they had already started consuming high-fiber study snacks during that recall.

Maternal body composition and anthropometrics. Each participant was provided with a body weight scale and guidelines for weighing themselves (appendix C and D) at home. Researchers advised participants to place their scale on a tile or linoleum floor. They were asked to weigh themselves in the morning before eating and at the same time each week (i.e. Tuesdays at 7:30 a.m.). Women were instructed to wear little to no clothing to avoid inaccuracies. Participants in the usual care group emailed or texted their body weight to researchers weekly and women in the intervention group entered their weight into the LST app in the measurement section.

#### Analysis of Data

Total fiber intake. Total fiber intake for each participant was measured using NDSR's Daily Totals output report. Grams of total fiber per day for each participant were averaged at each time point (baseline, 6-weeks, and 12-weeks) and over the length of the study.

Fiber and energy intake from snacks. Snacks were participant-identified during 24-hour diet recalls and were recorded in NDSR as "snacks." Energy (kcal) and fiber (grams) from snacks were determined at each data collection point (baseline, 6-weeks, and 12-weeks) and over the length of the study using NDSR's Meals and Daily Totals output reports. Averages were calculated for both snack kcal and fiber at each data collection point and over the length of the study.

GWG. Pre-pregnancy BMI was calculated using self-reported pre-pregnancy weight and measured height at the baseline visit. Reported weekly body weight was used to assess each participant's GWG over the length of the 12-week study. Gestational weight gain over the length of the study was calculated by subtracting body weight at week one from weight at week twelve.

Percent energy intake from snacks. Percent energy (kcal) intake from daily snacks was determined for each participant using NDSR's Daily Totals output report. Energy from daily snacks was divided by total energy intake to determine this percentage. Daily percent energy intake from snacks was averaged at each data collection point (baseline, 6-weeks, and 12-weeks) and over the length of the study for each participant.

Statistical Analysis. SPSS Version 24 was the software used for statistical analysis. Statistics were done using an intent-to-treat analysis with a 0.05 level of significance. To answer the primary research question, a regression analysis using usual care versus intervention group, along with change in percent energy (kcal) from snacks from 0-12 weeks as variables were used to assess the relationship between percent energy (kcal) intake from snacks and GWG from 0-12 weeks. A t-test was used for the secondary research question, which focused on the difference between the intervention and usual care groups for fiber intake from snacks and total fiber intake. Descriptive statistics were also used to analyze primary and secondary questions.

## **Chapter 4: Results**

As aforementioned, the purpose of this thesis project was to gain a better understanding of how snacks affect GWG, energy intake, and fiber intake. It was also of interest to determine whether subjects in the intervention group would continue snacking on high fiber foods following discontinuance of study snacks from 6- to 12-weeks. All women enrolled in the parent study were included in this thesis project. Objectives included: observing changes in fiber intake from snacks, overall daily fiber intake, and GWG over the length of the study.

### **Subject Characteristics**

A total of 25 pregnant women were originally enrolled in the parent study. Only subjects that completed the entire study (n=20) were included in the analysis. A total of 5 participants were not included due to enrollment in a conflicting research study (n=1) and dropping out before the post-study appointment (n=4). The average maternal age, gestational age, and BMI at entry was 29.6 years, 13.6 weeks, and 26.5 kg/m<sup>2</sup> (overweight), respectively. The majority identified their race as white (85%), had earned at least a graduate degree (50%), and had a household income of 100K-125K (40%). There were no significant baseline differences between the usual care and intervention groups. Demographic data are provided in Table 1.

