COMIRB Protocol

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Protocol #: 19-1366
Project Title: My Baby My Move+
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I. Hypotheses and Specific Aims:

Statement of Purpose: The proposed study will implement and test the feasibility of a theoretically-based (e.g., social cognitive theory), peer-led wellness intervention, "My Baby My Move+" (MBMM+) to reduce excessive gestational weight gain (EWGW) by targeting physical activity, mood, and sleep.

The aims of the proposed research are to:

- Aim 1. Determine feasibility (i.e., acceptability and demand) of the MBMM+ program.
- Aim 2. Examine the impact of the MBMM+ program on EGWG at 12 weeks post-baseline to determine estimates of effect size for a future, larger randomized trial.

II. Background and Significance:

Up to 50% of pregnant women in the U.S. gain weight in excess of the Institute of Medicine (IOM) guidelines (i.e., excessive gestational weight gain (EGWG)). EGWG leads to poor maternal (e.g., pre-eclampsia, gestational diabetes, postpartum weight retention) and child (e.g., preterm birth, large for gestational age weight at birth) outcomes. It also sets the stage for long-term overweight/obesity for both mother and child. There are few efficacious intervention strategies for reducing EGWG and among those, physical activity is one promising strategy. Prenatal physical activity is associated with a variety of health benefits (e.g., reducing risks for gestational diabetes, pre-eclampsia, depression, and body image dysphoria). There is also a need to increase prenatal physical activity as approximately 80% of pregnant women are not meeting recommended levels. One reason for low prenatal activity is that pregnant women are concerned with and lack knowledge/skills about how to safely and effectively participate in physical activity. Increasing knowledge and skills about physical activity may improve prenatal physical activity participation, lower safety concerns, and in turn, reduce EGWG.

To increase the likelihood one will consistently engage in regular prenatal physical activity, knowledge and skill building need to be coupled with strong motivation. Our pilot work suggests that focusing on the interrelationship among physical activity, mood, and sleep is of particular importance to instilling motivation for prenatal activity. Many women struggle with poor mood during pregnancy with prevalence rates ranging from 12%-51%. Pregnant women also suffer from poor sleep quality, which is associated with negative mood during pregnancy. In a vicious circle, poor sleep quality and depressed mood can hinder the very physical activity patterns that have been shown to significantly reduce

depressive symptomatology and improve sleep quality during pregnancy. Moreover, poor sleep and mood are also related to EGWG. Women who understand through self-regulation how physical activity benefits their mood and sleep may be more motivated to continue with activity. Thus, physical activity interventions may be more effective if they simultaneously target mood and sleep. Given this, there is a significant need to develop sustainable and scalable interventions that emphasize the importance of both understanding the benefits of physical activity, mood and sleep during pregnancy and developing strategies to support and motivate safe and effective engagement in prenatal physical activity to ultimately reduce EGWG. To our knowledge there are no published intervention studies examining this triad to reduce EGWG. Moreover, there are limited efficacious prenatal physical activity interventions currently available. A recent review of the literature related to physical activity and pregnancy highlights that little is known about the efficacy for physical activity interventions during pregnancy. Only three of the nine studies reviewed showed significant effects on physical activity and most studies had major limitations including: 1) use of self-report to measure physical activity as compared to objective physical activity measures; 2) high attrition rates, 3) underpowered, 4) devoid of a theoretical framework; and 5) none focused on the triad of physical activity, mood, and sleep. Thus, there is a clear need for developing effective, theoretically-based prenatal physical activity interventions that target these modifiable outcomes.

