Cover Page for Protocol

Official study title:	Preventing excessive weight gain and maternal and infant fat accretion by increasing fiber intake and changing the maternal microbiome during pregnancy
NCT number:	NCT04868110
Document date:	1/12/2022

Preventing excessive weight gain and maternal and infant fat accretion by increasing fiber intake and changing the maternal microbiome during pregnancy
Principle Investigator: Dr. Holly Hull

University of Kansas Medical Center
Department of Dietetics and Nutrition
3901 Rainbow Blvd, Kansas City, KS, 66160
Phone: 913-588-5358

KUMC IRB # STUDY00145397
Protocol Version 11

SPECIFIC AIMS

Excessive gestational weight gain (GWG) is directly linked to greater fat accrual and retention[1] shifting 83% of normal weight women into an overweight or obese BMI category at 1 yr post-pregnancy[2]. Excessive GWG, experienced by 56% of U.S. pregnant women[3,4], increases offspring fat accrual and risk for overweight or obesity development, a characteristic of 31.8% of US children[5]. Excess adiposity levels drive disease development[6], leading to the prediction of a rapid generational decline in life expectancy[7] and a surge in medical care costs (~$150 billion/yr)[8].

During normal pregnancy, maternal metabolism shifts to support fetal growth[9] likening to the development of the metabolic syndrome (MetS)[10-13] including increases in: fat mass[10,11], blood lipids[12], coagulation[13], inflammation, and insulin resistance[12]. No intervention has been design considering the MetS state of pregnancy. Further, prior interventions to prevent excessive GWG were designed based on successful non-pregnant adult ***weight loss*** studies[14], however, incremental ***weight gain*** is critical for fetal development. Meta-analyses reported a minimal effect of prior interventions[15-24] with limited maternal or infant health benefit[17,22-29]. A critical gap is testing an intervention designed to address the unique MetS state of pregnancy. To address this gap, we will test the effect of a high fiber (HFib) diet (>30g/day), designed to address the unique MetS state of pregnancy, to reduce GWG, fat accretion, and improve maternal diet quality.

The benefits of a HFib diet are supported extensively in the literature. Fiber protects against increasing body weight[30-33], promotes fat loss[34-39], increases satiety[40], and improves the metabolic and inflammatory profiles[30,41-47]. Evidence that a HFib diet can reduce body weight and fat mass ***independent of a reduction in energy intake*** was highlighted in a recent meta-analysis[48] and a RCT in adults with MetS[49,50]. The effect is hypothesized in part to be mediated through the powerful prebiotic effect of fiber that favorably shifts the gut microbiota leading to reduced weight gain[48], inflammation[51], improved metabolic profile[51], and prevention of fat accrual[34-37,51]. ***Our working hypothesis*** is that consuming a HFib diet (≥30 g/day) will reduce GWG and fat accretion by diluting energy density, reducing hunger thereby reducing energy intake, and changing the gut bacteria composition. Our pilot data (n=20) found a 12 wk HFib pregnancy intervention reduced Firmicutes and increased Bacteroidetes, which was associated with reduced weight gain and fat accretion[52]. Current fiber intake of pregnant women is 17.3 g/day[53], well below the recommended intake (28 g/day[54]), and triggering fiber to be classified as a *nutrient of concern*[55]. Thus, increasing fiber intake has high potential for impact. However, RCTs in pregnant women are lacking to understand if this is an effective intervention strategy.

The project objective is to block randomize n=56 pregnant women to either a HFib diet or usual care. Eighteen weekly lessons will educate women on eating a HFib diet. To ensure fiber intake is met, daily snacks (10-12 g/day) will be provided. Weight gain, fat accretion, and stool microbiota will be measured twice during pregnancy (pre- and post-intervention) and assessed at 2 months, 6 months, and 12 months postpartum. Infant body composition will be measured at 2 weeks,2 months, 6 months, and 12 months. The aims are:

Primary Aim 1: **Assess the between group difference in maternal weight gain and fat accretion**. *H1*: The HFib group will gain less weight and accrue less fat mass when compared to the control group.

Primary Aim 2: **Compare fiber intake and dietary quality between groups**. *H2*: The HFib group will consume more fiber and have a higher diet quality during pregnancy and postpartum.

Secondary Aim 1: **Characterize between group differences in the gut microbiome composition and diversity (alpha and beta)**. *H1*: The HFib group will have a greater change in gut microbiota composition, taxonomy, and diversity that will be detected during pregnancy and postpartum.

Secondary Aim 2: **Determine if there are between group differences in early infant fat accrual.** *H2*: Offspring born to women in the HFib group will have lower fat accrual.

Secondary Aim 3: Determine if there are differences in markers of metabolic, inflammatory, and brain health during pregnancy and postpartum. *H3*: The HFib group will be characterized by more favorable levels of metabolic, inflammatory, and brain health markers at all time points measured.

Impact: Prior intervention design has not addressed the MetS state of normal pregnancy. Dietary fiber counteracts the components of the MetS. Increasing fiber intake may positively impact the drivers of poor maternal outcomes that prior studies failed to show. *Our study has potential to succeed where others have failed because we designed treatment to target the metabolic shifts that occur during normal pregnancy*. This proposal is innovative because we are measuring the intervention impact on fat accrual and the microbiota in mother and early offspring fat accrual. This proposal would fill a *large research gap*.

RESEARCH STRATEGY

A) SIGNIFICANCE

A1) **Why maternal excessive weight gain is an important problem**: Overall, 55% of women gain excessive gestational weight[3,4] though disparities exist within BMI groups; 62% of women with a high normal BMI (22-24.9 kg/m^2) and ~70% of overweight and obese women gain excessively[3,4]. Maternal overweight and excessive gestational weight gain (GWG) are associated with poor offspring outcomes including increased infant fat mass (FM)[3,56] and increased FM in childhood[57,58] and adulthood[59]. Research shows a strong relationship between maternal excessive GWG and offspring obesity development[60,61], diabetes, and cardiovascular disease[62,63]. Maternal conditions related to excessive GWG include hypertension[64,65] and gestational diabetes (GDM)[66,67]. Many women develop overweight or obesity during the childbearing years[68]. Women who gain excessively are more likely to retain 10 to 20 lbs at 12 months postpartum[69]. Effective interventions to prevent excessive GWG are desperately needed.

Ideally, women would enter pregnancy at an appropriate body weight. However pre-conception interventions have yet to be tested, proven viable, or successful. Many primary care physicians do not counsel patients on weight loss, diet, and exercise due to inadequate resources and feelings of ineffectiveness[70]. *This highlights the importance of interventions during pregnancy*. Pregnancy is an important time period that "programs" disorders and a time when many pregnant women are more likely to adopt healthy behaviors for the well-being of their baby[14]. Several interventions have been completed with varying success and are discussed below.

A2) **Intervention lack of success**: Four meta-analyses[16,18,20,24] and five systematic reviews[15,22-25] show limited success in published interventions. For interventions including diet and physical activity (PA), three[71-73] found improvement in rate of adherence to IOM guidelines while ten[74-83] did not see improvements in adherence. Studies compared differences by BMI groups and found effectiveness in normal weight but not overweight/obese participants[84,85]. Two studies in obese pregnant women provided counseling with a Registered Dietitian at one session[86] or 10 sessions[87] focusing on diet and found improved dietary quality[87] and reduced GWG[86,87]. The greatest success (80% gained <10.6 kg) was found in a study of overweight/obese women using personalization of diet and PA (walking program using pedometers) and consistent self-monitoring[72]. This study was especially impressive as the intervention started at 16-20 wks and the entire cohort had already gained excessively.

A3) **Lessons from prior studies**: Failed studies cite poor outcomes were due to PA not being desirable during pregnancy[79], needing one provider delivering counseling to ensure consistent messages[74], the intervention was not intensive enough[75,84,85], too infrequent of contact[75,79,84], the need to emphasize caloric restriction[84], the intervention started too late[78] or was too short[79], the need to involve significant others[76], and poor adherence[75,81]. Successful studies were intensive, set calorie and PA goals and used self-monitoring[20].

Interventions predominantly based on diet only (e.g., a single goal (SG)) versus interventions changing multiple behaviors (e.g., multiple goal (MG)) were suggested to be the most effective[20]. This is hypothesized to be because the MG approach requires focus on several messages resulting in the intensity of the intervention being diluted, because there is better adherence in SG diet only interventions with only one behavior to focus on changing, and specific components in the SG diet interventions might have benefits not explored[20].

A4) **Benefits of dietary fiber**: One identified nutrient thought to exert this beneficial effect is dietary fiber. Data suggest that dietary fiber can aid in weight loss and maintenance[88-90], promote satiety and reduce hunger[40], reduce inflammation[91], and exert clinical benefits by controlling glucose, insulin levels and lipid levels[49,92]. NHANES 2005-2010 data found in adult males and females the average intake of fiber is only 16.8 g/day[93] which is well below the recommended intake of 25 g/day for females and 38 g/day for males[54]. Studies report a high fiber diet in non-pregnant adults was rated as acceptable to maintain for six months[40]. The maternal physiologic state changes during the course of normal pregnancy to support the growth of the fetus[9]. As pregnancy progresses the metabolic adaptations occurring represent a transient excursion into a metabolic syndrome (MetS) like state, one that is analogous to the worsening of the metabolic profile seen during development of MetS. Dietary fiber exerts protective benefits on several components of metabolic syndrome[94] that could be beneficial during pregnancy.

A5) **Success of a SG intervention**: In a large RCT funded by the NIH (R01 HL094575)[50] in non-pregnant adults with MetS, the effectiveness of two interventions were compared for weight loss and metabolic changes; MG vs. SG. Both groups met face-to-face (FTF) in groups for 12 sessions over three months. The MG followed the American Heart Association dietary guidelines and the SG focused all lessons on achieving dietary fiber (no calorie or PA goals) intake ≥30 g/day. At 12 months, the MG group lost -2.7 kg, while the SG group lost -2.1 kg and both groups saw improvements in dietary quality, insulin resistance, lipids, inflammation, glucose levels and blood pressure. Both groups decreased kcal/d, however the MG group had a greater decrease (-464 versus -200 kcal at 12 months). Olendski[49] tested the effectiveness two simple messages in a three group design: 1) calorie restriction + high fiber, 2) calorie restriction + low saturated fat and 3) MG intervention (a combination of restricted kcals, high fiber, and low fat). The intervention lasted 3 months with biweekly FTF individual meetings with a Dietitian. At six months, no between group difference was found for body weight lost; -7 lbs for MG, -9.1 lbs for fiber and, -10.2 lbs for saturated fat group. All groups improved dietary quality and cardiometabolic parameters. At six months, 83% of the fiber group were confident they could stick to their diet, whereas only 60% and 33% were confident in the saturated fat and MG groups, respectively (p=0.008). Taken together, no clear between group differences were found between a SG dietary fiber intervention and a MG intervention. This suggests in non-pregnant adults, both intervention types were effective.

