

## E. HUMAN SUBJECTS RESEARCH

### E1. Protection of Human Subjects

#### E1.1 Human Subjects Involvement and Characteristics

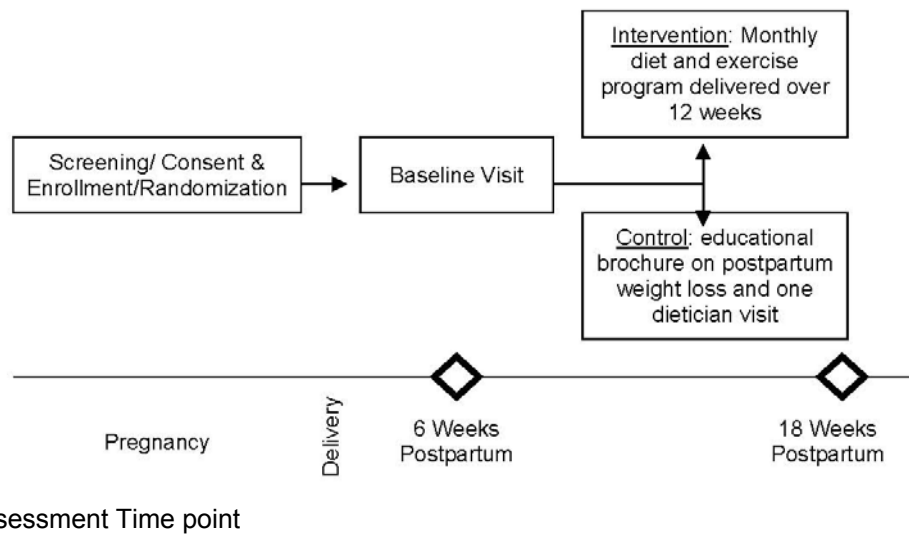
##### Study Design and Rationale for Study Design

We propose a pilot study that is a randomized controlled trial of the effects of adapting the behavioral intensive lifestyle intervention (ILI) of the DPP vs. usual care on postpartum weight retention, diet and exercise in overweight/obese (BMI  $\geq 25$  kg/m<sup>2</sup>) adult-age (18 years and older) African American women receiving perinatal care at Boston Medical Center (BMC). This pilot will be conducted over a 1-year study period and will provide information for a future randomized trial. Participants (n=60, 30 participants per group) will be recruited during pregnancy over 2 months in groups of 30 and each will participate in the program for 12 weeks. Outcome assessments will be measured at baseline (6 weeks postpartum) and post-test (18 weeks postpartum).

The primary specific aims are to:

- 1a) Pilot-test a culturally-tailored, clinic-based weight loss program with the goal of assessing the feasibility, receptivity, and potential utility of the program for overweight/obese postpartum African American women. A 2-armed randomized controlled trial will be undertaken for this evaluation, comparing the intervention participants (n=30) to control participants (n=30).
- 1b) Conduct a process evaluation to ensure high quality of program implementation and to obtain feedback from program participants and staff on their response to the program. Session observations and surveys and interviews with program participants and staff will be conducted to provide data on the feasibility and receptivity of the program.
- 2) Conduct a preliminary evaluation of the intervention's effectiveness on weight loss *assessing change in weight at the end of the intervention period (30 weeks postpartum)*, as compared to 6 week postpartum weight. Secondary outcomes will also be evaluated including change in behaviors as measured by change in physical activity, total daily caloric intake, and percent of total daily fat calories.

**Figure 1. Study Design (revised)**



##### Process of Consenting Patients

African American women receiving prenatal care at BMC will be screened for obesity, estimated date of delivery, and readiness to change at a regularly scheduled prenatal care visit. Screening will be conducted by an obstetrics provider *who will make it clear that participating in research is always voluntary and not participating will in no way affect the patient's care at Boston Medical Center. The screening will include 1) administration of the Stages of Change questionnaire (55); 2) determination of overweight/obesity as BMI  $\geq 25$*

kg/m<sup>2</sup> in pre-pregnancy weight by retrospective chart review; 3) administration of the Personal Health Questionnaire-9 (PHQ-9) (56). Women who meet eligibility criteria will be invited to consent to participation in the trial.

