Implementation of a Mediterranean Diet Program for Overweight or Obese Pregnant Women in a Low-resource Clinical Setting

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Implementation of a Mediterranean Diet Program for Overweight or Obese Pregnant Women in a Low-resource Clinical Setting

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Background, Rational, and Context

Maternal overweight and obesity are the most common medical conditions diagnosed in the United States[1-4] and are associated with serious adverse maternal and infant health outcomes.[2,4,5-7] The burden of the disease is stressing our health care system due to the increasing prevalence of obesity and related chronic conditions.[8,9] There is a linear association between increasing maternal body mass index (BMI) and pregnancy complications including gestational diabetes mellitus (GDM), hypertensive disorders of pregnancy (HDP), preterm birth (PTB), and cesarean delivery.[2,4,5-7] Gestational weight gain (GWG) that exceeds the Institute of Medicine (IOM) recommendations[10] occurs in approximately 50% of overweight or obese women[11] further increasing the risk of obstetrical complications.[5,6,12]Western-style diet is a major contributor to the obesity epidemic in the United States.[13,14]

Proper nutrition during pregnancy has multiple health benefits. A mother eating a healthy diet has a higher probability of meeting the demands required for a normal fetal development.[15,16] In addition, she is more likely to achieve the recommended gestational weight gain thereby reducing the risk of pregnancy-related complications.[15-19] Finally, a healthy diet is associated with a reduction of chronic conditions such as cardiovascular disease and diabetes later in life for both the mother and the infant.[16,20]

Behavioral lifestyle interventions aimed to optimize health and improve clinical outcomes of overweight [body mass index (BMI) 25.0-29.9 kg/m^2] or obese [BMI ≥30.0 kg/m^2] pregnant women are essential given the dramatic increasing prevalence of these conditions in the United

States.[1-4] Although several lifestyle dietary-based intervention programs evaluated in clinical trials demonstrated overall good efficacy controlling gestational weight gain in obese women,[17-19] the impact of these interventions on pregnancy and neonatal outcomes has been inconsistent.[21-23] Diet components,[21] quality of the nutritional program,[21] degree of diet adherence,[24] and duration of intervention[25,26] are factors that influence positively or negatively the clinical efficacy of a dietary intervention during pregnancy.

The Mediterranean diet (MedDiet) is a well-known healthy diet that consists of a large amount of plant-based foods such as fruits, vegetables, beans, and nuts with extra virgin olive oil (EVOO) as the principal source of fat. Dairy, fish, and poultry are consumed in moderation and red meat only eaten occasionally.[27] A growing body of evidence demonstrates that outside of pregnancy, the MedDiet is associated with a reduction of cardiovascular disease,[28,29] diabetes,[30,31] metabolic syndrome,[32] and certain cancers.[33] However, the potential clinical benefits of MedDiet in pregnancy are understudied with most data originating from clinical trials in Europe.[34,35] For example, a recent European randomized trial found that the consumption of the MedDiet during pregnancy reduced GWG,[36] GDM,[34,36] and increased birth weight in pregnancies which were at risk of low birth weight.[35] However, in the United States which has a pregnant population consuming predominantly the Western-style diet,[13] data are more limited and constricted to cohort studies.[37,38]

We propose to examine the feasibility of implementing a structured MedDiet program beginning in the first or early second trimester maximizing dietary intervention exposure throughout gestation for overweight or obese pregnant women in a low-resource setting. Our investigation will help to address health disparities by offering a unique opportunity to investigate this program in a socially vulnerable and highly racial/ethnic diverse pregnant population in the United States. We provide care to women living in zip codes areas (i.e., 28212, 28215, and 28217) characterized by elevated levels of unemployment (28%-32%), around 15% of the adult population did not complete high school, and the median annual income is between $33,781 and $45,983 (www.unitedstateszipcodes.org). Approximately 51% of our patients are uninsured with 6-10% requiring financial assistance for medical visits. The race/ethnic distribution consists of 10% White non-Hispanic, 25% Black non-Hispanic, and 59% Hispanic women. Approximately 50% of our pregnant population is overweight or obese.