A6) **Promising new intervention approach**: Encouraging appropriate GWG by improving dietary quality and encouraging PA are modifiable behaviors but the best practices to achieve these are unknown[95]. FTF individual counseling is effective but expensive and difficult to scale up for dissemination[96]. Group based phone counseling (GBPC) is novel and efficiently uses both the time and resources of the providers and participants. Pregnant women report[9] lack of time, resources and need for childcare as barriers to participating in lifestyle interventions. Participants “meet” as a group weekly by phone with a Registered Dietitian. GBPC interventions are effective for weight management in non-pregnant populations[97,98] with studies finding equivalent weight loss for FTF versus GBPC[99-101]. GBPC allows participants to interact with each other in real time and supports participant desired anonymity[99]. No studies have used GBPC to encourage appropriate GWG in pregnant women or used a novel intervention to pregnancy, a SG dietary fiber intervention.

B) **Innovation:** The proposed research is innovative because of the research team, the research design and idea, and the techniques used. Our team is using existing science to deliver interventions to high risk and high need patients. We are filling a research and clinical gap by packaging information that is already available into an effective intervention that in future studies can be embedded into routine clinical care. Using a SG intervention for weight loss and to improve metabolic health has been proven successful in non-pregnant adults but remains un-tested in pregnancy[50]. In pregnancy, the goal is not to induce weight loss, but ***blunt*** the rate of excessive gain. Promotion and adherence to a healthy lifestyle is of the utmost importance during pregnancy because we can positively impact the health of the mother and her baby.

C) **Approach/Preliminary Studies**

C1) **Preliminary study**: **multiple goal behavioral lifestyle intervention to reduce excessive GWG**: Drs. Hull and Goetz were co-PIs funded on a pilot study to test the effectiveness of a multiple goal behavioral lifestyle intervention (vs. UC) to prevent excessive GWG using GBPC. The primary outcome was the proportion of women gaining excessively based on 2009 IOM recommendations[69]. The intervention ran from 18 to 36 weeks and the intervention group met weekly by phone with a Dietitian for 60 minutes. All participants reported body weight weekly via text message. The curriculum included 18 lessons. Data are presented in Table 1. Fourteen women were enrolled into the multiple goal group and 12 women were enrolled into the UC group. We lost 3 subjects in the control group and lost zero subjects in the intervention. In the intervention group, 29% gained excessively while 78% of the UC group gained excessively. Additionally, the UC group gained more weight (p=0.010). Structured interviews were done in a sample of those completing the study (n=9). When asked, "What changes did you make due to the intervention?", 33% responded, "consumed more fruits/vegetables" and "controlled portions" while 22% said "consumed less sugar". When asked "What they liked about the program?", 44% replied "*monitoring body weight*". When asked "What they would recommend for future interventions?", responses included, *keep a variety of topics* and *set one goal for the entire program*. The data are promising.

Table 1: Preliminary results from pilot study to prevent excessive GWG

	Pre-pregnancy BMI (kg/m^2)	GWG (kg)	% gaining excessively
Usual Care (n=9)	29.3 ± 4.8	18.4 ± 7.3	78%
Intervention (n=14)	28.4 ± 8.6	11.8 ± 4.0*	29%

Means ± SD

*Significantly different from control group (p=0.010)

C2) **Population to be studied**: Women between 9 to 19 weeks pregnant with a BMI 18.5 – 45.0 kg/m^2 and between the ages of 18-45 years will be recruited from the University of Kansas Medical Center (KUMC) OB clinics. We will enroll all race/ethnic groups. Participant's routine OB care will be managed by their primary Obstetrician. Any interventions, laboratory or other evaluations, and decisions regarding delivery will be made by the primary Obstetrician. Groups of 6-10 subjects will be block randomized to control or the intervention group to ensure adequate size for optimal group dynamics. The intervention will start at 12-20 wks and last 18 weeks, ensuring intervention completion by 38 weeks in pregnancy. We will screen women to determine the current dietary fiber intake. If they are consuming 25 g/day of fiber or more, they will be excluded from the study. Women who do not have internet and phone access will be excluded from the study. Participants must be willing to consume provided snacks. Participants will also be excluded if they have history of gestational diabetes (GDM), diabetes, pre-eclampsia, hypertension, heart disease, hypothyroidism, or other metabolic abnormalities, current hyperemesis gravidarum, eating disorder, smoking, or are pregnant with multiples. Women that develop any of these medical conditions during pregnancy will be accounted for in the final analysis. Deviations from inclusion criteria will be at the discretion of the PI.

C3) **Recruitment**: We have access to the electronic clinic schedule, therefore we have the exact date and time of the recruit's OB visit. We have worked directly with physicians and staff providing an in service at meetings to ensure a smooth recruiting process so that we do not impede clinic flow. Annually, 1800 women are managed in the OB clinics at KUMC. Additionally, we will recruit using an electronic flyer via social media. Individuals who have agreed to future contact from previous studies will also be approached if eligible via email or phone.

C4) **Curriculum development**: The interventions were designed based on the theoretical framework of the social cognitive theory (SCT)[102]. Bandura proposed that people attain and then maintain patterns of behavior and that behavior is based on the interaction of personal, environmental and behavioral factors. The consistency of behavior provides the foundation for development of our intervention strategy. Within the SCT there are several constructs that are directly related to weight control programs[103,104]. **Table 2** provides examples of the constructs and behavioral strategies and examples of how these will be used in the study.

Table 2. Behavioral strategies used within the study	
Behavioral Strategy	Examples of how used within the study

Behavior Shaping	*Participants are taught to modify their fiber intake according to recommendations.*
Goal Setting	*The Dietitian teaches sensible goal setting and assists participants to set personalized goals (e.g., fiber intake) to achieve appropriate GWG.*
Self-Monitoring	*Participants will report their body weight and fiber intake weekly & be taught self-monitoring.*
Feedback & Reinforcement	*Participants receive weekly feedback that includes reinforcement & strategies to overcome barriers.*
Social/Peer Support	*Group sessions provide peer support and interaction to model and teach behaviors.*
Stimulus Control	*Lessons provide coping & behavioral strategies to decrease cues for undesirable behaviors and to increase those for healthy behaviors.*
Relapse Prevention	*The Dietitian facilitates the development of a contingency plan to address high risk situations based on Marlatt and Gordon's relapse prevention model* [105]

C5) **General intervention description**: Group video conferencing will be used to deliver the intervention. The weekly 60-minute lessons for the Hfib group provide information on how to obtain ≥30 g/day of fiber (details below).

C5a) General layout of the group sessions: The session will start with a review of the prior week's goals, with support and encouragement from group members and the Dietitian (5-10 minutes). A group discussion will occur with group members relating and/or providing personal insight and support. The Dietitian will lead discussion and engage the women by asking opened ended questions, providing encouragement and troubleshooting as needed. Each week there will be a structured lesson with an assignment to be completed after the session (20-30 minutes). The last 10-20 minutes of the session will be devoted to goal setting, discussion, questions, and wrap-up. For best group dynamics on video, 5-10 women are optimal.

C5b) Video System: Group sessions will be conducted using Zoom video conferencing system (Zoom Video Communications, Inc., San Jose, CA). Participants will be given a link with a password and instructed to call in 5 minutes prior to group start. A log will be generated to track attendance. All conference calls will be recorded for quality assurance and to serve as additional training for the group leader.

C5c) Hfib intervention details: The 60-minute weekly group sessions (18 total) will focus on eating a high fiber diet both during and after pregnancy. The dietary reference intake (DRI) for fiber during pregnancy is 28 g/day and 25 g/day for females of reproductive age[54]. *The goal is for participants to gain within 2009 IOM recommendations*[69]. To achieve this, all participants will be encouraged to consume ≥30 g/day of fiber. The Hfib intervention will receive a fiber goal (no calorie goal). This is intentional because we want to remove the driver of what is known to induce weight loss (calorie goal) and determine if a fiber goal without a calorie goal can *blunt* excess GWG. Because the goal is to keep the Hfib intervention simple, we are focusing on the one behavior with the best evidence to control weight gain; consuming ≥30 g/day fiber. Discussion will encourage problem solving, provide educational information, and social engagement during the video calls. Participants will be taught to track their daily total fiber intake in REDCap. Participants will be encouraged to follow a balanced diet emphasizing fruits and vegetables, whole grains, low-fat dairy and lean protein. General PA recommendations during pregnancy will be mentioned but no focus or reinforcement of this behavior will take place . All participants will be given a body weight scale and report body weight weekly. Participants will receive a notebook containing handouts and assignments specific to each weekly topic. Dietitians will facilitate the lessons and lead discussion.

In order to improve adherence to a high fiber diet, all participants will receive daily high fiber snacks (see **table 3**). In pregnant women, the average daily fiber intake is 15 g/day. Therefore, by providing two snacks, we will increase the fiber intake to close to the goal of ≥30 g/day fiber. The box will include multiple flavors of Kind bars, chickpeas and snap peas. Additionally, they will receive whole grain cereals including whole wheat puffins and wheat Chex. All foods are shelf stable from 12 months to 18 months. The snacks will be pre-portioned for one serving with recommendations to consume 2 snacks per day. Lessons will focus on how to increase fiber intake with education on foods that contain fiber, high fiber recipes, and how to make over current recipes to contain more fiber. Their weekly progress towards the fiber goal will be monitored closely through REDCap fiber tracker. If they are not meeting the daily fiber goal, a dietitian will call the participant to discuss barriers, troubleshoot any challenges associated with diet adherence and develop a plan to increase fiber intake.

Table 3. A list of high fiber snacks for one week.							
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Snack 1	Kind bar	Snap peas	Kind bar	Chex	Kind bar	Snap peas	Chex
Snack 2	Puffins	Chex	Chickpeas	Snap peas	Puffins	Kind bar	Chickpeas
Fiber/day (g)	12	10	12	10	12	12	10

C5d) Monitoring & Compliance: Participants will submit a daily log electronically through REDCap (Research Electronic Data Capture) to report number of servings of high fiber food groups (e.g., fruits, vegetables, whole grains, legumes, nuts and seeds). Participants will be given a body weight scale and asked to report their body weight weekly.Research staff will review compliance weekly and contact participants who need support and provide accountability. Participants will be flagged for follow-up if they are not attending calls, not completing daily REDCap logs, or if they are consistently below their fiber goal as assessed by biweekly 24-hour recalls. Participants will also be contacted if they report a body weight change ± 5 pounds over two weeks.