The screen includes several items that are part of clinical care, BMI assessment and depression assessment. Only the Stages of Change questionnaire is administered solely for research purposes.

The obstetrics provider who knows the patient will introduce the information about the study, and invite patients to participate. The research coordinator will be available by beeper to complete the informed consent process. The research coordinator will explain the rationale of the study, and what programs are involved. Women interested in the study will sign a consent form on or after the screening visit. *Under rare circumstances when the research coordinator is unavailable another co-investigator may perform the consent. Consent will not occur in the presence of the provider.*

*Informed Consent Procedures: Investigators will explain the study to potential participants and answer any questions they may have before administering the consent form following the Recruitment Script for Investigator-Initiated In-Person Contact; this script is attached at the end of this letter. The subjects will be asked to consent at the time of the current or a subsequent visit and informed that consent can be withdrawal if they change their mind. Eligibility screening will be conducted by investigators and staff prior to the consent process who will make it clear that participating in research is always voluntary and not participating will in no way affect the patient's care at Boston Medical Center. Patients will be asked to sign the Institutional Review Board (IRB)-approved written informed consent form if they have met inclusion criteria. The consent form will explicitly state the limits of confidentiality due to the group session setting and interaction with their Birth Sister.*

## **Inclusion/Exclusion Criteria**

Inclusion criteria:

1. BMI  $\geq 25$  kg/m<sup>2</sup>
2. Readiness to change (contemplation, preparation and action)
3. Language: English-speaking

Exclusion criteria:

### *Pre-Natal*

1. Signs of moderate to severe depression based on the PHQ-9 (defined as total score  $\geq 10$  or a response  $\geq 1$  on the item "thoughts that you would be better off dead, or of hurting yourself in some way). These women will be given an appointment for complete mental health assessment with a licensed clinical social worker and will be encouraged to enter treatment in the BMC Department of Psychiatry.
2. Pre-existing type 2 diabetes as defined by prior fasting blood glucoses  $> 126$  mg/dl or on insulin or sulfonylureas or other diabetes medications for diagnosed type 2 diabetes.
3. Other serious medical illnesses requiring supervision beyond a healthy pregnancy follow-up schedule.
4. Clinical judgment.

### *Post-Partum*

5. *Signs of moderate to severe post-partum depression based on the Edinburgh Postnatal Depression Scale (EPDS) which has been validated for detecting postpartum depression (defined as total score  $\geq 10$  or a response  $\geq 1$  on the item "the thought of harming myself has occurred to me"). These women will also be given an appointment for a complete mental health assessment with a licensed clinical social worker and will be encouraged to enter treatment in the Boston Medical Center Department of Psychiatry. Therefore, these subjects will not be participating in the intervention program. This reason for discontinuation will be clearly stated in the informed consent form.*

Given that our intervention is designed for postpartum women, we will need to enroll participants while they are pregnant. Participants will be randomized to receive either the intervention or usual care *after they have consented during the prenatal period. The intervention will not begin* until the Baseline visit (6 weeks postpartum) and the subjects will no longer be classified as "vulnerable" at that time.

## **E1.2 Sources of Materials**

Data will be collected at the baseline visit which will be the 6 weeks postpartum appointment that is regularly scheduled (women will be randomized at baseline) *and* 18 weeks postpartum (post-intervention) (see Tables 2 and 3 below). Data collection will be conducted by a trained research assistant at a separate visit to the Weight Management Research Center. Usual care participants will be reminded of their visit by letter. Intervention participants will be reminded at the group session immediately prior to data collection time point. Data collected will include weight, BMI, 3-day food log, pedometer readings, and questionnaires described below. All participants will be compensated 25.00 dollars for each assessment visit, at the 3 time points per participant.