We expect our investigation will provide new insights on the implementation process, the factors that facilitate or prevent adherence and sustainability, and preliminary data on the clinical efficacy of this healthy diet style. Our findings will serve as the foundation of larger clinical trials powered to evaluate pregnancy and neonatal outcomes, clinical studies designed to investigate predictive, risk, diagnostic, and prognostic novel biomarkers, and prospective cohort studies that examine long-term maternal and neonatal health effects. We plan to apply to grants offered by the National Institutes of Health (NIH) in the maternal health and nutrition-related research sections, to the Maternal and Child Health Nutrition Training Program, and Maternal and Child Health-Initiated Innovative Research Studies. We plan to translate the findings of our study into clinical practice as the screening tools, educational material, and meal guides in English and Spanish developed in this study will be optimal for use in routine obstetrical practice. We are committed to work with the leadership and administration of our organization to restructure the prenatal nutritional program.

Therefore, if our study is successful in implementing a sustainable evidence-based dietary program, the next step will be to establish a specialized nutritional prenatal care service designed to prevent clinical complications and improve pregnancy outcomes. This will involve

increasing the dedicated time and frequency of comprehensive dietary counseling sessions during gestation. These sessions will be independent from routine prenatal care visits. In addition, we plan to work with local government and private healthy diet organizations to help socially vulnerable pregnant women overcome nutritional challenges.

Objectives and Hypothesis

Primary Objective

To examine the feasibility and adherence to a MedDiet program initiated in the first or early second trimester of gestation (6-16 weeks) among overweight and obese women.

Hypothesis: Overweight and obese pregnant women enrolled in the MedDiet program have an elevated level of adherence facilitated by the design of a comprehensive dietary program with free home-delivered meals, nuts, and EVOO bottles. This hypothesis will be tested by examining adherence to the MedDiet program using a validated screening tool.[39]

Secondary Objectives

1. To estimate the preliminary efficacy of a MedDiet intervention controlling gestational weight gain and reducing adverse pregnancy outcomes (APO).

   Hypothesis: Overweight or obese pregnant women consuming MedDiet have low rates of excessive gestational weight gain and adverse pregnancy outcomes. This hypothesis will be tested by comparing gestational weight gain and pre-selected pregnancy outcomes between women allocated in each dietary group.

2. To estimate the preliminary impact of MedDiet intervention on maternal cardiometabolic profile.

   Hypothesis: MedDiet leads to favorable effects on cardiovascular clinical parameters and cardiometabolic biomarkers in pregnancy. This hypothesis will be tested by comparing maternal cardiovascular parameters trends and cardiometabolic biomarkers during pregnancy among the studied groups.

Methods and Measures

Study Design

Type of study

This is a prospective, randomized, pilot study with a behavioral intervention. Sixty participants diagnosed as overweight (BMI 25.0-29.9 kg/m^2) or obese (BMI ≥ 30.0 kg/m^2) in the first or early second trimester of gestation will be invited to participate. Participants will be randomized to a MedDiet program or the currently offered American College of Obstetricians and Gynecologists (ACOG)-based dietary counseling program at Myers Park and North Park OBGYN Clinic(s) in Charlotte, North Carolina.

Duration of Study and Participating Site

This will be a multi-center study including Myers Park OB/GYN Clinic and North Park OB/GYN Clinic which are academic obstetrical practices providing prenatal care to a socially vulnerable and highly racial/ethnic diverse population. All new scheduled prenatal visits will be screened in Epic for eligibility by our research team.

We anticipate full completion of the study by July 2025.