C5e) Usual care group: Those randomized to the UC group will be cared for by their obstetrician using standard treatment. Standard treatment consists of attending regularly scheduled visits where patients are weighed and evaluated. The standard visit schedule is once monthly until 32 wks gestation, bi-weekly for 32-37 wks gestation, weekly until delivery, and at 6 wks post-partum. At the first prenatal visit, they will receive the standard nutrition and physical activity counseling along with literature outlining recommendations provided by the obstetrics team. Women in the UC group will report body weight weekly via REDCap. In the multiple goal pilot study, the control group reported body weight weekly. This minimal contact did not impact the rate of excessive GWG, as the rate of excessive GWG in the control group was 78%.

C5f) Adherence: Adherence will be assessed based on participants meeting their prescribed fiber goal (≥30g/day average) as well as by call attendance ≥75% (14 or more calls attended). Starting in week two of the intervention, one 24-hour dietary recall will be collected every two weeks (9 recalls total) to determine fiber intake. Participants will be considered adherent if their number of days meeting fiber goal/number of days reported is ≥75%.

C6) **Standard training and quality assurance**: Dr. Goetz has considerable experience (over 10 years) delivering weight management interventions and as a trainer (R01 DK076063, HL11842, DK094833). Dr. Goetz will provide initial and ongoing training for the Dietitians who will lead the group sessions. Dr. Goetz will randomly select 20% of the calls and using the checklist, make sure >80% of the content was covered. If >80% of the content was not covered, the Dietitian will be re-trained focusing on deficient areas.

C7) **Maternal & infant assessments**: Listed in **Table 4** is an outline of study visits and procedures. In C7a-i, details are provided regarding maternal & infant outcomes that will be collected.

Table 4. An outline of study visits and procedures.						
	During Pregnancy		**Postpartum**			
Study procedure	**Baseline: 12-20wks**	**End of Intervention: 30-38wks**	**2 weeks**	**2 months**	**6 months**	**12 months**
Questionnaires	•	•	•	•	•	•
Maternal anthropometrics	•	•	•	•	•	•
Maternal body composition (BodPod, BIA)	•	•		•	•	•
Maternal vitals	•	•	•	•	•	•
Maternal pregnancy test			•	•	•	•
Maternal DXA scan				•	•	•
Maternal diet recalls	•	•	•	•	•	•
Maternal veggie meter	•	•		•	•	•
Maternal olfactory testing	•	•		•		•
Maternal urine	•	•	•	•	•	•

Maternal cognitive testing	•	•		•	•	•
Maternal stool	•	•		•	•	•
Maternal blood draw	•	•		•	•	•
Maternal actigraphy	•	•		•	•	•
Infant anthropometrics			•	•	•	•
Infant skin folds			•	•	•	•
Infant body composition (PeaPod)			•	•	•	
Infant stool			•	•	•	•
Infant DXA scan			•			•
Infant diet recalls			•	•	•	•
Breast milk				•	•	
Satisfaction survey (Hfib only)		•				
Process evaluation (Hfib only)		•				

C7a) Gestational weight gain: GWG will be calculated following the NIH LIFE-Moms protocol[106]. Self-reported pre-pregnancy weight will be replaced with baseline study measured body weight and subtracted from weight measured at 34 weeks to calculated GWG. When data are missing, we will extract body weight at delivery admission from the electronic medical record. GWG guidelines will be used to classify excessive GWG[69].

C7b) Questionnaires: Questionnaires will be given to assess maternal pregnancy and infant birth characteristics at study visits, via REDCap surveys, and over the phone throughout the study. Examples include maternal health (medical and obstetric history), self-reported race/ethnic background, income, education, household information (marital status, baby father's health, etc.), hunger and satiety, emotional health, gastrointestinal health, supplement use, alcohol consumption, drug use, infant sex, birth weight, birth length, and gestational age, to name a few[107-109]. One survey will ask about liking or disliking of foods to assess perception of taste and olfaction, which can influence what foods people choose to eat. The survey will be taken through a link (https://uconn.co1.qualtrics.com/jfe/form/SV_aVFeLIsOTSVSCzk) which is hosted by the University of Connecticut and the corresponding data will be stored on their server. Once the survey has been scored, the results will be sent to the study team. No identifying information except a participant ID will be included in the survey.

C7c) Satisfaction survey: Satisfaction will be measured with three questions measured on a 5-point Likert scale at the completion of the study: "How confident are you that you will stick to the study diet?"; "I am always hungry on this diet"; and "This diet is a benefit to my health". Responses for the confidence question will be: not at all, not very, somewhat, very and extremely confident. Responses for the hunger and benefit to health questions will be: strongly agree, agree, neutral, disagree and strongly disagree.

C7d) 24-hour dietary recall: Three multiple-pass 24-hour dietary recalls (2 weekday and 1 weekend day) will be collected by trained research staff at baseline, end of intervention, and 2, 6, and 12 months postpartum to characterize energy and nutrient intake (1 in person, 2 via phone per each visit using a standardized food amounts booklet). One 24-hour recall will be obtained every four weeks during the intervention to assess fiber goal adherence, Multiple-pass 24-hour recalls accurately estimate dietary intake[110,111] and contain less reporting bias than diet records[110,112]. One 24-hour dietary recall will be administered to the child's caregiver at 2 weeks, 2 months, 6 months, and 12 months to characterize the diet of the child. The recalls will be entered into the Nutrition Data System for Research (NDS-R, version 2020, Minneapolis, MN) for macro- and micronutrient analysis.

C7e) Fecal Sample Collection: Stool will be collected five times throughout the study (baseline, end intervention, and 2, 6 and 12 months postpartum) from the mother and four times throughout the study from the infant (2 weeks, 2 months, 6 months, and 12 months). OMNIgene GUT and OMNImet GUT stool collection kits (DNAGenotek, Canada) will be shipped to women with specific instructions on collection and storage at home. Women will bring collected samples to their study visit. DNA extraction will be completed at KUMC under the supervision of Dr. Matthew Taylor. Library preparation and microbial profiling using 16S V4 sequencing will be completed at KU Lawrence.

C7f) Anthropometry: Body weight will be assessed on the same calibrated scale (Detetco Scales, Webb City, MO) throughout the study duration for the mother and a calibrated pediatric scale for the infant (Scale-Tronix, White Plains, NY). Height will be measured using a wall mounted stadiometer (Accu-Hite, Seca Corp, Hanover, MD) for the mother and length using a length board (Shorr Productions) for the infant. Two or more measurements will be taken, and the average recorded. Infant head and waist circumferences will be measured two or more times, and the average recorded.

C7g) Maternal and infant body composition: Maternal body composition will be assessed using the Selinger four-compartment model[113] at baseline, end of intervention, and 2, 6, and 12 months postpartum. The 4C model includes body mass, body volume, total body water, and bone mineral content. Percent fat will be determined by the equation: %FM = ([2.747/BD] – [0.714*TBW/BW] + [1.129*B/BW] – 2.037) x 100; where BD is body density in kg/L, TBW is total body water in L, B is bone mineral in kg, and BW is body weight in kg[11]. Body mass will be measured by an electronic scale (Detetco Scales, Webb City, MO). Body volume will be assessed via air displacement plethysmography[26] (BodPod®; CosMed, Concord, CA)[114]. Women will wear minimal tight-fitting clothing (e.g. one-piece swimsuit) and a fitted hat. Body density will be calculated as body mass/body volume. Total body water will be assessed using bioelectrical impedance analysis (BIA; Tanita, Inc., TBF-310, Tokyo, Japan)[115]. Bone mineral content will be measured by dual-energy X-ray absorptiometry (DXA; GE Healthcare, Lunar Prodigy, Madison, WI). DXA is contraindicated during pregnancy since radiation emission is considered harmful to the fetus[116], so bone mineral content will be assessed at 2 weeks postpartum[1,11,117]. Infant body composition will be assessed via air displacement plethysmography[26] (PeaPod®; CosMed, Concord, CA)[114] at 2 weeks, 2 months, and 6 months (if infant ≤10kg). Infants are tested nude with a tight fitting hat[3]. Our Pea Pod® system has the larger tray allowing testing of infants with a body weight up to 10 kg.

C7h) Maternal and infant DXA: Dual energy x-ray absorptiometry (DXA; Prodigy, Madison, WI, encore software version 13.60) will be used to measure body composition and regional adipose tissue distribution. The DXA is located within the Dietetics & Nutrition Clinic inside the Smith West building at KUMC. Using specific anatomic landmarks as previously described, regions including the arms, legs and trunk will be demarcated[118]. Calculations for FM in each region and summed for regions comprising the central (trunk) and peripheral (arms plus legs) will be completed. If a child moves during the scan the scan may need to be re-done at the same or later visit, but no more than 6 total scans will be given over the duration of the study.

Pregnant women violate the assumptions used in other body composition methods, so a four-compartment model is performed where each component is measured separately to get a more accurate picture. The components include body mass, body volume, total body water, and bone mineral content. Since DXA is contraindicated in pregnancy, the bone mineral content component will be assessed via the DXA at 2 month postpartum to determine body composition during pregnancy. At 2 months, 6 months, and 12 months postpartum, a maternal DXA scan will be obtained because DXA is the only precise technique for measuring the location of body fat. Other body composition techniques give an estimate of total body fat only. DXA gives a measurement of central and peripheral fat and has the capability to estimate visceral adipose tissue (VAT). Central body fat (fat located around the organs), especially VAT, carries a much higher disease risk than peripheral body fat (fat in the extremities). Adults with type 2 diabetes and cardiovascular disease have higher levels of centrally located fat, whereas fat located in the peripheral region is cardioprotective[118,119]. For the infants, DXA is the only precise technique for measuring amount and location of body fat longitudinally. The PeaPod® can only measure infants up to 10 kg, which most children will outgrow between 4-6 months old. We need a precise measurement of body composition we can compare across all our timepoints up to 12 months old. While the DXA scan offers no direct benefit to the infant, the information obtained will yield generalizable knowledge of vital importance to this population. The prenatal period is shown in literature to be related to offspring obesity development and disease risk. Overall, 55% of women gain excessive gestational weight[4]. Excessive GWG leads to higher infant fat mass at birth[3,56], and therefore higher childhood fat mass[57,59-61]. Overweight and obesity in childhood are related to disease development later in life, leading to the development of the metabolic syndrome, diabetes, and cardiovascular disease[6,62,63]. With the current obesity epidemic, it is critical to understand if we can intervene during the prenatal period to impact fat accumulation

and distribution in the infants, which are important drivers of obesity occurrence, disease risk, and severity of disease development.