**Table 2. Study Procedures (new)**

	Baseline	Post-Test
Time Postpartum	6 Weeks	18 Wks
<b>Procedures</b>		
EPDS	X	
Weight, BMI, Waist circumference	X	X
Nutritional Attitudes Survey	X	X
Physical Activity Attitudes Survey	X	X
Multidimensional Body Relations Questionnaire	X	X
Participant Satisfaction Survey	X	X
Kaiser Physical Activity Survey	X	X
Pedometer data collected	X	X
Modified Block Food Frequency Questionnaire	X	X
Food Record collected	X	X

**Table 3. Summary of Data Collection for Study Cohort**

Data Element	Instrument†	Data Source
<b>Primary Study Outcomes</b>		
Weight, BMI, Waist circumference	-	Clinical exam
Nutrition Attitudes	NAS	Interview
Physical Activity Attitudes	PAAS	Interview
Body Image Attitudes	MBSRQ	Interview
Feasibility and acceptability of program	PSS	Interview
<b>Secondary Study Outcomes</b>		
Change in Physical Activity	KPAS, Pedometer	Interview
Change in total caloric intake and fat calories	FFQ, food records	Interview

NAS= Nutritional Attitudes Survey, PAAS= Physical Activity Attitudes Survey, MBSRQ= Multidimensional Body Relations Questionnaire, PSS= Participant Satisfaction Survey, KPAS= Kaiser Physical Activity Survey, food records = 3 day food diaries, FFQ = modified Block Food Frequency Questionnaire.

### Outcome Measures

Outcomes will be measured at baseline (6 weeks postpartum) *and* post-test (30 weeks postpartum). All participants will be compensated 25.00 dollars for each assessment visit, at the 2 time points per participant.

### Primary Outcomes

**Specific Aim 1a:** To pilot-test a culturally-tailored, clinic-based weight loss program with the goal of assessing the feasibility, receptivity, and potential utility of the program for overweight/obese postpartum African American women. A 2-armed randomized controlled trial will be undertaken for this evaluation, comparing the intervention participants (n=30) to control participants (n=30).

**Specific Aim 1b:** To conduct a process evaluation to ensure high quality of program implementation and to obtain feedback from program participants and staff on their response to the program. Session observations and surveys and interviews with program participants and staff will be conducted to provide data on the feasibility and receptivity of the program.

The primary outcomes for these aims include attendance at the group sessions, barriers to attendance, and satisfaction with the sessions. The latter will be elucidated both by a Participant Satisfaction Survey (PSS) (see Appendix B) and in a de-briefing session at the end of the intervention with the participant and Birth

Sister. A Process Evaluation involving data collection to assess interventionists' expertise; program recruitment, delivery and retention; and participant and interventionists' response to program.

Nutrition Attitudes: To evaluate change in nutrition attitudes, we will measure nutrition attitudes at baseline (6 weeks postpartum) *and* post-test (18 weeks postpartum) using the Nutritional Attitude Survey (NAS) (see Appendix C). The NAS is a 24-item self-report questionnaire designed to measure attitudes toward the adoption of a low-fat diet. The NAS consists of 4 subscales labeled "Helpless/Unhealthy," "Meat Preference," "Food Exploration," and "Health Consciousness" (64).

Physical Activity Attitudes: To evaluate change in physical activity attitudes, we will measure physical activity attitudes at baseline *and* 18 weeks postpartum using a questionnaire based on the Physical Activity Questionnaire (PAQ) by Corbin and Lindsey (65), which is a questionnaire that was developed to examine attitudes or reasons for engaging or refraining from physical activity. We have modified the PAQ to reflect our study cohort and called it the Physical Activity Attitudes Survey (PAAS) (see Appendix D).

Body Image Attitudes: To evaluate change in body image, we will measure body image attitudes at baseline *and* 18 weeks postpartum using the Multidimensional Body-Self Relations Questionnaire (MBSRQ). This is a 36 item questionnaire that has already been utilized to assess predictors of weight loss in low- income women with children (36,66).

**Specific Aim 2:** To conduct a preliminary evaluation of the intervention's effectiveness on weight loss and *assessing change in weight at the end of the intervention period (18 weeks postpartum)*, as compared to 6 week postpartum weight. Secondary outcomes will also be evaluated including change in behaviors as measured by change in physical activity, total daily caloric intake, and percent of total daily fat calories.

Change in Weight: We will measure weight 6 weeks postpartum *and* 18 weeks postpartum (post-intervention) on the same scale at the Weight Management Research Center. Participants will be weighed without shoes in light clothing on a Balance Model #CQ250XL11 Scale with a 500-pound capacity. Both change in weight and change in BMI will be evaluated. Height will be measured to the nearest 1 millimeter, using a calibrated stadiometer. Measures will be taken twice and averaged. BMI will be calculated in kg/m<sup>2</sup>.