Study population (Table 1)

Inclusion Criteria	Exclusion Criteria
• Viable singleton pregnancy in the first trimester (6 0/7- 16 6/7 weeks); includes twins reduced to singleton spontaneously or vanishing twin syndrome • BMI ≥ 25.0 kg/m^2; calculated by dividing maternal weight in kilograms by height in meters squared using a calibrated scale and standard metric measure (BMI calculator available at www.cdc.gov) • Confirmed intrauterine pregnancy by ultrasound exam (6-16 weeks) • Age 18 years or older • Primary language of English or Spanish	• BMI < 25.0 kg/m^2 • Known pre-pregnancy diabetes • Hemoglobin glycosylated (A1C) > 5.7% at first prenatal visit • Pre-pregnancy hypertensive disease • Non-viable pregnancy • Known allergies to an essential component(s) of MedDiet • Inability to read or write in primary language • Mental incapacity to make medical decisions • Food insecurity

Sample Size

Since this is a pilot study, we aim to enroll 60 participants with 30 per study arm. Based on the patient population at Myers Park, we anticipate the following racial/ethnic breakdown of subjects.

Table 2 Anticipated Enrollment (all subjects will be female)

Race	Non-Hispanic	Hispanic	Total
Asian	**1**	**0**	**1**
Black or African American	**15**	**0**	**15**
White	**6**	**36**	**42**
More than One Race	**2**	**0**	**2**
Total	**24**	**36**	**60**

Methods and Intervention

- Fig 1 and Table 3 provide a detailed view of the study activities.
- With the purpose of overcoming language barriers, the dietary program was developed in English and Spanish. Multiple aids were created including practical educational tools, recipes, shopping list, and meal portion guidance to improve engagement and enhance sustainability.

Randomization and Study Groups:

- Following informed consent and eligibility confirmation, subjects will be randomized in blocks of 4 using a single sequence computer-generated random number[40] to balance for baseline BMI category (overweight or obese Random allocation number assigned to MedDiet program (intervention group) or ACOG-based nutritional counseling (control group) will be in a sealed opaque envelope.
    - Subjects allocated to the ACOG-based Dietary Program (Control Group) will receive:
        - Following ACOG recommendation, routine counseling on healthy eating will be provided. This will include advice on the consumption of grains, fruits, vegetables, protein, and dairy foods recommended during pregnancy (Nutrition During Pregnancy | ACOG) [41] (www.myplate.gov). (Appendix A-F (English)/Appendix G-L (Spanish))
        - Diet adherence will be assessed using a Routine Diet Adherence Questionnaire (Appendix M (English)/Appendix N (Spanish)).
        - Six traditional healthy meals will be shipped by ModifyHealth LLC directly to the participant's home every 3 weeks between enrollment and until the subject is approximately 38 weeks pregnant.
        - Participants will receive canola oil and a healthy snack during their enrollment visit and during their routine 26-30 week prenatal visit
    - Subjects allocated to the MedDiet Program (Intervention Group) group will receive:
        - Counseling based on the principles of the traditional MedDiet[27] with a focus on a general change in diet instead of micronutrients or macronutrients. (Appendix O-P;SS-UU (English)/Appendix Q-R; VV-XX (Spanish)
        - Diet adherence will be assessed using a modified version of the validated MedDiet Adherence Questionnaire.[39] (Appendix S (English)/Appendix T (Spanish))
        - Six traditional MedDiet meals will be shipped by ModifyHealth LLC directly to the participant's home every 3 weeks between enrollment and until the subject is approximately 38 weeks pregnant.
        - Participants will receive olive oil and nuts during their enrollment visit and during their routine 26-30 week prenatal visit.