There are numerous established benefits of prenatal physical activity including reduced EGWG [6] [7]. However, many pregnant women do not engage in the recommended amount of physical activity with less than 20% of women in the US (as well as in CO) reporting regular physical activity [8, 9]. Given the benefits of prenatal physical activity and the short/long-term risk reduction in EGWG and obesity, respectively, it is evident that pregnancy is a critical time in a woman's life to adopt a physically active lifestyle. A recent review suggests there is a need for theoretically-based, well-designed prenatal physical activity interventions [10]. The proposed study addresses this need and underscores scientific rigor by utilizing a strong study design and theoretical framework based on the Social Cognitive Theory coupled with evidence-based strategies based in part from formative work to increase prenatal physical activity [11]. Pregnant women are at elevated risk for poor mood (i.e., depressive symptomatology) and sleep quality [12] [13]. Regular physical activity engagement reduces depressive symptoms as well as enhances sleep quality [14] [15]. In particular both walking and mindfulness yoga have been shown to decrease depressive symptomatology [14] [16]. Further, we posit that once women begin to engage in regular prenatal physical activity they will notice these improvements in sleep and mood via self-regulation (i.e., tracking of physical activity, sleep, and mood) which in turn, will further motivate them to continue to engage in physical activity. If found true, future interventions targeting this triad (i.e., physical activity, mood and sleep) may significantly improve the likelihood that women will sustain regular prenatal physical activity and thus, reduce or prevent EGWG. Moreover, enhancing sleep and mood may also directly reduce EGWG [17] [18]. Need for Peer Mentor Delivery Systems. Extant EGWG interventions mostly focus on testing clinical interventions in healthcare settings and lack integration into communities. Peer-mentors as delivery agents may be an effective strategy to translate prenatal physical activity programs such as the MBMM+ program into the community [19-

23]. Studies suggest peer delivered interventions (i.e., trained volunteer peers) may be as effective as professional staff delivered interventions in
helping individuals improve and maintain physical activity [21, 22]. Pregnant women specifically have reported valuing interpersonal interactions to motivate and support behavior change such as physical activity with other pregnant women (i.e., peers they can identify with) [21, 23, 24]. Additionally, utilizing peer mentors may mitigate reliance upon professional staff and provide a low cost opportunity for dissemination [21, 22] of evidence-based practices improving likelihood of future scalability. The proposed study plans to test the feasibility of a peer-delivered, theoretically-based intervention (i.e. MBMM+).
The proposed study aims to reduce EGWG by uniquely targeting the triad: prenatal physical activity, mood, and sleep quality. There are no known EGWG interventions using this approach. One of the foci of this proposal is the potential sustainability of MBMM+. Few EGWG interventions have focused on the potential sustainability of peer-led, community-based programs and therefore despite being effective, dissipate over time. We propose to develop and test a potentially feasible as well as sustainable EGWG intervention to instill good healthy habits (e.g., prenatal physical activity, good sleep hygiene, stress management) during and beyond pregnancy.

III. **Preliminary Studies/Progress Report:**
This proposal extends a pilot program called My Baby, My Move (MBMM; PI: Leiferman J), funded by the Centers for Disease Control and Prevention aimed at developing and implementing a prenatal physical activity intervention to promote regular engagement in moderate-intensity physical activity. The development of the MBMM intervention stemmed from conducting individual and focus group interviews with over 65 pregnant women to better understand what facilitates and prevents engagement in prenatal physical activity [24]. The 8-week MBMM intervention was beta-tested on 66 pregnant women (n=33 MBMM intervention; n=33 educational control group) during mid-late second trimester throughout third trimester. Total physical activity (light, moderate, vigorous) increased in the intervention group by over 80 minutes from baseline to 3 months postpartum [294 min/wk (SD 89.8) to 373.1 min/wk (SD 146)] whereas the control group decreased over time [309 min/wk (SD 146.6) to 302 (SD 112.1)]. The intervention was also successful in increasing certain known mediators of physical activity, such as behavioral skills (e.g., self-regulation) [pre: mean 32.75(SD 8.8)//post: mean 39.33(SD 5.30) (p=0.03)] and social support [pre: mean 26.17 (SD 8.94)//post: mean 33.75 (SD 10.01) (p=0.02)]. The process evaluation for the MBMM program found high fidelity in intervention delivery, average attendance (88% for each session over an 8 week period) and high satisfaction with the program (1.3 on a 5 point scale, with 1 being extremely satisfied). A major limitation to these data is that we did not collect data on EGWG. Additionally physical activity data were self-report and standard of care was used as a comparison group. Although these data are encouraging and in the hypothesized direction, based on feedback from participant post-intervention qualitative interviews (unpublished) and current recommended evidence-based strategies, we are proposing to test an enhanced version of MBMM called MBMM+ that will 1) examine the impact of the intervention on EGWG, 2) add in-depth information on new topics related to mood (stress-management,

mindfulness, wellness wheel, family/life balance) and sleep (good sleep hygiene, sleep/energy balance) given their inter-relatedness to EGWG and physical activity, 3) add a comprehensive objective assessment of physical activity, 4) add an appropriate comparison group that controls for time and attention (i.e. health education group); 5) add yoga as a programmatic activity component throughout program, and 6) increase participant/peer leader contact time by addition of more small group participant interactions with peer leaders. To do so, we will increase the length of intervention from eight to 12 wks as well as the dose from one session/wk to two sessions/wk.