**Table 1. Baseline Subject Characteristics**

Variable	Intervention (n=12)	Usual Care (n=8)	Total (n=20)	Significance (p-value)
Maternal age, years	29.0 ± 3.5	30.5 ± 3.2	29.6 ± 3.4	0.346
Gestational age at entry, weeks	13.0 ± 3.1	14.4 ± 3.9	13.6 ± 3.4	0.371
Pre-pregnancy height, cm	161.2 ± 6.6	163.2 ± 6.5	162.0 ± 6.5	0.511
Pre-pregnancy weight, kg	68.9 ± 18.1	71.1 ± 12.8	70.0 ± 15.8	0.762
Pre-pregnancy BMI, kg/m <sup>2</sup>	26.3 ± 5.7	26.8 ± 5.7	26.5 ± 5.6	0.845
<sup>a</sup> Total weight gain, kg	4.7 ± 2.1	6.3 ± 2.3	5.4 ± 2.3	0.149
Education: <i>n</i> (%)				
High school or less	1 (8.3)	1 (12.5)	2 (10.0)	
Post-secondary to less than graduate	7 (58.3)	1 (12.5)	8 (40.0)	
Graduate degree or more	4 (33.3)	6 (75.0)	10 (50.0)	
Race: <i>n</i> (%)				
White	12 (100.0)	5 (62.5)	17 (85.0)	
Asian	0 (0.0)	1 (12.5)	1 (5.0)	
Hispanic	0 (0.0)	1 (12.5)	1 (5.0)	
Other	0 (0.0)	1 (12.5)	1 (5.0)	
Ethnicity: <i>n</i> (%)				
Hispanic/Latino	0 (0.0)	1 (12.5)	1 (5.0)	
Non-Hispanic	12 (100.0)	7 (87.5)	19 (95.0)	
Household Income: <i>n</i> (%)				
25K-50K	1 (8.3)	1 (12.5)	2 (10.0)	
50K-75K	4 (33.3)	1 (12.5)	5 (25.0)	
75K-100K	2 (16.7)	1 (12.5)	3 (15.0)	
100K-125K	4 (33.3)	4 (50.0)	8 (40.0)	
>125K	1 (8.3)	1 (12.5)	2 (10.0)	
All data are reported as Mean ± SD unless otherwise noted.				
<sup>a</sup> Total weight gain during the 12-week study intervention				

## Dietary Intake

*Diet recalls.* A total of 173 diet recalls were included in the analysis for this thesis project. All participants (n=20) provided 3 recalls at each time point. Seven 24-hour diet recalls were excluded from analysis, all of which were baseline recalls from participants in the intervention group. These recalls were excluded because subjects started the intervention (consuming high fiber study snacks) during these recalls, which would not have been a true representation of their baseline intakes. Baseline macronutrient intake was not different between groups at baseline (Table 2). Mean number of snacks consumed at each time point are shown in Table 3. The overall trend was that subjects in both groups were consuming fewer snacks at the end of the study when compared to baseline intakes.

**Table 2. Baseline Macronutrient Intake Distribution**

Variable	Intervention (n=12)	Usual Care (n=8)	Significance (p-value)
Carbohydrate, g ( <sup>a</sup> % total kcal)	239.7 ± 44.5 (46.5)	218.3 ± 87.5 (50.8)	0.262
Fat, g (% total kcal)	89.6 ± 26.6 (38.0)	66.0 ± 31.9 (32.3)	0.081
Protein, g (% total kcal)	78.6 ± 18.3 (15.4)	70.5 ± 27.1 (16.9)	0.368

All data are reported as Mean ± SD.  
<sup>a</sup>% total kcal was calculated by dividing mean energy (kcal) intake from each macronutrient by mean total energy (kcal) intake at baseline.

**Table 3. Mean Number of Snacks Consumed at 0-, 6-, and 12-weeks**

Variable	Intervention (n=12)	Usual Care (n=8)
Number of Snacks, <i>n</i>		
Baseline	1.6 ± 0.73	2.2 ± 1.15
6-Weeks	1.8 ± 0.73	2.2 ± 1.21
12-Weeks	1.4 ± 0.85	1.7 ± 0.98

All data are reported as Mean ± SD.

Fiber intake. Table 4 includes information about total fiber intake and fiber intake from snacks only at 0-, 6-, and 12-weeks. Total fiber intake at the end of the 12-week study was significantly higher (p=0.023) in the intervention group (26.2 grams), than in the usual care group (16.7 grams). At 6-weeks, fiber intake from snacks was significantly higher (p=0.015) in the intervention group (9.6 grams), than in the usual care group (4.5 grams). Fiber intake from snacks was not significantly different between groups at the 12-week time point.

**Table 4. Total and Snack Fiber Intake at Baseline, 6-weeks, and 12-weeks**

Variable	Intervention (n=12)	Usual Care (n=8)	Significance (p-value)
<b>Total Fiber Intake, g</b>			
Baseline	21.2 ± 7.4	18.3 ± 7.8	0.409
6 weeks	32.0 ± 9.6	16.6 ± 9.0	0.002*
12 weeks	26.2 ± 10.0	16.7 ± 4.9	0.023*
<b>Snack Fiber Intake, g</b>			
Baseline	5.1 ± 2.8	4.1 ± 1.9	0.419
6 weeks	9.6 ± 4.5	4.5 ± 3.6	0.015*
12 weeks	4.9 ± 4.3	3.4 ± 2.2	0.371
All data are reported as Mean ± SD unless otherwise noted. *p-value <0.05			

Energy intake. Energy intake did not differ between groups at 6- and 12-weeks (Table 5), despite the intervention group consuming significantly greater total fiber than the usual care group at 6- and 12-weeks (Table 4). There were no significant between group differences in regards to energy intake during the entire 12-week study period (Table 5).