Baseline Visit:

- All subjects will participate in a 30-minute baseline Nutritional Assessment and Diet Counseling Session regardless of the arm they are randomized to. This will occur during their initial prenatal visit at 6-16 weeks of pregnancy. The following items will be covered in this visit:
    - Subjects will complete an enrollment questionnaire to obtain demographic and baseline diet/physical activity information (Appendix U (English)/Appendix V (Spanish))
    - Subjects will complete a form for ModifyHealth so their free meals will be delivered to their home (Appendix VV (Spanish)/ Appendix WW (English))
    - Additional subject enrollment data will be collected by the enrolling research teammate regarding a history of eating disorders, tobacco/alcohol/substance use, insurance coverage, phone number, and email (Appendix W(Spanish)/Appendix SS (English)).
    - Subjects will complete the Federation of Gynecology and Obstetrics (FIGO)[42] Nutrition Checklist (Appendix X (English)/Appendix Y (Spanish)). This is a validated tool used to assess the subject's quality of diet. It consists of six yes/no questions (www.figo.org) and at least one "no" response will be classified as a suboptimal diet.[42]
    - All subjects will have a total of 8 ml of blood drawn for the following tests:
        - C-reactive protein (CRP) panel
        - metabolic panel that includes glucose level
        - the lipid panel
        - hemoglobin A1c

      The blood sample collection form will be completed at each timepoint (Appendix Z)

    - All subjects will receive dietary advice for the diet they have been randomized to by a registered dietitian with expertise in nutrition during pregnancy (ST, Co-I). (Appendix A-C; F (English)/Appendix G-;-L (Spanish) or Appendix O-P (English)/Appendix Q-R (Spanish))
        - Educational materials for each diet program such as recipes, shopping lists, and meal plans will be discussed, and the material will be printed for the participant's use at home. (Appendix A-F (English)/Appendix G-L (Spanish) or Appendix O-P; SS (English)/Appendix Q-R; VV (Spanish))
        - Routine counseling of physical activity and exercise based on ACOG recommendations (ACOG Committee Opinion No 804) will be provided. If there are no clinical contraindications, women will be encouraged to start with low intensity, short periods of exercise at least 4 times a week. (Appendix A-F (English)/Appendix G-L (Spanish) or Appendix O-P (English)/Appendix Q-R (Spanish))
    - All subjects will be screened for household food insecurity, as well as, reliable transportation, housing, and a support system using the standard OB Social Worker Assessment questionnaire which all patients complete as part of their routine care (Appendix AA (English)/Appendix BB (Spanish)).[43] Women who screen positive for household food insecurity will be excluded from the study and referred to our clinic

social worker or registered dietitian for information on community resource assistance such as Loaves and Fishes, a Charlotte-based food bank.

- Participants will be counseled to control gestational weight gain (GWG) following the Institute of Medicine (IOM) recommendations:
  - Total GWG of 15-25 lb. for overweight women (BMI 25.0-29.9 kg/m^2)
  - Total GWG 0f 11-20 lb. for obese women (BMI ≥ 30.0 kg/m^2).[10]

Trimester Visits:

- An additional ~20-minute in-person, virtual, or phone call dietary counseling sessions will be scheduled at the following time points (Figure 1).
  - Between 20-24 weeks of pregnancy
  - Between 26-30 weeks of pregnancy
  - Between 34-38 weeks of pregnancy

  These sessions will include the following:

  - The following questionnaires will be completed:
    - Routine Healthy Diet Assessment Questionnaire ((Appendix M (English)/Appendix N (Spanish)) or the MedDiet Assessment Questionnaire (Appendix S (English)/Appendix T (Spanish))
    - Diet and Physical Activity Recall (Appendix CC (English)/Appendix DD (Spanish))
    - Trimester Collection Form (Appendix EE-GG)
  - Education and reinforcement of diet recommendations will be provided by addressing the subjects' questions and issues.
  - Subjects will receive recipes specific for the ACOG Routine Healthy Diet ((Appendix D-E (Englig)/Appendix J-K (Spanish)) or the MedDiet ((Appendix TT-UU (English)/ Appendix WW-XX (Spanish)). Recipes will either be printed for the subjects or sent via EPIC
  - If no clinical contraindications were established during the baseline visit, subjects will be encouraged to gradually increase their length and intensity of physical activity and exercise as tolerated from the first trimester until delivery. This will be based on ACOG recommendations.[44]
  - Participants will continue to be counseled to control gestational weight gain following the IOM recommendations:
    - Total GWG of 15-25 lbs for overweight women (BMI 25.0-29.9 kg/m^2)
    - Total GWG of 11-20 lb. for obese women (BMI ≥ 30.0 kg/m^2).[10]
  - The time length for all sessions will be recorded.
  - Between 26-30 weeks, all subjects will have a total of 8 ml of blood drawn for the following tests:
    - C-reactive protein (CRP)
    - metabolic panel that includes glucose level
    - the lipid panel (total cholesterol, triglycerides, high-density lipoprotein (HDL) cholesterol, and low-density lipoprotein (LDL) cholesterol)
    - hemoglobin A1c