IV. Research Methods

A. **Outcome Measure(s):** The Assessment Table (Table 1) displays all primary and secondary outcomes, associated measures, and the timeline of data collection. Data will be collected at four timepoints: T1) baseline, T2) 6-weeks post-baseline, and T3) 12- week post-baseline (i.e. end of intervention) and T4) at time of delivery.

Assessment tools (scale and Fitbit) will be delivered to participants after eligibility is confirmed and after they complete the online consent and baseline survey at a time and location of their choosing. A scale and Fitbit with a brief one-page protocol will be delivered to the participants by the Study Coordinator. Seven-days after delivery, the Study Coordinator will pick up the Fitbit (from all participants) and scale (from control participants). The participants will leave these materials at a specific location for the Study Coordinator. There will be no contact between them. During this time, the Study Coordinator will either drop off a hard copy of the curriculum (or send an electronic copy)as well as incentives for the intervention group participants (yoga mat and pedometer). The team has instituted strict protocols to minimize exposure related to COVID-19. This includes:

- No contact with participants; the Study Coordinator will leave the materials mentioned above at a specific location dictated by the participant (e.g. front porch).
- The Study Coordinator will wear a mask at all times when doing deliveries of assessment and programmatic materials.
- The Study Coordinator will complete a symptoms checklist and take their temperature prior to dropping off assessment and programmatic materials. This will be shared with the PI prior to delivery.
- The Study Coordinator will keep hand sanitizer in their car and use before and after delivery of assessment and programmatic materials.
- The research team will follow all safety protocols instituted by the University of Colorado regarding COVID-19 and human subjects research.

<u>Weight Gain.</u> Weight will be collected at T1 and T3 for all intervention and control participants. Participants will be asked to record their weight three times on one day and send a picture (via text or email) to a member of the research team during the 7-day assessment week. Individuals will be asked to remove their clothes and shoes and keep on their undergarments and weigh themselves first thing in the morning before they eat anything. Total GWG will be captured three times consecutively and then averaged across these three weight recordings. Total GWG will be compared to the IOM guidelines at T1

and T3 and calculated as: +, -, or 0 with respect to the guidelines (based on each woman's pre-pregnancy BMI-determined GWG category) such as GWG above the guidelines (+), below guidelines (-), or within the guidelines (0) [39]. Participants randomized to the intervention group will also be given a TANITA scale to measure weight at home daily (the research team will send weekly reminders via email or text). Women will step on the scale and note their weight on a tracking log at the same time each day. Participants will email copies of tracking logs weekly to the study coordinator. Please see appendix for tracking log.

Physical activity. All participants (intervention and control) will wear a Fitbit Charge 3, which is a wrist worn physical activity tracker, for a 7-day period during T1 and T3. Fitbit counts the minutes of activity/steps each day. The use of Fitbit devices have been validated in pregnant women (St-Laurent, Mony, Mathieu, & Ruchat, 2018). Activity will also be formally assessed with all participants using an adapted version of the *Leisure-Time Exercise Questionnaire (LTEQ*; Godin & Shepherd, 1985) at three time points (T1, T2, and T3). Additionally, participants will be assessed using the short form of the International Physical Activity Questionnaire (IPAQ; Hallal, 2004). Participants will complete the consent and survey electronically prior to the Fitbit and Scale delivery. Women will be asked to report how many days per week and minutes per day they engaged in regular exercise behavior. Reported minutes per day will be multiplied by days per week to calculate minutes per week of regular exercise behavior. The LTEQ is a valid and reliable measure of leisure-time exercise behavior (Godin & Shepherd, 1985) and has been used with pregnant women to better understand their exercise behavior (Sattler et al., 2018). Although, primary outcome physical activity data will be assessed by the Fitbit, LTEQ data will help further describe modes and intensities of physical activities. Women randomized to the intervention arm of the study will also informally track their daily physical activity on a tracking log. Participants will email copies of tracking logs weekly to the study coordinator.