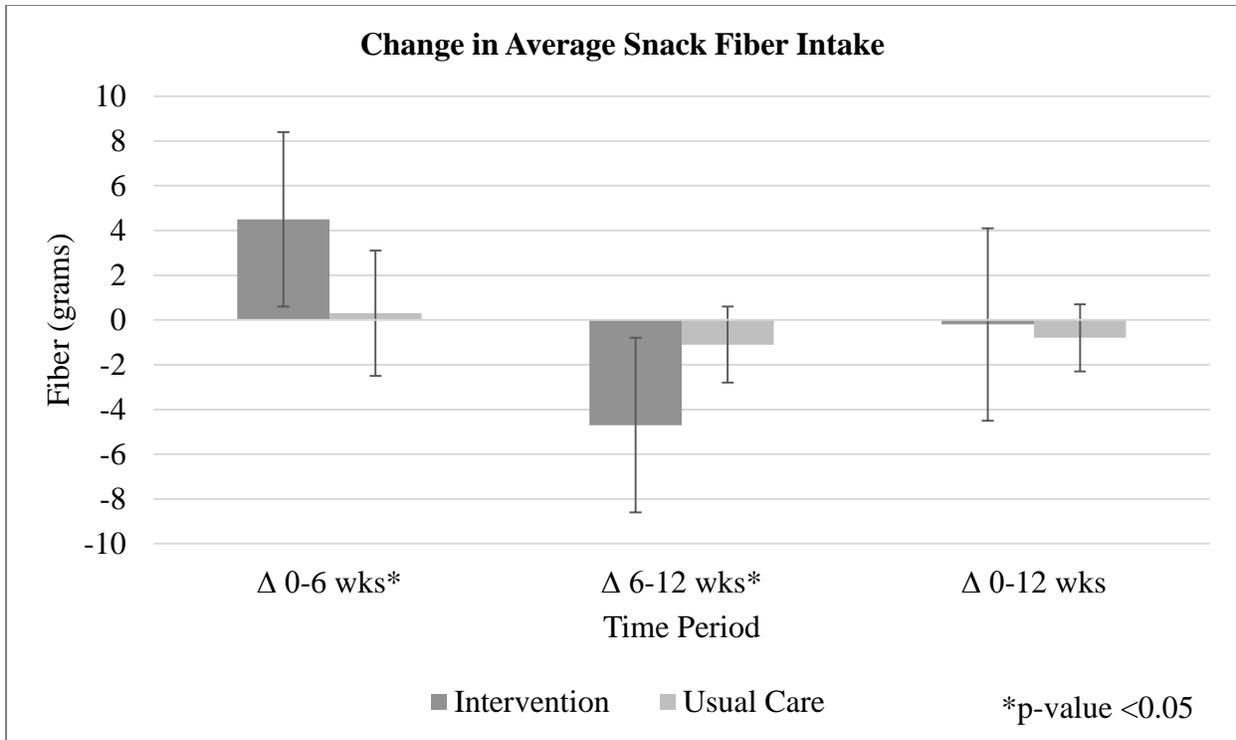
**Table 5. Total and Snack Energy Intake at 0-, 6-, and 12-weeks**

Variable	Intervention (n=12)	Usual Care (n=8)	Significance (p-value)
Total Energy Intake, kcal			
Baseline	2038.8 ± 362.0	1715.0 ± 692.6	0.186
6 weeks	2023.3 ± 292.1	1711.1 ± 793.6	0.226
12 weeks	2005.6 ± 388.3	1622.1 ± 623.1	0.106
Snack Energy Intake, kcal			
Baseline	379.0 ± 191.5	329.2 ± 196.2	0.579
6 weeks	390.7 ± 190.9	358.9 ± 198.8	0.724
12 weeks	294.8 ± 245.1	244.1 ± 135.8	0.602
All data are reported as Mean ± SD unless otherwise noted.			

*Changes in fiber and energy intake.* Average fiber intake from snacks significantly increased (+4.5 grams; p-value=0.017) in the intervention group when study snacks were provided (0-6 weeks) and energy from snacks increased minimally (+11.7 kcals; p-value=0.830). When high fiber snacks were discontinued, fiber intake from snacks in the intervention group significantly decreased to slightly below baseline (-4.7 grams; p-value=0.025). Further details on changes in fiber and energy intake from snacks are provided in Table 6 and Figure 1.