C7i) Process evaluation: Data will be collected throughout the intervention to assess barriers to recruitment and study retention, participant acceptability and intervention adherence, and how well the intervention was implemented. Participants that drop will be contacted and asked to complete a brief interview to provide feedback. Semi-structured interviews will be conducted at the final assessment (34 wks). Participants will be asked about their perception of the intervention including both positive and negative aspects and any challenges that were encountered, pros and cons of using group video counseling to promote healthy behaviors during pregnancy, and their overall satisfaction with the intervention. Interviews will be audio recorded and transcribed verbatim. Comments will be coded, categorized into themes and used to refine and further develop future interventions.

C7j) Safety monitoring: All subjects will be given a body weight scale and report body weight weekly. This allows close supervision of progression of each participant to ensure the intervention is not overly effective and all women are gaining adequate body weight. If a woman gains or loses more than 5 lbs over a two-week period, she will be flagged and contacted. If she is in the Hfib group, total weight gain recommendations will be reviewed and her dietary habits and fiber intake will be reviewed and reinforced. Rapid weight changes or any other safety concerns will be reviewed by our study physician for safety purposes. The participant's provider will be notified if physician deems necessary.

C7k) Maternal blood draw: Maternal venous blood will be collected at 5 times through the study (baseline, end of intervention, 2 months, 6 months, and 12 months postpartum) after an overnight fast by a trained phlebotomist. A total of two 4-mL EDTA (lavender top) tubes (1 will be filled ½ full), one 10-mL EDTA, one 7.5-mL serum (tiger top) tube, and one-8.5mL serum tubes will be collected. At the baseline visit and additional one 6-mL ACD (yellow top) plasma vacutainer will be collected for ApoE genotyping. All tubes will be placed on ice and processed within 24 hours, including aliquoting for analysis. All tubes will be appropriately labeled with the study identification number, date (mm/dd/yyyy), and time (24-hour time, hh:mm). Blood samples will be analyzed to assess biomarkers related to cardiometabolic health (including serum lipids, glucose metabolism, and inflammation), gut metabolites (short chain fatty acids) and neuronal health (including assessment of underlying ApoE genetics). Samples will be sent to Quest Diagnostics for cardiometabolic markers (standard lipid panel (total cholesterol, triglycerides, HDL-C, LDL-C (calculated), Cholesterol/HDL ratio (calculated), and non-HDL-C (calculated)), hemoglobin A1C, plasma glucose, serum insulin, and high sensitivity- C-reactive protein). All other samples will be stored at −80°C for analysis. Batched samples will be analyzed at KUMC according to the protocols of the manufacturer using the following formats:, SIMOA (neurofilament-light and inflammatory cytokines), and polymerase chain reaction (ApoE genotype). Unused samples will be banked for future evaluations related to nutrition and brain healthincluding free cell RNA analysis at KUMC.

C7l) Actigraphy: Maternal physical activity and sleep will be monitored using the ActiGraph wG3TX-BT. The device will be worn at the wrist for 7 days around 5/6 study visits (baseline, end of intervention, 2 months, 6 months, and 12 months postpartum). Participants will not be able to view any device data. Participants will also be asked to keep a sleep and activity log during this time. Participants will be mailed the device and given instructions for use prior to each study visit, along with an activity and sleep tracker. Following the 7-day monitoring period, participants will return the device and log back to the study team. Data collected from the device are available at https://www.actigraphcorp.com/actigraph-wgt3x-bt/ and include raw acceleration, steps, METs, total sleep time, sleep efficiency, and others related to activity and sleep. Participants will download an application on a home device that will allow them to daily sync the activity information via Bluetooth and send it to the cloud-based data management platform https://actigraphcorp.com/centrepoint/.

C7m) Maternal vitals: Blood pressure & heart rate will be assessed 6 times throughout the study (baseline, end of intervention, 2 weeks 2 months, 6 months, and 12 months) using the Omron HEM 907XL IntelliSense Professional Digital Blood Pressure Monitor. Participants will be instructed to sit quietly for 5 minutes in the upright position with feet flat on the floor. After completing the period, blood pressure cuff will be placed around

the upper arm and assessment completed per manufacturer's recommendations. The measurement will be repeated until 2 are within 5 mmhg agreement.

C7n) Veggie meter: Maternal carotenoid skin content will be assessed at 5 time points (baseline, end of intervention, 2 months, 6 months, and 12 months) using the veggie meter. Participants will insert a finger into the machine. The machine uses LED light to detect pigments. Three measurements will be taken and averaged, each lasting 10-45 seconds.

C7o) Maternal cognitive testing: The NIH Toolbox Cognition Battery will be used to assess cognitive function in several different domains, including executive function, language, episodic memory, processing speed, and attention 5 times throughout the study (baseline, end of intervention, 2 months, 6 months, and 12 months). The test will be administrated by a trained team member on an Apple iPad. Consistent with the toolbox recommendations, collected data will be emailed to a member of the study team and archived on the P-Drive. The record is not required to be kept on the iPad and can be expunged after confirmation that it has been archived on the P-Drive.

C7p) Maternal olfactory testing: Participant olfaction will be evaluated at 4 times throughout the study (baseline, end of intervention, 2 months, and 12 months). Each patient will be tested with fourteen different scents using aromatherapy inhaling scents (rose, eucalyptus, clove, lemon, garlic, coffee, spearmint, orange, cinnamon, lavender, rosemary, anise, peppermint, and ginger). The scents will be available at two concentrations (1x and 2x), and the participants will be asked to nasally inhale each scent for 10 seconds. The participants will be presented with the 1x sticks and asked to state if a smell is present and to correctly identify the odor. If an odor is not detected or correctly identified, the 2x concentration of the same odor will be added to the remaining lot of inhalant sticks.

C7q) Infant skinfolds: Skinfolds will be assessed 4 timepoints for the infant (2 weeks, 2 months, 6 months, and 12 months). Six skinfolds will be measured to represent AT distribution in order to compare to larger trials that do not have DXA. All measurements will be collected using standardized procedures to our laboratory. All skinfolds will be identified using anatomical landmarks and taken on the right side of the body using Lange calipers (Beta Technology, Santa Cruz, CA). Skinfolds will be taken in order from head to toe and then repeated in that same order. If two skinfold measurements differ by more than 1 mm, a third measurement will be taken. The two measurements within 1 mm will be averaged and used for analysis. Biceps and triceps skinfolds will be measured at the midline of the anterior and posterior surface of the arm, respectively, on the mid-point between acromial process of the scapula and olecranon process of the ulna. Subscapular skinfold will be measured at the lower angle of the scapula. Suprailiac skinfold will be measured anteriorly to the midaxillary line and superiorly to the iliac crest, along the natural cleavage of the skin. The thigh skinfold will be measured at the mid-point between patella (knee cap) and inguinal crease at the anterior surface of the thigh. Flank skinfold will be measured immediately above the iliac crest at the mid-axillary line. Central FM will be calculated by adding the subscapular, suprailiac and flank skinfolds and dividing by three Peripheral FM will be calculated by adding the thigh, biceps and triceps skinfolds and dividing by three.

C7r) Maternal urine & pregnancy test: Urine will be collected at all 6 maternal timepoints. Prior to maternal DXA at all post-partum visits (2 weeks, 2 months, 6 months, and 12 months), the urine will be used to perform a pregnancy test. Urine will be collected and aliquoted into 10, 2-mL cryovials and stored at -80°C. Urine will be used to test for polyfluoroalkyl substances. Unused samples will be banked for future evaluations related to nutrition and brain health at KUMC.

C7t) Breastmilk analysis: Participants who choose to breast feed will be asked to pump one breast until empty, homogenize the breastmilk by stirring, and return 20-mL to the study team for nutrient analysis. Participants will be asked to do this at 1 month, 2 months, 3 months, 4 months, 5 months, and 6 months, freeze it, and return it to the study team at the 2-month and 6-month visits. The remainder of the breastmilk collected can be kept by the participant and fed to their infant. Any leftover sample after initial nutrient analysis will be banked for future evaluations related to nutrition and brain health and KUMC.

C8) **Steps to maximize adherence and retention**: We will be using incentives for study visits, incentives for reporting goals, and regular short-term performance and feedback.

C8a) Incentive system: Participants will be compensated $100 for each of the 6 study visits: baseline, end intervention, 2 weeks postpartum, 2 months postpartum, 6 months postpartum, and 12 months postpartum totaling up to $600 for completion of all visits. Participants asked to return for repeat infant DXA (no more than 2 at each study timepoint) will be compensated an additional $50. Compensation will be provided on a ClinCard, which is given at enrollment. After each visit study staff will load their unique card number with the respective pay. Participants can use the card anywhere Mastercard is accepted, and study staff does not have access to where the money will be spent.

C8c) Monitoring retention: When participants miss a session or reporting of behaviors, they will be contacted and a standardized protocol according to attendance and adherence demands will be used to make every effort to retain the participant or encourage reporting. This will be documented and used for program evaluation.

C9) **Statistical analysis:** The purpose of this study is to attain feasibility data therefore the small sample size does not afford the power to detect significance but to identify promising trends and relationships.

Analysis for Aim 1 *H1*: A t-test will be used to determine if there is a difference in maternal weight gain and fat accretion between the two groups.

Analysis for Aim 2 H2: A t-test will be used to quantify if there is a difference in fiber intake and dietary quality between the two groups.

Analysis for secondary Aim 1 H1: Repeated measures ANCOVA will be used to assess the difference in gut microbiome composition and diversity from baseline to study end between groups.

Analysis for secondary Aim 2 H2: A t-test will be used to determine if there is a difference in infant fat accrual between groups.

Analysis for secondary Aim 3 H3: A t-test will be used to determine if there is a difference in metabolic, inflammatory, and brain health markers.

Process evaluation: A process evaluation will be completed.