### **Secondary Outcomes**

Secondary outcomes will be evaluated, including change in behaviors as measured by change in physical activity, total caloric intake, and percent of total daily fat calories. These changes will be measured as a preliminary evaluation of the intervention's effectiveness. The measures will be obtained at baseline (6 weeks postpartum) *and* 18 weeks postpartum (post-intervention).

Change in Physical Activity: We will measure change in physical activity using the Kaiser Physical Activity Survey (KPAS) (67) which was designed to obtain information about women's physical activity habits and to include gender-relevant items in a survey that reflects activities done in women's lives (see Appendix E). The KPAS housework and caregiving and occupation indexes reflect mostly light-to-moderate intensity activities over the past week or past year and the KPAS has demonstrated good reliability and is reasonable accurate in detecting regular housework/caregiving, occupation, sports/exercise, and active leisure activities among women with a broad range of physical activity habits. In this respect we felt it would more accurately capture change in physical activity in our participants than the Modifiable Activity Questionnaire (MAQ) used to assess physical activity in the DPP (68). We will compare physical activity in the intervention group versus the control group with respect to average hours per week of moderate physical activity.

3-Day Pedometer Recordings: We will also measure average number of steps per day measured by pedometer readings. Yamax DIGI-WALKER pedometers will be used as an objective measure of physical activity. Pedometer readings will be used to assess walking and since other activities will be undercounted by this method we will capture those activities with the KPAS. We will use methods previously developed (69,70) to collect 3-day measures at the 2 assessment visits. Pedometer feedback has been shown to enhance counseling for weight loss by increasing physical activity through self-monitoring behavior (71).

Change in total caloric intake and total fat calories: We will measure change in total caloric intake and total fat calories by using the 3 day food logs as well as the Food Frequency Questionnaire (FFQ) from the reduced Block questionnaire (72). The Block FFQ is designed to assess nutrient intake levels as well as specific foods and food groups over extended periods of time. Dietary data from the National Health and Nutrition Examination Survey was used to construct the food list, portion sizes, and corresponding nutrient values for foods on the questionnaire. The Block provides overall calorie intake and macronutrient composition of the diet. The reduced version of Block FFQ is a validated food survey that contains 60 food items and is intended to capture all nutrients in the diet including dietary fat intake. The survey requires approximately 15 minutes to self-administer (73). FFQs are attractive methods in studies because of their low respondent burden and ease of administration, but the method relies heavily on memory and the questions posed to respondents are open to interpretation (74).

Another approach commonly employed to determine nutrient intake is the use of food diaries. In contrast to FFQs, food diaries allow more precise determination of portion sizes, do not rely on memory and are not limited to selection from a predetermined list of foods. They are not practical for large studies because they require extensive participant training, have a high respondent burden and require lengthy data entry by trained personnel (74). A concern for this study is that food records may cause participants to alter their food intake so may not represent participants' usual dietary intake. Instructions for keeping 3-day food logs will be given to the participants both verbally by the research dietician with aide from Birth Sisters and in written form (see Appendix F for written instructions). 3 day logs will be instructed to be kept for 2 weekdays and 1 weekend day. 3 day food logs will be analyzed by the research dietician for total daily calories and percent fat intake using a Nutrition Data System for Research software version 2008 (Program 060308) developed by the Nutrition Coordinating Center (University of Minnesota, Minneapolis, MN)(75).

### **Other Measures**

Demographic Characteristics: Race/ethnicity, marital status, age, zip code, relationship status, self-reported weight and self reported activity level and total daily caloric intake.

Medical History: Past or concurrent diseases and family history.

Safety Measures: Vitals, concomitant medications and supplements.

Participant Contact Log: Interventionists will keep records of each contact made with the participant including date and time of the contact, information and referrals provided, plans of action created for the participant. These records will be completed immediately following each participant contact. Research staff will pick up records monthly for review to ensure quality control.