**Table 6. Changes in Daily Snack Fiber and Energy Intake at 0-, 6-, and 12-weeks**

Variable	Intervention (n=12)	Usual Care (n=8)	Significance (p-value)
<sup>a</sup> Δ in fiber, grams			
0-6 weeks	4.5 ± 3.9	0.3 ± 2.8	0.017*
6-12 weeks	-4.7 ± 3.9	-1.1 ± 1.7	0.025*
0-12 weeks	-0.2 ± 4.3	-0.8 ± 1.5	0.728
Δ in energy, kcals			
0-6 weeks	11.7 ± 201.0	29.8 ± 147.4	0.830
6-12 weeks	-95.9 ± 185.0	-114.9 ± 177.8	0.823
0-12 weeks	-84.3 ± 281.5	-85.1 ± 131.7	0.994
All data are reported as Mean ± SD unless otherwise noted.			
<sup>a</sup> change			
*p-value < 0.05			



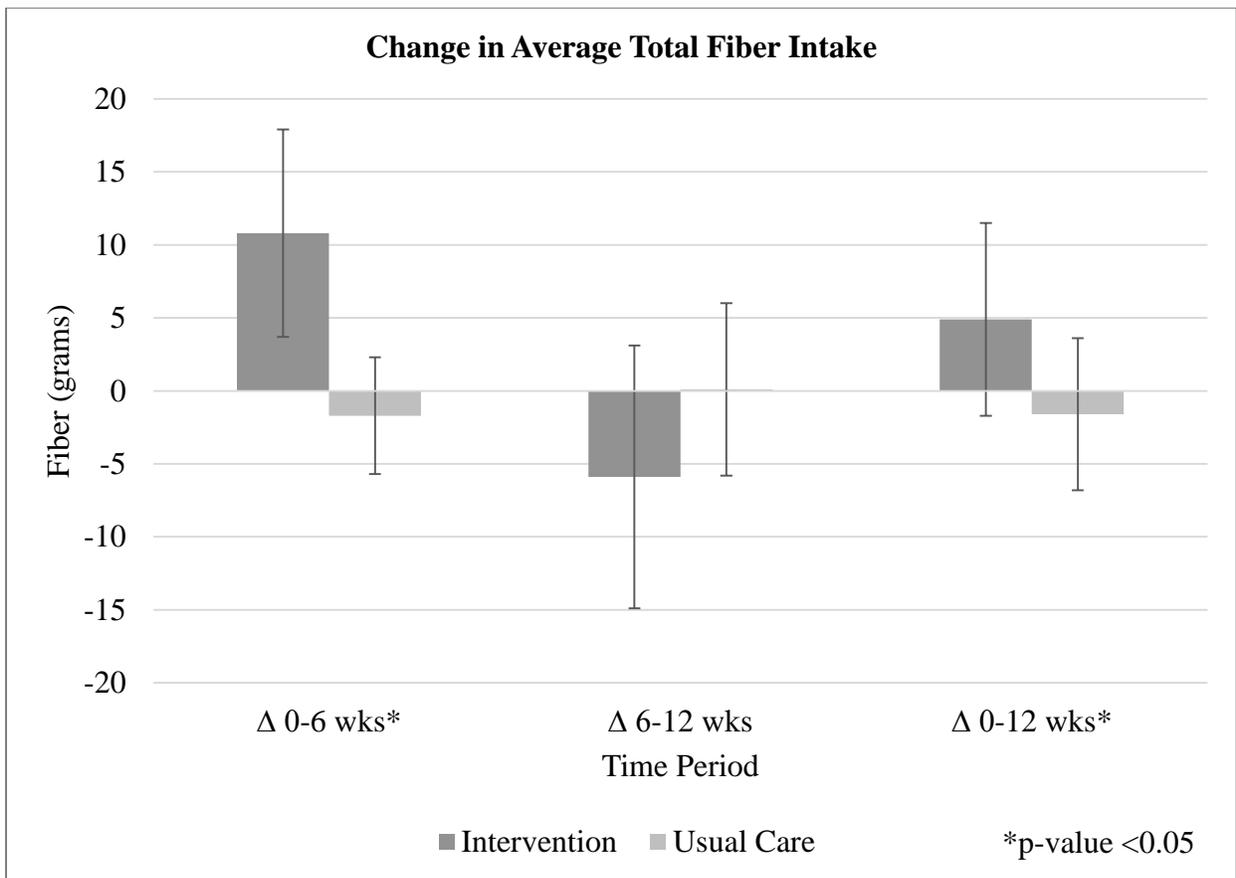
**Figure 1. Change in Average Snack Fiber Intake**

From baseline to 6-weeks, average total fiber intake significantly ( $p$ -value=0.000) increased by 10.8 grams in the intervention group, while average energy intake decreased by 15.5 calories. During the second half of the study (6-12 weeks), snack fiber consumed by participants in the intervention group decreased by 5.9 grams/day. Over the entire 12-week study period, the intervention group significantly ( $p$ =0.030) increased total fiber intake by 4.9 grams (Figure 2). Conversely, total fiber intake for the usual care group decreased by 1.6 grams ( $p$ =0.030) over the 12-week study. Additional details about total fiber and energy intake are provided in Table 7.