C10) **Study challenges**: A primary study challenge is the recruitment and retention. Dr. Hull has completed protocols successfully recruiting participants from the OB clinics at KUMC. Dr. Weiner, KUMC head of OBGYN, reports 1800 annual deliveries take place at KUMC with ~40% overweight. A second challenge is to assure the fidelity of the interventions. Dr. Goetz will listen to 20% of GBPC sessions and compare the content delivered to a standardized checklist. If less than 80% of content is covered, Dr. Goetz will re-train the Dietitian. A third challenge is to ensure subjects are attending sessions and reporting behaviors. We had a high degree of weekly reporting in our pilot study and anticipate a similar response rate in this pilot.

C11) **Expected results**: We anticipate the Hfib intervention will successfully prevent excessive GWG. The Hfib intervention holds promise to be delivered in routine clinical care. If the results are positive, the next study would be to adapt and embed the Hfib intervention in routine clinical care. The literature supports preventing excessive GWG has a high likelihood to greatly improve the health of both mothers and their offspring however there is variable success in published interventions. This supports the need to design and test interventions informed by prior study failures.

C12) **Environment**: The environment at KUMC is well suited to conduct this research.

References:

1. Butte NF, Ellis KJ, Wong WW, Hopkinson JM, Smith EO. Composition of gestational weight gain impacts maternal fat retention and infant birth weight. *American journal of obstetrics and gynecology.* 2003;189(5):1423-1432.
2. Endres LK, Straub H, McKinney C, et al. Postpartum weight retention risk factors and relationship to obesity at 1 year. *Obstetrics and gynecology.* 2015;125(1):144-152.
3. Hull HR, Thornton JC, Ji Y, et al. Higher infant body fat with excessive gestational weight gain in overweight women. *American journal of obstetrics and gynecology.* 2011;205(3):211 e211-217.
4. Badon SE, Dyer AR, Josefson JL, Group HSCR. Gestational weight gain and neonatal adiposity in the Hyperglycemia and Adverse Pregnancy Outcome study-North American region. *Obesity (Silver Spring).* 2014;22(7):1731-1738.
5. Fryar CD, Carroll MD, Ogden CL. *Prevalence of overweight and obesity among children and adolescents: United States, 1963-1965 through 2011-2012.* Atlanta, GA2014.
6. Llewellyn A, Simmonds M, Owen CG, Woolacott N. Childhood obesity as a predictor of morbidity in adulthood: a systematic review and meta-analysis. *Obes Rev.* 2016;17(1):56-67.
7. Ahmad FB, Bastian B. *Quarterly provisional estimates for selected indicators of mortality, 2015-Quarter 1, 2017.* National Center for Health Statistics. 2017.
8. Cawley J, Meyerhoefer C, Biener A, Hammer M, Wintfeld N. Savings in Medical Expenditures Associated with Reductions in Body Mass Index Among US Adults with Obesity, by Diabetes Status. *Pharmacoeconomics.* 2015;33(7):707-722.
9. Kaaja RJ, Greer IA. Manifestations of chronic disease during pregnancy. *Jama.* 2005;294(21):2751-2757.
10. Lassek WD, Gaulin SJ. Changes in body fat distribution in relation to parity in American women: a covert form of maternal depletion. *Am J Phys Anthropol.* 2006;131(2):295-302.
11. Lederman SA, Paxton A, Heymsfield SB, Wang J, Thornton J, Pierson RN, Jr. Body fat and water changes during pregnancy in women with different body weight and weight gain. *Obstetrics and gynecology.* 1997;90(4 Pt 1):483-488.
12. Knopp RH, Ruder HJ, Herrera E, Freinkel N. Carbohydrate metabolism in pregnancy. VII. Insulin tolerance during late pregnancy in the fed and fasted rat. *Acta Endocrinol (Copenh).* 1970;65(2):352-360.
13. Greer IA. Thrombosis in pregnancy: maternal and fetal issues. *Lancet.* 1999;353(9160):1258-1265.
14. Phelan S. Pregnancy: a "teachable moment" for weight control and obesity prevention. *American journal of obstetrics and gynecology.* 2010;202(2):135 e131-138.
15. Campbell F, Johnson M, Messina J, Guillaume L, Goyder E. Behavioural interventions for weight management in pregnancy: a systematic review of quantitative and qualitative data. *BMC Public Health.* 2011;11:491.
16. Streuling I, Beyerlein A, von Kries R. Can gestational weight gain be modified by increasing physical activity and diet counseling? A meta-analysis of interventional trials. *The American journal of clinical nutrition.* 2010;92(4):678-687.
17. International Weight Management in Pregnancy Collaborative G. Effect of diet and physical activity based interventions in pregnancy on gestational weight gain and pregnancy outcomes: meta-analysis of individual participant data from randomised trials. *BMJ (Clinical research ed.* 2017;358:j3119.
18. Gardner B, Wardle J, Poston L, Croker H. Changing diet and physical activity to reduce gestational weight gain: a meta-analysis. *Obes Rev.* 2011;12(7):e602-620.
19. Vincze L, Rollo M, Hutchesson M, et al. Interventions including a nutrition component aimed at managing gestational weight gain or postpartum weight retention: a systematic review and meta-analysis. *JBI database of systematic reviews and implementation reports.* 2019;17(3):297-364.
20. Thangaratinam S, Rogozinska E, Jolly K, et al. Effects of interventions in pregnancy on maternal weight and obstetric outcomes: meta-analysis of randomised evidence. *BMJ (Clinical research ed.* 2012;344:e2088.
21. Peaceman AM, Clifton RG, Phelan S, et al. Lifestyle Interventions Limit Gestational Weight Gain in Women with Overweight or Obesity: LIFE-Moms Prospective Meta-Analysis. *Obesity (Silver Spring, Md.* 2018;26(9):1396-1404.

22. Muktabhant B, Lumbiganon P, Ngamjarus C, Dowswell T. Interventions for preventing excessive weight gain during pregnancy. *The Cochrane database of systematic reviews.* 2012;4:CD007145.
23. Tanentsapf I, Heitmann BL, Adegboye AR. Systematic review of clinical trials on dietary interventions to prevent excessive weight gain during pregnancy among normal weight, overweight and obese women. *BMC Pregnancy Childbirth.* 2011;11:81.
24. Oteng-Ntim E, Varma R, Croker H, Poston L, Doyle P. Lifestyle interventions for overweight and obese pregnant women to improve pregnancy outcome: systematic review and meta-analysis. *BMC medicine.* 2012;10:47.
25. Thangaratinam S, Rogozinska E, Jolly K, et al. Interventions to reduce or prevent obesity in pregnant women: a systematic review. *Health technology assessment.* 2012;16(31):iii-iv, 1-191.
26. Cahill AG, Haire-Joshu D, Cade WT, et al. Weight Control Program and Gestational Weight Gain in Disadvantaged Women with Overweight or Obesity: A Randomized Clinical Trial. *Obesity (Silver Spring, Md.* 2018;26(3):485-491.
27. Trak-Fellermeier MA, Campos M, Melendez M, et al. PEARLS randomized lifestyle trial in pregnant Hispanic women with overweight/obesity: gestational weight gain and offspring birthweight. *Diabetes, metabolic syndrome and obesity : targets and therapy.* 2019;12:225-238.
28. Dodd JM, Louise J, Deussen AR, et al. Effect of metformin in addition to dietary and lifestyle advice for pregnant women who are overweight or obese: the GRoW randomised, double-blind, placebo-controlled trial. *The lancet Diabetes & endocrinology.* 2019;7(1):15-24.
29. Kunath J, Gunther J, Rauh K, et al. Effects of a lifestyle intervention during pregnancy to prevent excessive gestational weight gain in routine care - the cluster-randomised GeliS trial. *BMC medicine.* 2019;17(1):5.
30. Ludwig DS, Pereira MA, Kroenke CH, et al. Dietary fiber, weight gain, and cardiovascular disease risk factors in young adults. *JAMA.* 1999;282(16):1539-1546.
31. Newby PK, Muller D, Hallfrisch J, Qiao N, Andres R, Tucker KL. Dietary patterns and changes in body mass index and waist circumference in adults. *The American journal of clinical nutrition.* 2003;77(6):1417-1425.
32. McKeown NM, Meigs JB, Liu S, Saltzman E, Wilson PW, Jacques PF. Carbohydrate nutrition, insulin resistance, and the prevalence of the metabolic syndrome in the Framingham Offspring Cohort. *Diabetes care.* 2004;27(2):538-546.
33. Schulze MB, Liu S, Rimm EB, Manson JE, Willett WC, Hu FB. Glycemic index, glycemic load, and dietary fiber intake and incidence of type 2 diabetes in younger and middle-aged women. *The American journal of clinical nutrition.* 2004;80(2):348-356.
34. Davis JN, Hodges VA, Gillham MB. Normal-weight adults consume more fiber and fruit than their age- and height-matched overweight/obese counterparts. *J Am Diet Assoc.* 2006;106(6):833-840.
35. Howarth NC, Huang TTK, Roberts SB, McCrory MA. Dietary fiber and fat are associated with excess weight in young and middle-aged US adults. *Journal of the American Dietetic Association.* 2005;105(9):1365-1372.
36. Kristensen M, Toubro S, Jensen MG, et al. Whole grain compared with refined wheat decreases the percentage of body fat following a 12-week, energy-restricted dietary intervention in postmenopausal women. *The Journal of nutrition.* 2012;142(4):710-716.
37. Tucker LA, Thomas KS. Increasing total fiber intake reduces risk of weight and fat gains in women. *J Nutr.* 2009;139(3):576-581.
38. Rhodes ET, Pawlak DB, Takoudes TC, et al. Effects of a low-glycemic load diet in overweight and obese pregnant women a pilot randomized controlled trial. *American Journal of Clinical Nutrition.* 2010;92(6):1306-1315.
39. Maple-Brown LJ, Roman NM, Thomas A, Presley LH, Catalano PM. Perinatal factors relating to changes in maternal body fat in late gestation. *J Perinatol.* 2013;33(12):934-938.
40. Turner TF, Nance LM, Strickland WD, Malcolm RJ, Pechon S, O'Neil PM. Dietary adherence and satisfaction with a bean-based high-fiber weight loss diet: a pilot study. *ISRN Obes.* 2013;2013:915415.
41. Weickert MO, Roden M, Isken F, et al. Effects of supplemented isoenergetic diets differing in cereal fiber and protein content on insulin sensitivity in overweight humans. *The American journal of clinical nutrition.* 2011;94(2):459-471.