    The blood sample collection form will be completed at each timepoint (Appendix Z)
- For each meal received from ModifyHealth, subjects will be asked to take share a photo (via REDCap using the subject's cell phone number or email, EPIC, or in-person) of the uneaten food.

Data on subjects' history and pregnancy/neonatal outcomes will be collected via EPIC:

- The following data will be collected from EPIC for all subjects
    - Medical history (Appendix HH (Spanish)/Appendix TT(English)))
    - Reproductive, and obstetric history including all prior pregnancy complications/outcomes and neonate outcomes (Appendix II (Spanish)/Appendix UU(English)))
    - Current pregnancy labs (Appendix JJ)
    - Current pregnancy, scans, complications, progress reports, clinic reports, hospital reports
    - Current pregnancy outcomes (Appendix KK)
    - Neonatal outcomes will be collected up to 6-weeks post-delivery including all birth data and complications (Appendix LL)

- Data regarding any adverse events will be collected on the Adverse Event form. (Appendix MM).
- Data collected on data collection forms (Appendix HH-LL) and then transferred to REDCap.

Fig 1. Overview and Intervention

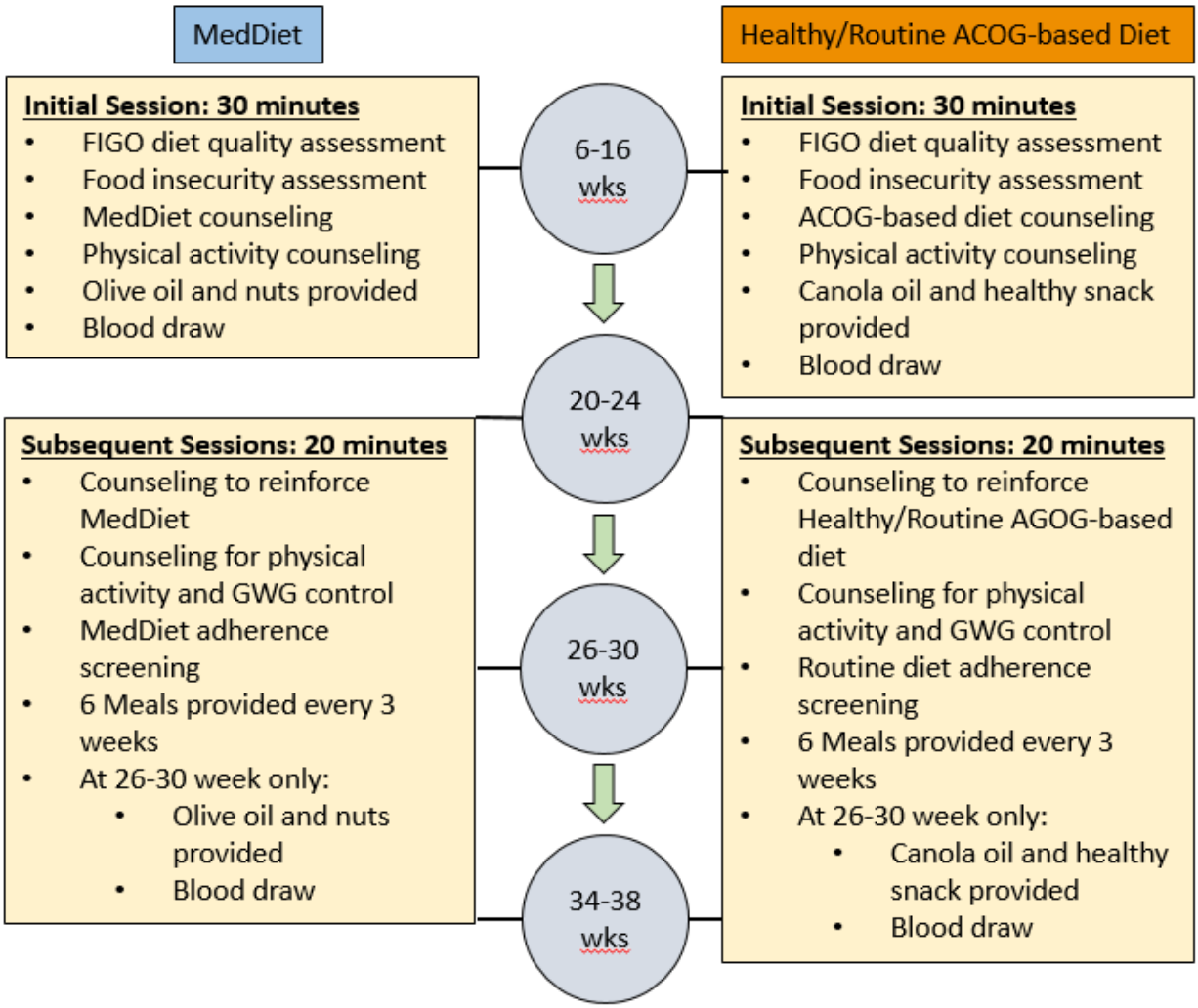

Table 3

	Screening/ Enrollment/ Randomization		Between 20-24 weeks of pregnancy		Between 26-30 weeks of pregnancy		Between 34-38 weeks of pregnancy	
	Routine Diet	MedDiet	Routine Diet	MedDiet	Routine Diet	MedDiet	Routine Diet	MedDiet
Informed consent	X	X						
Inclusion/ Exclusion criteria	X	X						
Medical record release	X	X						
Medical, reproductive, & obstetric history*	X	X						

Nutrition (FIGO) checklist	X	X						
Food insecurity screening	X	X						
Diet information & handouts provided	X	X						
Diet and physical activity counseling	X	X	X	X	X	X	X	X
Blood draw for: **1. CRP** **2. metabolic panel** **3. Lipid panel** **4. A1C**	X	X			X	X		
MedDiet adherence screening				X		X		X
Routine Diet adherence screening			X		X		X	
6 meals delivered every 3 weeks	X	X	X	X	X	X	X	X
Olive oil and nuts provided		X				X		
Canola oil and healthy snack provided	X				X			
Exercise/food recall and general assessment questionnaire			X	X	X	X	X	X
Pregnancy data collected*	X	X	X	X	X	X	X	X
Delivery data collected**								
Neonatal data collected**								