**Table 7. Changes in Total Daily Fiber and Energy Intake at 0-, 6-, and 12-weeks**

Variable	Intervention (n=12)	Usual Care (n=8)	Significance (p-value)
<sup>a</sup> Δ in fiber, grams			
0-6 weeks	10.8 ± 7.1	-1.7 ± 4.0	0.000*
6-12 weeks	-5.9 ± 9.0	0.1 ± 5.9	0.122
0-12 weeks	4.9 ± 6.6	-1.6 ± 5.2	0.030*
Δ in energy, kcals			
0-6 weeks	-15.5 ± 387.3	-3.8 ± 293.0	0.943
6-12 weeks	-17.8 ± 345.4	-89.1 ± 430.3	0.686
0-12 weeks	-33.3 ± 440.1	-92.9 ± 202.4	0.726

All data are reported as Mean ± SD unless otherwise noted.  
<sup>a</sup> change  
 \*p-value < 0.05



**Figure 2. Change in Average Total Fiber Intake**

Percent Energy Intake from Snacks and GWG

Mean percent energy intake from snacks at baseline, 6-weeks, and 12-weeks for the intervention group was 19%, 19%, and 15%, respectively. Similarly, the usual care group’s percent energy intake from snacks at baseline, 6-weeks, and 12-weeks was 19%, 21%, and 15%, respectively. A regression analysis assessed the relationship between GWG, percent energy (kcal) intake from snacks, and group differences. The dependent variable was total weight gain (kg) over the length of the study using self-reported weight. There was no significance found when using change in % energy from snacks as a predictor variable for weight gain. Borderline significance (p=0.167) was seen when looking at between group difference, meaning that a change in intervention group weight over the length of the study was lower relative to the usual care group’s change in weight. Specifically, subjects in the intervention group gained 1.48 kg less than those in the usual care group over the entire study period. Group differences primarily explained 3.4% ( $r^2 = 0.034$ ) of the variance in body weight. More details about the regression analysis can be found in Table 8.

**Table 8. Percent Energy Intake from Snacks and Weight Gain from 0-12 weeks**

Variable	Unstandardized Beta	Coefficients Standard Error	Significance (p-value)
<sup>a</sup> Δ % energy from snacks (0-12 weeks)	0.04	0.05	0.508
Usual Care vs. Intervention	-1.48	1.03	0.167

<sup>a</sup> change  
Adjusted R<sup>2</sup>=0.034  
Dependent variable: total weight gain (kg) for 12 weeks  
Predictors: control vs. intervention; % change in kcal from snacks over 12-week study period

## **Chapter 5: Discussion**

The main objectives of this thesis project were to measure change in fiber intake (snacks vs. overall), energy intake (snacks vs. overall), and GWG over the length of the study in pregnant women completing a high fiber diet intervention. Recent literature (9, 15) suggests that individuals who consume fiber-containing foods as snacks tend to have a normal BMI and higher diet quality. Research also suggests that women with planned eating behaviors tend to gain gestational weight appropriately (6), whereas women consuming energy-dense, nutrient-poor foods as snacks and who reportedly “ate for two” tend to gain excess gestational weight (6, 8). It was anticipated that pregnant women enrolled in the intervention group who were consuming fiber-rich snacks and had a goal to consume  $\geq 30$  grams daily fiber, would gain appropriate gestational weight.

### **Sample**

A total of 20 participants (80%) completed the entire study out of the 25 originally enrolled. All women in the usual care group (n=8) were successful in completing the study in its entirety. Five women in the intervention group dropped out (n=4) of the study or were excluded (n=1). One woman was hospitalized soon after her initial study visit and was unable to fulfill study expectations. Another participant reported dropping due to the required time commitment. Two participants did not give reasons for discontinuing. This may have been due to the extra time commitment that came with being in the intervention group. We also had to exclude data gathered from one participant (intervention group) after she began since she was enrolled in a conflicting research study.