Other relevant Measures: Breastfeeding practice, self monitoring of weight and frequency, and race and weight of the Birth Sister.

Information about study personnel access to participants' individually identifiable private information is included below.

### **E1.3 Potential Risks**

Risks to Participation in Screening and Study Assessments – Participants may be uncomfortable or embarrassed about answering questions regarding diet, exercise habits, or depression. To minimize this risk, participants will be informed that they may skip a question that they are uncomfortable with or stop the interview at any time. There is also a potential risk of inadvertent disclosure of protected health information; our steps to minimize this are described below.

Risks to Participation in the Intervention – While exercise and diet recommendations are based on the best evidence and extensive investigator experience, some participants may experience adverse effects of either dietary change or exercise recommendations.

Risk of Breach of Confidentiality – All study personnel with access to identifiable information are required to complete NIH-mandated training for protection of human participants, as well as BMC-mandated HIPAA

training. Data stripped of personal identifiers will be stored in password-protected computer files accessible only to the study personnel; linkage to personal identifiers will be kept in a separate locked file.

### Management of Pre-Existing Depression and Suicide Risk –

- Screening: Women showing signs of moderate to severe depression based on the PHQ-9 (defined as a total score  $\geq 10$  or a response  $\geq 1$  on the item “thoughts that you would be better off dead, or of hurting yourself in some way) will be given an appointment for a complete mental health assessment with a licensed clinical social worker and will be encouraged to enter treatment within the BMC Department of Psychiatry.
- Intervention: *There will be no formal monitoring for post-partum depression or suicide risk during the intervention period; if a participant reports suicidal or depressive feelings at any time during the course of the study, they will be referred for a complete mental health assessment. We feel that this is justifiable as high-risk participants will have been discontinued at their baseline visit based on their EPDS score. Post-partum depression and suicide risk are also not outcomes of this pilot and feasibility study and are not risks of participation.*

### Risks to Lactating Women – Postpartum women have distinct dietary needs and restrictions during lactation.

- *Total Daily Calories: In order to address these needs, the study dietitian will estimate daily calorie targets for participants in the intervention arm using the Mifflin-St Jeor equation<sup>1</sup> (Female:  $BMR = 10 (\text{weight}) + 6.25 (\text{height}) - 5 (\text{age}) - 161$ ), multiplied by an activity factor which will be 1.375 for most subjects estimating light activity + **500 kcalories for lactation needs.**<sup>2</sup>*
- *Protein: For protein, the RDA recommends at least 71 grams of daily protein intake (based on 1.1 g/kg body weight for the reference body weight) for lactating women and therefore subjects in the intervention arm will be counseled regarding increasing protein intake to meet the RDA. **Dietary protein requirements will be modified to meet any newly updated Dietary Reference Intake (DRI) guidelines and recommendations.***
- *Vitamin and Mineral Supplementation: In addition to protein and calorie needs, per DRI recommendations the subjects will be provided with a daily multivitamin and calcium citrate supplement (500 mg) and be counseled to consume foods high in Calcium and Vitamin A due to increased nutrient needs during lactation. It is standard of care in our obstetrics clinical practice to provide a multivitamin and calcium citrate supplement to all women in pregnancy and postpartum who come to our clinic and thus there will be no additional budgetary concerns for our project.*
- *Additional Dietary Surveillance: There is a need for a brief dietary surveillance system for lactating women to ensure that they are adhering to these recommendations and therefore our research dietitian will administer a food frequency questionnaire (FFQ) at baseline, mid-study and at the end of the study period to intervention groups. The subjects in the intervention arm will meet with a dietitian during 50% of the scheduled study visits to review the FFQ and to ensure adequate caloric and protein intake. The control group will meet with a dietitian once as per standard of care.*

## **E2. Adequacy of Protection Against Risks**

### **E2.1 Recruitment and Informed Consent**

Women who meet all of the inclusion and none of the exclusion criteria will be considered eligible for enrollment. These women will be approached in-person by the research coordinator at a regularly scheduled obstetrics appointment (approximately 28 weeks or 7 months pregnancy), which will serve as the screening and enrollment date, and informed consent will be administered. Informed consent will only be administered by study personnel. Potential participants will be given ample opportunity to review the informed consent form prior to study enrollment. A retrospective chart review to screen for obesity in pre-pregnancy weight will be performed by a research assistant prior to a regularly scheduled prenatal care visit.