*Data will be collected through medical records

**Data will be collected at 6 weeks post-delivery through medical records.

Outcomes

- Diet Adherence Assessment: Adherence of both groups will be assessed with a questionnaire based on a validated diet adherence questionnaire[39] during counseling sessions as described above. Questionnaires will be scored with a "1" assigned to all responses corresponding to the recommended guidelines and a "0" assigned to all responses which do not correspond to the recommended guidelines. The level of adherence will be defined based on the scale score as: ≤4 low adherence, 5-11 moderate adherence, and ≥ 12 high adherence.
- GWG**:** Total GWG will be calculated by subtracting the participant's weight (lbs.) at the initial prenatal visit from the weight (lbs.) at time of the delivery or at the last prenatal visit. GWG in the first trimester (6-13 weeks), second trimester (14-26 weeks), and third trimester (27-40 weeks) will also be calculated. Calibrated weight scales will be used at our clinic and at the hospital. Compliance rate of GWG based on IOM guidelines for overweight and obese women[10] will be compared between the MedDiet and the control group.
- Adverse Pregnancy Outcomes (APO): We will examine the most common Adverse Pregnancy Outcomes (APO) associated with overweight and obesity (Table 3).[2,4,5-7,45-51] Definition and management of all APO will follow the standardized guidelines at Myers Park OBGYN clinic.

Table 3 Adverse Pregnancy Outcomes (APO)

APO	Prevalence in Pregnant Women
HDP (preeclampsia, eclampsia, or gestational hypertension)	4-6% of overweight/obese women BMI ≥30[45] 12% in women with a BMI ≥40[46]
GDM	6-14% in overweight/obese women[47]
PTB	10.2% in US in 2021 was 10.2% (www.cdc.gov); data suggest increased risk among overweight/obese women [48-50]
Cesarean Delivery	29.9% in NC in 2020 (www.cdc.gov); There is a dose-response relationship between pre-pregnancy BMI and cesarean delivery rate.[4,7,51]
Large for Gestational Age (LGA) infant	Data suggestion relationship between LGA (birth weight >90th percentile) and overweight /obese women[7,51]

- Cardiovascular parameters: MedDiet is associated with reduction of blood pressure (BP) in non-pregnant adult overweight or obese women**.**[52] Physiological changes of blood pressure (BP) during pregnancy are characterized by reduction of BP in the second trimester with return to the pre-pregnancy level late in the third trimester and postpartum period.[53] Heart rate (HR) increases by 20% to 25% over baseline during gestation.[54] Maternal BP and HR will be obtained by a calibrated automated oscillometric device during prenatal visits from the first to the third trimesters following the standardized technique established in our clinic. Trends of BP and HR throughout gestation will be compared among women allocated in the intervention and the control groups.
- Cardiometabolic biomarkers: Consumption of MedDiet is associated with lower levels of total cholesterol,[53] reduces insulin resistance preventing type 2 diabetes[30,31] and GDM,[34,36] and reduces markers of subclinical inflammation such as C-reactive protein (CRP).[55] Pregnancy is characterized by increased levels of total cholesterol, low-density lipoprotein (LDP), high-density lipoprotein (HDL), and triglycerides, especially in the second and third trimester,[56] and pregnancy is a state of increased insulin resistance.[57] There is limited knowledge about the effect of MedDiet on cardiometabolic biomarkers during pregnancy. Maternal lipid profile, random glucose level, hemoglobin A1C, and CRP levels will be compared at baseline (6-16

weeks) and at 26-30 weeks of gestation among participants in the intervention and the control groups. The labs will be obtained at the same time of scheduled blood draws for routine prenatal labs.

Analytical Plan

This is prospective randomized pilot study of sixty participants who will be randomly allocated in the MedDiet group or in the control group. Because this is a pilot study, a sample size was not calculated. Results will be analyzed initially using descriptive statistics. Comparison between groups will be done using chi square tests for proportions, and t-tests or ANOVA procedures for continuous variables. Regression analysis will be performed to identify independent outcome predictors. Other inferential statistical analysis will be conducted as appropriate.

Human Subjects Protection

Screening and Recruitment

Approximately 30 new prenatal visits are scheduled in our clinic weekly and we anticipate 10 of those patients will be eligible. All pregnancy confirmation visits will be screened by a research member (PI, Co-PI, study coordinator) in Epic to establish eligibility. The following PHI will be collected for screening purposes:

- Name
- MRN
- Age
- BMI
- Diagnosis of pre-pregnancy diabetes
- Hemoglobin glycosylated (A1C) value at pregnancy confirmation visit
- Diagnosis of pre-pregnancy hypertensive disease
- Confirmation of viable singleton pregnancy
- Gestational age of pregnancy
- Primary language of English or Spanish
- Food allergies

Screening data will be entered into an Excel spreadsheet stored on a secure drive which only the research team will have access to.