Women enrolled in this study were highly educated with 50% having a graduate degree or more. Subjects primarily identified their race and ethnicity as white (85%) and non-Hispanic (95%), respectively. These characteristics lead us to believe that many women participating in our study were not of low socioeconomic status (SES). Had our study subjects been more representative of a low SES population, they may have faced more barriers throughout this study. Possible barriers may have been related to transportation, consistent access to a cell phone for weekly phone calls, and access to healthy foods.

### Fiber Intake

Fiber intake was observed with a focus on the quantity consumed from snacks vs. total daily intake. At baseline, intervention participants consumed an average of 20 grams of fiber per day, which is lower than the recommended amount of 28 grams per day for pregnant women (27). Average fiber intake from snacks alone was 4.7 grams, which was 23.5% of total daily fiber intake. Similar observations were seen in a study by McGill et al. (2015) analyzing NHANES data and finding that fiber intake from snacks typically contributes  $\geq 20\%$  of total fiber intake in adults (1).

From 0- to 6-weeks, participants in the intervention group increased their daily fiber intake to 32 grams, which met the goal of the intervention ( $\geq 30$  grams) and fulfilled current fiber recommendations. From 6- to 12-weeks, there was approximately a 50% decrease in the change in total daily fiber intake, which is also when high fiber study snacks were no longer provided. Total daily fiber intake at conclusion of the study was 4.9 grams higher than baseline intake in the intervention group. The usual care group reported a 1.6 gram decrease in fiber intake from baseline to 12-weeks. Though intervention participants did not sustain their increased fiber intake over the entire study period, it was positive that they had an overall increase in fiber from

0- to 12-weeks. A higher fiber intake is desired for its many health benefits, especially its association with a lower BMI and increased satiety (21-25). Continuance of a higher fiber intake will likely be beneficial to these women long-term.

### Energy Intake

Energy intake from snacks decreased in both groups from 0- to 12-weeks. Total daily energy intake during this time also decreased in both groups with no between group significance. A possible explanation for lower energy intake from snacks is that subjects may have been consuming  $\geq 1$  snack during baseline recalls, but may have had a decrease in snack frequency during their 12-week recall period. For example, a woman consuming two 150-calorie snacks during her baseline recall and only one 150-calorie snack during her 12-week recall would see a 150 calorie decrease over the length of the study.

### Gestational Weight Gain

The primary study objective was to assess the relationship between percent energy (kcal) from snacks and its contribution to GWG. Our study found that percent energy intake from snacks was not a significant predictor of GWG. This was a desired finding as it shows that providing high-fiber snacks to participants in the intervention group did not result in significant weight gain. Additionally, we found that subjects in the intervention group had lower GWG relative to the usual care group from baseline to 12-weeks. It is possible that the intervention groups' higher fiber intake may have played a key role in lessening weight gain during this study. An observational study by Olafsdottir et al. reported similar findings – that an inverse relationship exists between higher fiber intakes and GWG in overweight women (12). Adding to this observation, there has also been evidence that diets including more fiber offer a satiating effect (23, 26, 27) and have helped adults maintain a healthy BMI (28).

## Limitations

Several limitations exist for this study. First, the sample size was small and only low fiber consumers (<20 grams/day) were included. Second, there is a chance that intervention participants may not have followed study protocol as written. We know that some intervention participants didn't regularly attend the group phone discussions, so they may not have realized the importance of consuming at least 30 grams of daily fiber. Absence from these phone calls may have resulted in women not learning strategies to increase fiber intake. Self-reported pre-pregnancy body weight, pre-pregnancy height and weekly body weight during the study may have been misreported by participants. To improve data accuracy, participants were all given the same body weight scales and instructions for consistently weighing themselves. Participants were also given monetary incentives as motivation for weighing themselves weekly.

Limitations may also exist in the accuracy of reported food intake, as people tend to underreport perceived "unhealthy" eating behaviors and over-report perceived "healthy" eating behaviors. For instance, it is more likely that someone will over-report the amount of broccoli they consumed and under-report the amount of cake they consumed. Our research staff used the multiple-pass method during diet recalls to help avoid this issue. Another possible limitation was coding eating occasions as snacks versus meals (breakfast, brunch, lunch, or dinner). Labeling eating occasions as "beverage only" may have also been a limitation as some women may have considered calorie-containing drinks a snack while others may have labeled them as a beverage only. All snacks and meals for this study were participant-identified, so individual beliefs about what eating occasions constitute as a snack may vary. To date, there is not a standard definition of a snack, rather there are multiple methods that have been used in research (10, 11, 17, 18). Lastly, a few participants in the intervention group started consuming high fiber study snacks

during baseline dietary recalls. Including those recalls would have inflated their baseline fiber intake value. Researchers excluded those diet recalls during data analysis to avoid this possible misrepresentation.