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<sup>1</sup> Mifflin MD, St. Jeor ST, Hill LA, Scott BJ, Daugherty SA, Koh YO. A new predictive equation for resting energy expenditure in healthy individuals. *Am J Clin Nutr* 1990; 51: 241-7.

<sup>2</sup> Food and Nutrition Board, Institute of Medicine. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (macronutrients)*. Washington, DC: National Academy Press; (2002).

Our study includes women age 18 and older who are pregnant. The different needs of girls under age 18 years are not addressed by our proposed intervention and the proposed intervention will not meet the needs of these minors. This age-based inclusion criterion was established because the specific obesity-related risks of adult postpartum African American women are the focus of the proposed intervention

## **E2.2 Protections Against Risk**

### **Risks Related to Participation in Screening and Study Assessments**

*Therapeutic Misconception and Voluntary Participation:* The measures that we have put in place to concerning therapeutic misconception and voluntary participation are present in the recruitment and informed consent procedures. Providers who may also be investigators will make it clear to potential subjects that participating in research is always voluntary and not participating will in no way affect the patient's care at Boston Medical Center. This will also be stated in the informed consent form using the following text: "Your Boston Medical Center doctor may also be an investigator of this research study. As an investigator, your Boston Medical Center doctor is interested both in your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study. You do not have to participate in any research study offered by your Boston Medical Center doctor. Please be aware that taking part in this study does not take the place of your regular visits to your Boston Medical Center doctor or personal physician."

### **Risks Related to Weight Loss and Exercise Intervention**

While exercise and diet recommendations are based on the best evidence and extensive investigator experience, some participants may experience adverse effects of either dietary change or exercise recommendations. Because dietary change or exercise may pose special risks for postpartum women, we will minimize these risks through close monitoring by the study investigators.

### **Risks to Confidentiality**

Since this is a clinical trial set in the context of a pre-existing clinical setting, it is possible that participants may be revealed as such when they come in for study-related visits. All participants will be informed of this possible risk during the informed consent process.

All study personnel with access to identifiable information are required to complete NIH-mandated training for protection of human participants, as well as BMC-mandated HIPAA training. Data stripped of personal identifiers will be stored in password-protected computer files accessible only to the study personnel; linkage to personal identifiers will be kept in a separate locked file.

*Protection of Confidentiality of Audiotapes:* Audiotapes will be used solely for the purpose of process evaluation and quality assurance, and no one outside of the research team will have access to these tapes. The audiotape will solely be labeled with the session number and date. Names of participants will not be noted on the tapes and are not necessary, as the purpose of the tapes is for quality control. When the tapes are transcribed, participant names will be replaced by the title "PARTICIPANT". However, attendance records will be maintained for sessions, as these data are necessary for dose analyses. A note taker will be available at sessions, and this individual will help verify quality of transcriptions. They will be maintained in a locked cabinet in the PI's office and only accessible by the study coordinator and research behaviorist. Tapes will be destroyed within 6 months subsequent to review.

*Protection of Confidentiality of Group Sessions:* All group sessions will follow the same basic structure. Sessions will begin with the subjects being welcomed by study staff and a review of the topics to be covered in that day's session. Subjects will also be reminded at the beginning of each session that personal information shared during the session is confidential and should not be shared outside of the session. We will emphasize the importance of the need for confidentiality to all subjects.

Participants will be clearly informed about the limits of protecting confidentiality in the informed consent form. All medical and research staff are required to report child abuse per Massachusetts General Laws, Chapter 119, Section 51A; participants will be notified in the consent form about this requirement. Subject charts and samples will not contain patient identifiers. A master code list linking the subjects' identity to collected data will

*be password protected. Upon data analysis, staff statisticians will have access to a database stripped of the master code list. Subjects' records will be kept in locked file cabinets, and the computer database will be password protected and remain on the study coordinator's hard drive and encrypted back-up hard drive. The password will be known by the PI and study coordinator.*