42. Davy BM, Davy KP, Ho RC, Beske SD, Davrath LR, Melby CL. High-fiber oat cereal compared with wheat cereal consumption favorably alters LDL-cholesterol subclass and particle numbers in middle-aged and older men. *The American journal of clinical nutrition.* 2002;76(2):351-358.
43. Pereira MA, Jacobs DR, Jr., Pins JJ, et al. Effect of whole grains on insulin sensitivity in overweight hyperinsulinemic adults. *The American journal of clinical nutrition.* 2002;75(5):848-855.
44. Fukagawa NK, Anderson JW, Hageman G, Young VR, Minaker KL. High-carbohydrate, high-fiber diets increase peripheral insulin sensitivity in healthy young and old adults. *The American journal of clinical nutrition.* 1990;52(3):524-528.
45. McKeown NM, Meigs JB, Liu S, Wilson PW, Jacques PF. Whole-grain intake is favorably associated with metabolic risk factors for type 2 diabetes and cardiovascular disease in the Framingham Offspring Study. *The American journal of clinical nutrition.* 2002;76(2):390-398.
46. Lutsey PL, Jacobs DR, Jr., Kori S, et al. Whole grain intake and its cross-sectional association with obesity, insulin resistance, inflammation, diabetes and subclinical CVD: The MESA Study. *Br J Nutr.* 2007;98(2):397-405.
47. Marshall JA, Bessesen DH, Hamman RF. High saturated fat and low starch and fibre are associated with hyperinsulinaemia in a non-diabetic population: the San Luis Valley Diabetes Study. *Diabetologia.* 1997;40(4):430-438.
48. Jovanovski E, Mazhar N, Komishon A, et al. Can dietary viscous fiber affect body weight independently of an energy-restrictive diet? A systematic review and meta-analysis of randomized controlled trials. *The American journal of clinical nutrition.* 2020;111(2):471-485.
49. Olendzki BC, Ma Y, Schneider KL, et al. A simple dietary message to improve dietary quality: Results from a pilot investigation. *Nutrition (Burbank, Los Angeles County, Calif.* 2009;25(7-8):736-744.
50. Ma Y, Olendzki BC, Wang J, et al. Single-component versus multicomponent dietary goals for the metabolic syndrome: a randomized trial. *Ann Intern Med.* 2015;162(4):248-257.
51. Paul HA, Bomhof MR, Vogel HJ, Reimer RA. Diet-induced changes in maternal gut microbiota and metabolomic profiles influence programming of offspring obesity risk in rats. *Sci Rep.* 2016;6:20683.
52. Herman A, Taylor M, Yu G, Hull HR. A high fiber diet during pregnancy favorably impacts the microbiota. *Obesity (Silver Spring, Md.* 2019;22(1S).
53. Bailey RL, Pac SG, Fulgoni VL, 3rd, Reidy KC, Catalano PM. Estimation of Total Usual Dietary Intakes of Pregnant Women in the United States. *JAMA Netw Open.* 2019;2(6):e195967.
54. *Dietary reference intakes for energy, carbohydrates, fiber, fat, fatty acids, cholesterol, protein and amino acids.* Institute of Medicine Panel on Macronutrients;2005.
55. Millen BE. *Scientific report of the 2015 Dietary Guidelines Advisory Committee.* February 2015.
56. Hull HR, Dinger MK, Knehans AW, Thompson DM, Fields DA. Impact of maternal body mass index on neonate birthweight and body composition. *American journal of obstetrics and gynecology.* 2008;198(4):416 e411-416.
57. Crozier SR, Inskip HM, Godfrey KM, et al. Weight gain in pregnancy and childhood body composition: findings from the Southampton Women's Survey. *The American journal of clinical nutrition.* 2010;91(6):1745-1751.
58. Kaar JL, Crume T, Brinton JT, Bischoff KJ, McDuffie R, Dabelea D. Maternal Obesity, Gestational Weight Gain, and Offspring Adiposity: The Exploring Perinatal Outcomes among Children Study. *The Journal of pediatrics.* 2014;165(3):509-515.
59. Reynolds RM, Osmond C, Phillips DIW, Godfrey KM. Maternal BMI, Parity, and Pregnancy Weight Gain: Influences on Offspring Adiposity in Young Adulthood. *J Clin Endocr Metab.* 2010;95(12):5365-5369.
60. Sridhar SB, Darbinian J, Ehrlich SF, et al. Maternal gestational weight gain and offspring risk for childhood overweight or obesity. *American journal of obstetrics and gynecology.* 2014;211(3):259 e251-258.
61. Mourtakos SP, Tambalis KD, Panagiotakos DB, et al. Maternal lifestyle characteristics during pregnancy, and the risk of obesity in the offspring: a study of 5,125 children. *BMC Pregnancy Childbirth.* 2015;15:66.
62. Reilly JJ, Armstrong J, Dorosty AR, et al. Early life risk factors for obesity in childhood: cohort study. *BMJ (Clinical research ed.* 2005;330(7504):1357.

63. Parsons TJ, Power C, Manor O. Fetal and early life growth and body mass index from birth to early adulthood in 1958 British cohort: longitudinal study. *BMJ (Clinical research ed.* 2001;323(7325):1331-1335.
64. Cnattingius S, Bergstrom R, Lipworth L, Kramer MS. Prepregnancy weight and the risk of adverse pregnancy outcomes. *The New England journal of medicine.* 1998;338(3):147-152.
65. Michlin R, Oettinger M, Odeh M, et al. Maternal obesity and pregnancy outcome. *Isr Med Assoc J.* 2000;2(1):10-13.
66. Linne Y, Barkeling B, Rossner S. Natural course of gestational diabetes mellitus: long term follow up of women in the SPAWN study. *Bjog.* 2002;109(11):1227-1231.
67. Catalano PM, Roman NM, Tyzbir ED, Merritt AO, Driscoll P, Amini SB. Weight gain in women with gestational diabetes. *Obstetrics and gynecology.* 1993;81(4):523-528.
68. Williamson DF, Kahn HS, Remington PL, Anda RF. The 10-year incidence of overweight and major weight gain in US adults. *Arch Intern Med.* 1990;150(3):665-672.
69. *Weight gain during pregnancy: Reexamining the guidelines.* Washington (DC): Institute of Medicine, National Research Council, Committee to Reexamine IOM Pregnancy Weight Guidelines;2009.
70. Leverence RR, Williams RL, Sussman A, Crabtree BF, Clinicians RN. Obesity counseling and guidelines in primary care: a qualitative study. *Am J Prev Med.* 2007;32(4):334-339.
71. Claesson IM, Sydsjo G, Brynhildsen J, et al. Weight gain restriction for obese pregnant women: a case-control intervention study. *BJOG.* 2008;115(1):44-50.
72. Mottola MF, Giroux I, Gratton R, et al. Nutrition and exercise prevent excess weight gain in overweight pregnant women. *Med Sci Sports Exerc.* 2010;42(2):265-272.
73. Hui A, Back L, Ludwig S, et al. Lifestyle intervention on diet and exercise reduced excessive gestational weight gain in pregnant women under a randomised controlled trial. *BJOG.* 2012;119(1):70-77.
74. Asbee SM, Jenkins TR, Butler JR, White J, Elliot M, Rutledge A. Preventing excessive weight gain during pregnancy through dietary and lifestyle counseling: a randomized controlled trial. *Obstetrics and gynecology.* 2009;113(2 Pt 1):305-312.
75. Guelinckx I, Devlieger R, Mullie P, Vansant G. Effect of lifestyle intervention on dietary habits, physical activity, and gestational weight gain in obese pregnant women: a randomized controlled trial. *The American journal of clinical nutrition.* 2010;91(2):373-380.
76. Huang TT, Yeh CY, Tsai YC. A diet and physical activity intervention for preventing weight retention among Taiwanese childbearing women: a randomised controlled trial. *Midwifery.* 2011;27(2):257-264.
77. Ilmonen J, Isolauri E, Poussa T, Laitinen K. Impact of dietary counselling and probiotic intervention on maternal anthropometric measurements during and after pregnancy: a randomized placebo-controlled trial. *Clinical nutrition (Edinburgh, Scotland).* 2011;30(2):156-164.
78. Jackson RA, Stotland NE, Caughey AB, Gerbert B. Improving diet and exercise in pregnancy with Video Doctor counseling: a randomized trial. *Patient education and counseling.* 2011;83(2):203-209.
79. Gray-Donald K, Robinson E, Collier A, David K, Renaud L, Rodrigues S. Intervening to reduce weight gain in pregnancy and gestational diabetes mellitus in Cree communities: an evaluation. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne.* 2000;163(10):1247-1251.
80. Olson CM, Strawderman MS, Reed RG. Efficacy of an intervention to prevent excessive gestational weight gain. *American journal of obstetrics and gynecology.* 2004;191(2):530-536.
81. Kinnunen TI, Aittasalo M, Koponen P, et al. Feasibility of a controlled trial aiming to prevent excessive pregnancy-related weight gain in primary health care. *BMC Pregnancy Childbirth.* 2008;8:37.
82. Shirazian T, Monteith S, Friedman F, Rebarber A. Lifestyle modification program decreases pregnancy weight gain in obese women. *American journal of perinatology.* 2010;27(5):411-414.
83. Dodd JM, Turnbull D, McPhee AJ, et al. Antenatal lifestyle advice for women who are overweight or obese: LIMIT randomised trial. *BMJ (Clinical research ed.* 2014;348:g1285.
84. Phelan S, Phipps MG, Abrams B, Darroch F, Schaffner A, Wing RR. Randomized trial of a behavioral intervention to prevent excessive gestational weight gain: the Fit for Delivery Study. *The American journal of clinical nutrition.* 2011;93(4):772-779.
85. Polley BA, Wing RR, Sims CJ. Randomized controlled trial to prevent excessive weight gain in pregnant women. *Int J Obes Relat Metab Disord.* 2002;26(11):1494-1502.