### Implications and Future Studies

Implications about fiber intake, snacking, and GWG can be drawn from this thesis study. Our intervention to increase fiber intake was successful, though it was not to the degree we had hoped since they did not sustain intakes of  $\geq 30$  grams of fiber over the entire study period. Our intervention design of providing high fiber snacks may be useful in future studies that are working towards increasing fiber intake. Future studies should look at ways to keep fiber intake up after snacks are no longer provided. Our study included a sample that was highly educated, unrepresentative of minority groups, and had high household incomes. Future studies should aim to include an equal distribution of women from all education levels, household incomes, races, and ethnicities. Future studies that include a more representative sample of the population will be able to apply their results to a greater percentage of women. We chose to include women in our study that were categorized as having a BMI in the upper normal to obese range. Studies have associated higher levels of excessive GWG with individuals classified as overweight or obese (2, 3). Future studies should take special consideration when determining their target population to ensure that it translates accordingly. Lastly, future studies that aim to include a larger sample size and have a greater focus on nutrition quality of foods consumed by participants may be more successful in defining the relationships that exist between snacking, fiber intake, and GWG.

## Conclusion

This study focused on snacking behaviors, fiber intake, and GWG in pregnant women participating in a high fiber diet intervention. An increase in daily fiber intake coinciding with a decrease in total energy intake displayed by the intervention group over the length of the study sheds some light on the satiating effect that fiber has on dietary intake. Secondly, an increase in energy from snacks was not a significant predictor of weight gain in participants. In conclusion, asking women to incorporate high-fiber snacks into their diet does not adversely affect their weight gain during pregnancy.

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## **Appendix A: Research Consent Form**

## 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  $\geq 30$  grams of fiber per day. Research has shown that most women fall well below this recommendation. A healthy diet with  $\geq 30$  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  $\geq 30$  grams or more of fiber per day can help pregnant women gain an appropriate amount of weight during their pregnancy.



KUMC IRB # STUDY00004032 | Approval Period 8/22/2016 – 7/14/2017 | FWA# 00003411

### **PURPOSE**

By doing this study, researchers hope to learn if consuming a diet of  $\geq 30$  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.

**Visit 1 (after enrollment between 10-15 weeks)**

This visit will occur in the basement of the Child Development Unit, located at 3901 Rainbow Blvd, Kansas City, KS, 66180. 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 your 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, 66180. 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 8 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	<input type="checkbox"/>	<input type="checkbox"/>
About any other health issues my child may experience	<input type="checkbox"/>	<input type="checkbox"/>
About my pregnancy and its after effects	<input type="checkbox"/>	<input type="checkbox"/>
About any other health issues I may experience	<input type="checkbox"/>	<input type="checkbox"/>

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



### **OPTIONAL SAMPLE STORAGE AND FUTURE USE**

#### **Purpose:**

You are being asked to provide a stool and urine samples, so that these samples can be saved for research in the future. By studying these samples researchers hope to understand how what you eat and what is in your environment influences bacteria and metabolites found in your stool and urine.

#### **What is involved?**

In order to do the research with your sample, researchers may need to know some things about you. This helps researchers answer questions about diseases. The information that will be given to the researcher may include what you eat, which personal care products you use, and how much weight you gain during pregnancy.

The cells in your body contain deoxyribonucleic acid, or DNA for short. DNA is passed down from your parents. It carries the genes that determine how you look and how your body works. Differences in genes may help explain why a particular drug is effective and safe in some people, but not in others. Differences in genes also may explain why some people get certain diseases, but others do not.

The study of DNA is called genetic research. Your entire genetic makeup will not be determined from this testing. Your DNA will only be used for research to understand disease and possibly develop new treatments.

RNA is made from DNA. RNA is short for ribonucleic acid. RNA is a genetic material that has a major role in making proteins. Proteins are the building blocks of your body, cells, and organs.

A biomarker is a substance, measured in blood or tissue that may reflect the severity or presence of a disease. Biomarker analysis may help determine how serious the disease is or assess early signs that the study drug is working, and to help researchers understand why some subjects will respond to or experience side effects from treatment, while others do not.

#### **How will information about me be kept private?**

KUMC will keep the list that links the code number to your name separate from your sample and information. Qualified researchers can submit a request to use the stored samples. A committee will review each request. There will also be an ethics review to ensure that the study is necessary and proper. Researchers will not be given your name or any other information that could identify you. Your samples will be de-identified which means there will be no link between your identity and samples. Once you have given us permission, you will not be able to cancel that permission because there is no way to identify which samples belong to you.