At the first prenatal visit, women who meet inclusion/exclusion criteria will be presented a flyer (Appendix NN (English)/ Appendix OO (Spanish)) and invited to participate in the study. Eligibility will be confirmed following informed consent and the Eligibility Form will be completed (Appendix PP).

Informed Consent

At the first prenatal visit, women who meet inclusion/exclusion criteria will be invited to participate in the study. Signed informed consent (Appendix QQ (English)/Appendix RR (Spanish))) will be obtained from each subject by a member of the research team. If the

research member obtaining consent is not fluent in Spanish, an interpreter will be used. Consent will be obtained in a private room with a closed door in the clinic during the subject's initial prenatal visit. Participants will be fully informed about the nature of the study and the potential risks of the dietary intervention, anticipated to be minimal as this is a behavioral intervention.

Spanish Speaking Subjects

All study related materials will be available in both English and Spanish. Qualified and trained Spanish language medical interpreters will be used to communicate with Spanish language participants if the investigators are not proficient in speaking Spanish.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will remain on the data collection forms. Any identifiable information collected on the forms will be blacked out after data has been entered into RedCap or the Excel linkage file. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, stored separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed (three years after closure of the study), consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.(Appendix MM)

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Appendix

1. Appendix A-F: ACOG-based Dietary Program - English
2. Appendix G-L: ACOG-based Dietary Program - Spanish
3. Appendix M: Routine Diet Adherence Questionnaire - English
4. Appendix N: Routine Diet Adherence Questionnaire - Spanish
5. Appendix O-P; SS-UU: MedDiet Program - English
6. Appendix Q-R; VV-XX: MedDiet Program - Spanish
7. Appendix S: MedDiet Adherence Questionnaire - English
8. Appendix T: MedDiet Adherence Questionnaire - Spanish
9. Appendix U: Enrollment Questionnaire - English
10. Appendix V: Enrollment Questionnaire - Spanish
11. Appendix W: Enrollment Data -Spanish
12. Appendix X: Federation of Gynecology and Obstetrics (FIGO)[42] Nutrition Checklist - English
13. Appendix Y: Federation of Gynecology and Obstetrics (FIGO)[42] Nutrition Checklist – Spanish
14. Appendix Z: Blood Sample Collection Form
15. Appendix AA: OB Social Worker Assessment Questionnaire –
16. Appendix BB: OB Social Worker Assessment Questionnaire -Spanish Data collection form
17. Appendix CC: Diet and Physical Activity Recall - English
18. Appendix DD: Diet and Physical Activity Recall - Spanish
19. Appendix EE: 1st Trimester Collection Form
20. Appendix FF: 2nd Trimester Collection Form
21. Appendix GG: 3rd Trimester Collection Form
22. Appendix HH: Medical History Form - Spanish
23. Appendix II: Reproductive, and Obstetric History Form -Spanish
24. Appendix JJ: Current Pregnancy Labs Form
25. Appendix KK: Current Pregnancy Outcomes Form
26. Appendix LL: Neonatal Outcomes Form
27. Appendix MM: Adverse Event Form

28. Appendix NN: Study Flyer – English
29. Appendix OO: Study Flyer - Spanish
30. Appendix PP: Eligibility Confirmation Form
31. Appendix QQ: Informed Consent - English
32. Appendix RR: Informed Consent – Spanish
33. Appendix SS Enrollment Data – English
34. Appendix TT Medical History Form – English
35. Appendix UU: Reproductive, and Obstetric History Form – English
36. Appendix VV _Information for ModifyHealth – Spanish
37. Appendix WW _Information for ModifyHealth –English