86. Thornton YS, Smarkola C, Kopacz SM, Ishoof SB. Perinatal outcomes in nutritionally monitored obese pregnant women: a randomized clinical trial. *Journal of the National Medical Association.* 2009;101(6):569-577.
87. Wolff S, Legarth J, Vangsgaard K, Toubro S, Astrup A. A randomized trial of the effects of dietary counseling on gestational weight gain and glucose metabolism in obese pregnant women. *Int J Obes (Lond).* 2008;32(3):495-501.
88. Lairon D. Dietary fiber and control of body weight. *Nutrition, metabolism, and cardiovascular diseases : NMCD.* 2007;17(1):1-5.
89. Slavin JL. Dietary fiber and body weight. *Nutrition (Burbank, Los Angeles County, Calif.* 2005;21(3):411-418.
90. Howarth NC, Saltzman E, Roberts SB. Dietary fiber and weight regulation. *Nutrition reviews.* 2001;59(5):129-139.
91. Hermsdorff HH, Barbosa KB, Volp AC, et al. Vitamin C and fibre consumption from fruits and vegetables improves oxidative stress markers in healthy young adults. *Br J Nutr.* 2012;107(8):1119-1127.
92. Grundy SM, Cleeman JI, Daniels SR, et al. Diagnosis and management of the metabolic syndrome: an American Heart Association/National Heart, Lung, and Blood Institute scientific statement: Executive Summary. *Crit Pathw Cardiol.* 2005;4(4):198-203.
93. Ning H, Van Horn L, Shay CM, Lloyd-Jones DM. Associations of dietary fiber intake with long-term predicted cardiovascular disease risk and C-reactive protein levels (from the National Health and Nutrition Examination Survey Data [2005-2010]). *Am J Cardiol.* 2014;113(2):287-291.
94. Carlson JJ, Eisenmann JC, Norman GJ, Ortiz KA, Young PC. Dietary fiber and nutrient density are inversely associated with the metabolic syndrome in US adolescents. *J Am Diet Assoc.* 2011;111(11):1688-1695.
95. Phelan S, Jankovitz K, Hagobian T, Abrams B. Reducing excessive gestational weight gain: lessons from the weight control literature and avenues for future research. *Women's health.* 2011;7(6):641-661.
96. Setse R, Grogan R, Cooper LA, Strobino D, Powe NR, Nicholson W. Weight loss programs for urban-based, postpartum African-American women: perceived barriers and preferred components. *Maternal and child health journal.* 2008;12(1):119-127.
97. van Wier MF, Ariens GA, Dekkers JC, Hendriksen IJ, Smid T, van Mechelen W. Phone and e-mail counselling are effective for weight management in an overweight working population: a randomized controlled trial. *BMC Public Health.* 2009;9:6.
98. Svetkey LP, Stevens VJ, Brantley PJ, et al. Comparison of strategies for sustaining weight loss: the weight loss maintenance randomized controlled trial. *Jama.* 2008;299(10):1139-1148.
99. Donnelly JE, Smith BK, Dunn L, et al. Comparison of a phone vs clinic approach to achieve 10% weight loss. *Int J Obes (Lond).* 2007;31(8):1270-1276.
100. Donnelly JE, Goetz J, Gibson C, et al. Equivalent weight loss for weight management programs delivered by phone and clinic. *Obesity (Silver Spring, Md.* 2013;21(10):1951-1959.
101. Befort CA, Donnelly JE, Sullivan DK, Ellerbeck EF, Perri MG. Group versus individual phone-based obesity treatment for rural women. *Eat Behav.* 2010;11(1):11-17.
102. Bandura A. *Social Foundations of Thought and Action: A Social Cognitive Theory. .* Englewood Cliffs, New Jersey: Prentice-Hall; 1986.
103. Bandura A. *Self-Efficacy: The Exercise of Control.* New York: WH Freeman and Co; 1997.
104. Bandura A. Social cognitive theory: an agentic perspective. *Annu Rev Psychol.* 2001;52:1-26.
105. Marlatt G. *Relapse Prevention: Maintenance Strategies in the Treatment of Addictive Behavior.* New York: Guilford Press; 1985.
106. Clifton RG, Evans M, Cahill AG, et al. Design of lifestyle intervention trials to prevent excessive gestational weight gain in women with overweight or obesity. *Obesity (Silver Spring, Md.* 2016;24(2):305-313.
107. Dewi M, Carlson SE, Gustafson KM, Sullivan DK, Wick JA, Hull HR. Programming of infant neurodevelopment by maternal obesity: potential role of maternal inflammation and insulin resistance. *Asia Pac J Clin Nutr.* 2017;26(Suppl 1):S36-S39.
108. Carlson SE, Colombo J. Docosahexaenoic Acid and Arachidonic Acid Nutrition in Early Development. *Adv Pediatr.* 2016;63(1):453-471.

109. Hidaka BH, Thodosoff JM, Kerling EH, Hull HR, Colombo J, Carlson SE. Intrauterine DHA exposure and child body composition at 5 y: exploratory analysis of a randomized controlled trial of prenatal DHA supplementation. *The American journal of clinical nutrition.* 2018;107(1):35-42.
110. Conway JM, Ingwersen LA, Vinyard BT, Moshfegh AJ. Effectiveness of the US Department of Agriculture 5-step multiple-pass method in assessing food intake in obese and nonobese women. *The American journal of clinical nutrition.* 2003;77(5):1171-1178.
111. Blanton CA, Moshfegh AJ, Baer DJ, Kretsch MJ. The USDA Automated Multiple-Pass Method accurately estimates group total energy and nutrient intake. *The Journal of nutrition.* 2006;136(10):2594-2599.
112. Hebert JR, Hurley TG, Chiriboga DE, Barone J. A comparison of selected nutrient intakes derived from three diet assessment methods used in a low-fat maintenance trial. *Public Health Nutr.* 1998;1(3):207-214.
113. Selinger A. *The body as a three component system. [University of Illinois at Urbana, doctoral thesis]*. Ann Arbor, Michigan, University of Illinois at Urbana; 1977.
114. Dempster P, Aitkens S. A new air displacement method for the determination of human body composition. *Med Sci Sports Exerc.* 1995;27(12):1692-1697.
115. Widen EM, Strain G, King WC, et al. Validity of bioelectrical impedance analysis for measuring changes in body water and percent fat after bariatric surgery. *Obesity surgery.* 2014;24(6):847-854.
116. Pregnancy and medical radiation. *Annals of the ICRP.* 2000;30(1):iii-viii, 1-43.
117. Marshall NE, Murphy EJ, King JC, et al. Comparison of multiple methods to measure maternal fat mass in late gestation. *The American journal of clinical nutrition.* 2016;103(4):1055-1063.
118. Yim JE, Heshka S, Albu JB, Heymsfield S, Gallagher D. Femoral-gluteal subcutaneous and intermuscular adipose tissues have independent and opposing relationships with CVD risk. *J Appl Physiol.* 2008;104(3):700-707.
119. Gallagher D, Kelley DE, Yim JE, et al. Adipose tissue distribution is different in type 2 diabetes. *The American journal of clinical nutrition.* 2009;89(3):807-814.

PROTECTION OF HUMAN SUBJECTS

This study will enroll pregnant women and their offspring. This study will block randomize 6-10 women into one of the following groups: a high fiber dietary intervention or UC. The primary aim is to assess the difference in maternal weight gain and fat accrual. All subjects will be given a body weight scale and report weekly their body weight. This allows close supervision of progression of each participant to ensure the intervention is not overly effective and all women are gaining adequate body weight. If a woman gains or loses more than 5 pounds over a two-week period, she will be contacted and her diet habits and fiber intake will be reviewed. Additionally, she will be asked if she is willing to provide her Obstetrician contact information and would like us to contact her Obstetrician. If so, a report will be sent to her Obstetrician. Infant growth will be charted and marked for review if crossing of two or more major percentile lines occurs. During pregnancy, maternal diet and body composition will be measured. A maternal DXA scan will be obtained at 2 weeks, 2 months, 6 months, and 12 months postpartum. Infant birth characteristics will be extracted from the electronic medical record. Infant body weight and body composition will be measured at 2 weeks, 2 months, 6 months, and 12 months using the Pea Pod. An infant DXA scan will be obtained at 2 weeks, 6 months, and 12 months.

RISKS TO HUMAN SUBJECTS

Human Subjects Involvement, Characteristics, and Design

(1) *Patient recruitment and informed consent*. All recruitment, consent, and data forms for the study proposal will be approved prior to any enrollment. Informed consent for continued testing is obtained by a trained research team member with NIH-approved Human Subjects' protection certification. Consent includes the standard elements: a study description, the potential risks, benefits and options for nonparticipation. All subjects are informed they are free to withdraw from the study without changes in their usual care. Consent is documented as a signed form and will be kept in a locked file at the study office. The study is conducted in accordance with ethical principles founded in the Declaration of Helsinki. The IRB review includes a review of all appropriate study documentation to safeguard the rights, safety and well-being of the subjects. The protocol, informed consent, written information given to the subjects, safety updates, annual progress reports, and any revisions to these documents are provided to the IRB by the principal investigators. The method of obtaining and documenting the informed consent and the contents of the consent will occur either in person or online and comply with GCP and all applicable regulatory requirement(s).

(2) *Describe the characteristics of the subject populations and identify criteria for inclusion and exclusion.* Subjects will consist of pregnant women and their infants. Pregnant women will be consented for their participation and the participation of their infant in the study. Women will be between the ages 18-45 years old; all racial/ethnic groups will be recruited between 9-19 weeks pregnant; can be first or greater pregnancy; BMI range: 18.5-45 kg/m^2. If they are consuming 25 g/day of fiber or more, they will be excluded from the study. Women who do not have internet and phone access will be excluded from the study. Participants must be willing to consume provided snacks. Participants will also be excluded if they have history of gestational diabetes (GDM), diabetes, pre-eclampsia, hypertension, heart disease, hypothyroidism, or other metabolic abnormalities, current hyperemesis gravidarum, eating disorder, smoking, or are pregnant with multiples. Deviations from inclusion criteria will be at the discretion of the PI. Women that develop any of these medical conditions during pregnancy will be accounted for in the final analysis. This will be conducted at the University of Kansas Medical Center. We will recruit 56 pregnant women who are between 9-19 weeks in gestation. These women will be patients from the University of Kansas OBGYN clinic. The race/ethnic breakdown of participants will be 12.5% Hispanic, 30% Black, 40% White, 12.5% Asian and 5% classified as other. Following randomization and baseline testing, the intervention will begin and follow up measures will be acquired during pregnancy for outcome measures.

(3) *Identify the sources of research material to be obtained from subjects.* In addition to data collected directly from participants infant birth characteristics (e.g., sex, gestational age at birth, birth weight, birth length, etc.) and health information up to 1 year of age and maternal delivery characteristics and 1 year pre- and post-partum health information will be extracted from the medical record. All participants will be assigned a nonidentifiable subject number. Data collected will be kept in Dr. Hull's locked research laboratory. Only study personnel and Dr. Hull have keys to access this area. Electronic data will be kept

on a password protected computer in Dr. Hull's laboratory on the shared drive. Only personnel approved by HSC and on the protocol will have access to the data.