The information about the uses and disclosures of your health information for the main study also applies to this future research. Even though these protections are in place, once your samples and information leave KUMC they may be used by other researchers/organizations who are not required to follow HIPAA rules. While it might not be protected by HIPAA, there may be other laws that protect your information from improper use. KUMC is not responsible for any sample or data that leaves its control. Reports about research done with your samples will not be given to you or your doctor. These reports will not be put into your medical record. The research will not have an effect on your care.

If results are published, your name and other personal information will not be given

**What are possible risks?**

The main risk of this optional research is possible loss of privacy and confidentiality. We will take reasonable precaution to reduce this risk. There is a small risk that if people other than the researchers were given your genetic information, 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. To minimize these risks, your genetic information will be kept confidential as discussed in this form.

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.



The researchers might share your medical information and blood samples with others outside KUMC who are also studying pregnancy and nutrition. If they share the information, it will not be labeled in a way that could identify you. Your samples will only be labeled with a code. Only Dr. Hull and her study team will know which code that belongs to your name. Codes and names will be kept in a locked file or on a computer with a password.

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.

The choice to share your samples and information is completely voluntary. You can decide not to have your samples used and still participate in the main study. 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



**Permission to contact you in the future**

We would like to contact you via phone and/or email, within 1 year after you end the study. You will be asked questions about your dietary/physical activity patterns and we will ask about your current body weight. We anticipate these calls/surveys will take approximately 10-15 minutes.

The information about the uses and disclosures of your health information in the main study also applies to future contact.

Yes, I agree to allow the study team to contact me in the future.

No, I do not agree to allow the study team to contact me in the future.

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



## **Appendix B: Diet Recall Form**



## **Appendix C: Guidelines for Weighing Yourself (Intervention Group)**



## Guidelines for Weighing Yourself

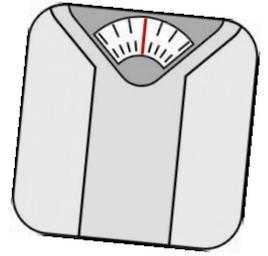


- 1. Place your body weight scale on a flat, non-carpeted surface**
  - Usually a bathroom has a tile or linoleum floor that would work perfect
- 2. Wear minimal to no clothing to avoid inaccurate measurements**
  - You could do this in the bathroom before showering
  - Be sure that you weigh yourself in the same amount of clothing each and every week
- 3. Weigh yourself at the same time every day**
  - Preferably in the morning before you eat anything and after you have visited the restroom
  - For this study we are only doing weekly body weights, so weigh yourself at the same time each week
  - For instance: at 7:30am every Wednesday
- 4. Step onto the scale platform and try not to move**
  - For the body weight scale we have given you, you do not need to tap the scale platform first
  - Stand for 5 seconds in order to get an accurate measurement
- 5. Send us your weight**
  - Enter your weight into the LST app in the measurements section
  - Don't forget to click "Save" instead of "Add" after you have typed it in
  - You can use spoken requests to do this if you prefer
- 6. Receive your payment**
  - Send your weight no later than Thursday at 5pm to receive your \$5 compensation
  - Your compensation will be applied directly to your ClinCard

## **Appendix D: Guidelines for Weighing Yourself (Usual Care Group)**



## Guidelines for Weighing Yourself



- 1. Place your body weight scale on a flat, non-carpeted surface**
  - Usually a bathroom has a tile or linoleum floor that would work perfect
- 2. Wear minimal to no clothing to avoid inaccurate measurements**
  - You could do this in the bathroom before showering
  - Be sure that you weigh yourself in the same amount of clothing each and every week
- 3. Weigh yourself at the same time every day**
  - Preferably in the morning before you eat anything and after you have visited the restroom
  - For this study we are only doing weekly body weights, so weigh yourself at the same time each week
  - For instance: at 7:30am every Wednesday
- 4. Step onto the scale platform and try not to move**
  - For the body weight scale we have given you, you do not need to tap the scale platform first
  - Stand for 5 seconds in order to get an accurate measurement
- 5. Send us your weight**
  - Write down your body weight and reply to the weekly reminder email from [pregnancy@kumc.edu](mailto:pregnancy@kumc.edu)
  - If you don't like emails then you can text your weight to 402-525-6643 with your initials so we know who you are
- 6. Receive your payment**
  - Send your weight no later than Thursday at 5pm to receive your \$5 compensation
  - Your compensation will be applied directly to your ClinCard