*The following text regarding confidentiality is also standard in all Boston Medical Center consent forms, "Information from this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or state and federal regulatory agencies such as the Office of Human Research Protection as applicable, and the Institutional Review Board of Boston University Medical Center. Information from this study and from your medical record may be used for research purposes and may be published; however, your name will not be used in any publications."*

### **Risks to Pregnant Women**

Due to the nature of our target study population, postpartum women, we will need to recruit participants during pregnancy. Women are enrolled at a regularly scheduled obstetrics appointment (approximately 28 weeks or 7 months pregnancy), however, they are not randomized to receive either usual care or the study intervention until the baseline visit 6 weeks postpartum. No study intervention, other than enrollment and minor screening procedures, are performed on participants when they are pregnant. We feel that this study poses no risk to women during their pregnancy.

During the study, staff will monitor participants for clinical emergency. If such a case arises, staff will immediately refer the participant to the appropriate BMC medical or mental health personnel. Participants requiring such an urgent medical intervention will be encouraged to continue participation in the study intervention, regardless of the treatment received. All adverse events are reported to the BMC Institutional Review Board (IRB).

### **E3. Potential Benefits of the Proposed Research to Human Subjects and Others**

- Screening and data collection activities – Potential study participants will be screened for inclusion in the study with PHQ-9 and all those with moderate or severe depression will be given an appointment for a complete mental health assessment by a licensed clinical social worker and will be encouraged to enter treatment within the BMC Department of Psychiatry. Though these individuals will not be eligible for our study, they will have mental health issues identified at an earlier stage and we will assist them in getting an assessment and perhaps earlier intervention for depression in pregnancy than would otherwise be possible.
- Intervention – Participants in the intervention arm may expect to receive significant benefit to their postpartum health and lactation activities through the intervention of nutrition education, monitored and unmonitored physical activity, and other postpartum education in wellness for mother and baby.
- Usual Care Group – The usual care group will be given questionnaires and pedometers and thus may indirectly receive some prompting for increased awareness of wellness activities, and thus may benefit indirectly from the study.
- Risk/Benefit Ratio – After reviewing the above risks and benefits to the potential participants and study participants, we feel that the potential benefits to the subjects and others outweigh the risks of the study.

### **E4. Importance of the Knowledge to be Gained**

This pilot study will provide the data necessary to develop a comprehensive multidisciplinary program to treat overweight and obesity in African American women at a time in their lives where they are most amenable to an intensive lifestyle intervention. If successful, this program would serve as a model for other wellness programs to specialize in this intervention and utilize resources to aid in reducing disparities in health care due to socioeconomic status and race and cultural issues.

Since overweight and obesity are epidemic in the US and especially in African American women, the importance of the knowledge to be learned from this pilot is crucial to the future treatment of obesity in this population should it be successful in promoting weight loss and weight maintenance postpartum. This can give important knowledge to a future public health effort targeted at reducing the disparity in overweight and obesity prevalence in the US.



### **E5. Data and Safety Monitoring Plan (substantially revised)**

As this study is minimal risk for subjects, we will not establish a Data Monitoring Board (DSMB). However, study investigators will meet on a monthly basis to review study data and reported adverse events. In addition to the procedures outlined in Section E1.3, data on potential adverse events will be collected at 18 weeks. Participants will be asked about recent hospitalizations and illnesses.

The PI will uphold the following responsibilities:

- The Principal Investigator (PI) and members of the staff will be responsible for reporting all new clinical experiences, exacerbations, and/or deterioration of any existing clinical condition occurring after a study subject has entered the study.
- The PI will be responsible for reporting Serious Adverse Events (SAEs) to the BMC IRB.
- The PI will be responsible for determining the causality of all AEs/SAEs subject to review by the BMC IRB.
- The PI and staff will be responsible for follow-up information on all AEs until resolution or an appropriate endpoint is reached.

The PI in concert with BMC IRB and other study investigators will be responsible for reviewing all reports of SAEs that occur in this study and for determining whether any corrective actions need to be taken regarding: management decisions of the PI and staff, whether protocol violations are congruous with patient welfare taking precedence over protocol, whether there are any issues among the research staff that need to be addressed, etc. The study investigators will be responsible to determine if the results of its review require a revision/modification of the RPN and/or the consent form.