(4) *Describe all potential risks.* No appreciable risk of physical, psychological, social, legal or other harm is expected. Blood will need to be drawn and may be associated with pain and the usual risks of blood letting. We are investigating between groups if differences are found for metabolic changes that occur during pregnancy. Many of the metabolic parameters we are exploring must be investigated in a fasted state or this would introduce error in the metabolic parameter (insulin, glucose, lipid panel, HbA1C, inflammatory markers). Measures will be collected at the CTSU Rainbow location and follow all safety protocols to ensure participant safety. In past protocols, we collect a fasting blood draw and took every precaution so that no harm comes to the mother or her baby. Women are instructed on the days leading up to their blood draw to drink plenty of water and to eat dinner and an evening snack if they are hungry the night before the blood draw. Appointments are scheduled first thing in the morning and we provide food and juice so that mothers eat immediately following the blood draw. We recorded no adverse events following this protocol. We have had no adverse events. All protocols are IRB approved and have undergone heavy scrutiny due to the special population we are working with. The DXA does emit radiation. In the moms, In the infants, three total body DXA scans will be completed over 12 months. The amount of radiation exposure for one DXA scan is equal to 0.001 mSV or the equivalent of exposure to 3 hours of natural background radiation. As a comparison, one chest x-ray is equal to 0.1 mSV or 10 days of exposure to natural background radiation. Over the course of 12 months, the total radiation exposure will be under a day of background radiation exposure. This is minimal especially considered it is spread over 12 months.

(5) *Describe the procedures for protecting against or minimizing any potential risks.* N/A. There are no known risks.

(6) *Discuss why the risks are reasonable in relation to anticipated benefits.* N/A. No known risks.

(7) *Plan for monitoring and reporting problems*. Adverse events will be assessed every 4 weeks during the dietary recalls during the 18-week intervention in the high-fiber group only. Baseline measurements will not be assessed for adverse events. Only adverse events related to gaining or losing too much weight or allergic reactions to the study food will be recorded. Research staff will immediately report any adverse events to the study PI for review. The study physician will review maternal and infant abnormal findings. If recommended by the study physician, abnormal findings will be communicated to the participant's physicians or infant's pediatrician.

(8) *Plan for handling study withdrawal/discontinuation*. Participants may discontinue study participation at any time in the study. Participants will be asked to sign a withdrawal consent. If participant does not sign a withdrawal consent, only data collected prior to withdrawal will be used.

Adequacy of Protection Against Risks

Describe plans for the recruitment of subjects and the consent procedures to be followed. Recruitment will be open to all pregnant women that meet the study inclusion criteria. The KUMC IRB will review and approve this study prior to implementation. Recruitment will only be performed under the supervision of the PI by trained research personnel who have completed human subjects and HIPAA training. Personnel will identify subjects who might be eligible by screening their electronic medical record in O2. Only medical information related to inclusion/exclusion criteria will be looked at. If determined eligible, research personnel will visit the patient at their scheduled clinic visit. OBGYN clinic staff will introduce study to potential subjects. Research personnel will discuss the study in detail and determine final eligibility. Participants missed at their OBGYN visit will be contacted via phone. If participants are interested, they will be followed up with via phone or email to determine enrollment and complete the informed consent. Informed consent will be obtained via phone or in person at the first study visit.

The women will be informed that the purpose of the study is to determine if a high fiber diet can help them gain the right amount of weight during pregnancy and that they will be placed in an intervention or control group. They will be told that if they participate in the study, regardless of their group assignment, that they will need to be seen two times during their pregnancy and four times after pregnancy. Further, they will be told if they are randomized to the intervention group they will be required to attend weekly video calls and report goals weekly to the study coordinator for 18 weeks.

Consent forms and HIPPA disclosure information per IRBs will be given to all subjects and their signatures witnessed. The consent forms will include a description of the study, nature of the data collection, the potential benefits and adverse reactions anticipated. Women will be assigned to group by random assignment provided by study statistician. The subjects will be told that their usual care would not be changed, withdrawn, or reduced if they chose to withdraw from the study at any time. The research team personnel will abide by all tenets of the University confidentiality policies, as well as the Privacy Protection for Research Subjects. All research staff will remain current in their NIH required Human Subjects protection and HIPAA certification.

Case Report Forms on all women will include medical information pertinent to the study (e.g., smoking history, blood pressure, pregnancy history, age, race, etc.) in addition to the information directly related to the study (e.g., height, pre-pregnancy and clinic weights, blood pressure, EDD by ultrasound or LMP, etc.). To maintain patient privacy, all case report forms, study reports and communications will identify the patient by the assigned patient number only. The medical record and originals of outcome data will be the source documents for the study. Any changes to the case report forms necessitated because they at are odds with source documents will be initialed and dated by the Study Coordinators; and all Case Report Forms will be reviewed and approved by signature of the PI. Data monitors and auditors from the IRBs, and regulatory authorities will have access to the patient's original medical records for verification of data gathered on the case report forms and to audit the data collection process. Subjects will be made aware of persons who may see their protected health information in the informed consent document and may choose not to enroll in the study based on the information provided them in accord with 2003 HIPAA regulations. The patient's confidentiality will be maintained and will not be made publicly available to the extent permitted by the applicable laws and regulations.

Data monitors and auditors from the IRBs, and regulatory authorities will have access to the patient's original medical records for verification of data gathered on the case report forms and to audit the data collection process. Subjects will be made aware of persons who may see their protected health information in the informed consent document and may choose not to enroll in the study based on the information provided them in accord with 2003 HIPAA regulations. The patient's confidentiality will be maintained and will not be made publicly available to the extent permitted by the applicable laws and regulations.

The investigators will conduct the study in compliance with the protocol given approval by the KUMC IRB. Any changes to the protocol will require written approval from these committees prior to implementation, except when the modification is needed to eliminate an immediate hazard(s) to patients or if the change(s) involves only logistical or administrative aspects of the trial. Any departures from the protocol will be fully documented in the case report form and source documentation. IRB review occurs each year and newly dates consent forms are issued. The Research Assistant will keep the study binder that includes all communication with the IRB and CVs for all study personnel, and study personnel approved roles. The ultimate responsibility for ensuring that the study binders are in order will fall to the PI (Hull).

Patient recruitment and informed consent. All recruitment, consent and data forms for the study proposal will be submitted to the KUMC IRB prior to enrollment using templates and educational materials formatted as previously IRB-approved in the pilot study. Informed consent will be obtained by trained research personnel who have completed the NIH-approved Human Subjects' protection certification. Consent includes the standard elements: a study description, the potential risks, benefits and options for non-participation. All participants will be informed that they are free to withdraw from the study without changes in their usual care. Consent will be documented as a signed form and will be kept in a locked file at the study office. The study will be conducted in accordance with ethical principles founded in the Declaration of Helsinki. The IRB will review all appropriate study documentation to safeguard the rights, safety and well-being of the subjects. The protocol, informed consent, written information given to the subjects, safety updates, annual progress reports, and any revisions to these documents will be provided to the IRBs by the investigator. The method of obtaining and documenting the informed consent and the contents of the consent will comply with GCP and all applicable regulatory requirement(s).

Study personnel will identify subjects who might be eligible under a waiver issued by the IRB to look only at medical information related to inclusion/exclusion criteria for the study. No personal health information will be recorded until consent for the study is obtained in writing.

Protection against risk. Although no appreciable risk of physical or mental harm is expected to result from the protocol, procedures for dealing with adverse effects are established. Subjects will be instructed to report immediately to the study coordinator if any health problem occurs and to call the PI (Hull) at any time if they have questions are concerns. In such an event, it is the PI responsibility to answer those concerns honestly and to reiterate to the subject that they should continue in the trial only if they feel entirely comfortable with it. Subjects who choose to withdraw from the study will be reassured if they indicate the desire to withdraw.

Subjects will be protected against the risk of breaking confidentiality by decoupling of names from databases. Each participant will be assigned a numerical study ID and informed consent forms that include the subject's signature will be stored separately in locked file cabinets. For ensuring confidentiality, these are generally acknowledged to be the best methods known for ensuring that names are not associated with data. Only selected research staff will have access to the subjects' data. Subjects' informed consent includes the HIPAA compliance documentation approved by the KUMC IRB. Research team personnel will abide by all tenets of the University confidentiality policies as well as the Privacy Protection for Research Subjects.

Potential Benefits of Proposed Research
Describe all potential benefits. There are no direct benefits for participation in the study outside of contributing to the knowledge and formulation towards interventions that are successful at helping women to achieve appropriate GWG. This study could contribute to ways to improve maternal and infant health outcomes of pregnant women by improving GWG by identifying novel methods that can be used to encourage appropriate GWG.

Importance of Knowledge to be Gained
We are targeting recruitment of pregnant women who have a pre-pregnancy BMI 18.5 – 45.0 kg/m_2. We are specifically targeting women at high risk of excessive GWG during pregnancy. Data show 56% of women gain excessively[3,4]. Excessive gestational weight gain (GWG) is associated with poor outcomes. Based on our data, we anticipate the following distribution among the 3 pre-pregnancy weight categories selected (BMI <24.9 = 40%; BMI 25-25.9 = 34%; BMI >30 = 26%). Due to the adverse health that is related to excessive GWG, it is imperative to seek interventions to prevent excessive GWG.

Data Safety and Monitoring Plan
Data security: All participants will be assigned a non-identifiable subject number. Data collected will be kept in Dr. Hull's locked research laboratory. Only study personnel and Dr. Hull have keys to access this area. Electronic data will be kept on a password protected computer in Dr. Hull's laboratory on the shared drive. Only personnel approved by HSC and on the protocol will have access to the data.

Data and safety monitoring plan: Monitoring will be handled by the PI and the research team.

INCLUSION OF WOMEN, MINORITIES, AND CHILDREN

Inclusion of Women: We are targeting pregnant women who have a pre-pregnancy BMI 18.5 – 45.0 kg/m_2. We are specifically targeting women at high risk of excessive GWG during pregnancy and at high risk of retaining a significant amount of body weight postpartum. Data show 56% of women gain excessively[3,4] and that excessive gestational weight gain (GWG) is associated with poor outcomes.

Inclusion of Minorities: We are including all racial/ethnic groups in this study. There will be no exclusion criteria based on race or ethnicity.

Inclusion of Children: The study will include offspring born to women participating in the study.