Mental Health will be formally assessed at T1, T2 and T3 by using four mood measures including: 1) Edinburgh Postnatal Depression Scale (EPDS), 2) General Anxiety Disorder-7 scale (GAD-7), 3) Perceived Stress Scale (PSS), and 4) Mindfulness Attention Awareness Scale- 5 (MAAS-5). Participants will complete the consent and survey electronically prior to the Fitbit and Scale delivery. The EPDS is a self-report 10-item tool that has been used extensively in the past to assist in the identification of women who may be suffering from depression (during pregnancy and postpartum). Each of the ten questions has four possible responses (ranging from 0 – 3) with a total score range of 0-30 and demonstrates high internal consistency [45]. The GAD-7 is a brief measure of anxiety. For a cutoff score of >=10, the GAD-7 has a sensitivity of 89% for Generalized Anxiety Disorder and a specificity of 82%. Perceived stress will be measured using the The Cohen Perceived stress scale which is a validated tool and is designed to measure "the degree to which situations in one's life are appraised as stressful". (Cohen, Kamarck, & Mermelstein, 1983). The PSS consists of 10 questions measured with a 5-item likert scale. Finally, the MAAS includes 5-items related to mindfulness and shows high internal validity (4). Women randomized to the intervention arm of the study will also informally track their

daily mood activity on a tracking log. Participants will email copies of tracking logs weekly to the study coordinator.

Sleep Quality. Sleep will be assessed in all participants at T1, T2 and T3. The Pittsburgh Sleep Quality Index (PSQI) is a 19-item self-rated questionnaire which assesses subjective sleep quality, latency, duration, and disturbances over a 1-month time interval. It also measures sleep medication usage and daytime dysfunction over the past month. Total PSQI has demonstrated construct validity and internal consistency in pregnancy [46]. Participants will complete the consent and survey electronically prior to the Fitbit and Scale delivery. Sleep data will also be collected from the Fitbit device during T1 and T3. Fitbit sleep data includes total minutes of sleep, as well as total minutes in REM sleep, light sleep, and deep sleep. Women randomized to the intervention arm of the study will also informally track their daily sleep activity on a tracking log. Participants will email copies of tracking logs weekly to the study coordinator.

Nutrition. Nutrition-related behaviors will be formally assessed in all participants at T1 and T3. The Three Factor Eating Questionnaire is a 51-item questionnaire developed by Stunkard and Messick (1985) to measure three dimensions of human eating behavior: 1) dietary restraint, or cognitive control of eating behavior, 2) dietary disinhibition, or disinhibition of cognitive control of eating, and 3) susceptibility to hunger. We will only use 18 items of the revised TFEQ from Cappelleri (2009). Participants will complete the consent and survey electronically prior to the Fitbit and Scale delivery.

Theoretical Mediators.

1) A modified version of the Exercise Self-Efficacy scale [47] will be used to assess participants' beliefs in their ability to participate in physical activity. Internal consistencies are good (Cronbach's $\alpha = .99$ across time points). All participants will complete this tool at T1 and T3. 2) Behavioral Skills (e.g. self-regulation) will be assessed using three tools: 1) a 15-item subscale used in Project Grad [48], 2) the Pregnancy Weight Gain and Attitude Scale (PWGAS) (Downs, 2003, 2004), and 3) a 3-item scale to assess perceived behavioral control (Downs, 2003, 2004). All participants will complete these tools at T1 and T3 3) Social support for physical activity will be measured using two tools: 1) Social Support and Physical activity Scale [49] which assesses perceived social support from both family and friends on a 13-item scale, and 2) the General Social Support Questionnaire (SSW) which measures social support and satisfaction with social support. The SSQ has good test-retest reliability and convergent internal construct validity. All participants will complete these tools at T1 and T3.

Delivery outcomes (i.e., delivery type (vaginal vs. caesarian section), birth weight and gestational age, intervention used (if any), and maternal weight at delivery) will be assessed via self-report survey through REDCap.

Demographics

Socio-demographics (e.g., race/ethnicity, marital status, age, parity, income, education, insurance coverage) will be assessed via baseline survey at T1.

Optional data collection procedures

Participants may be contacted at the conclusion of the study and given the opportunity to choose to participate in a phone or zoom interview to better understand their thoughts about

participation in the program (to what extent they were satisfied with the program and parts of the program they enjoyed and parts they think could be stronger, etc). The interviews will be approximately 45 minutes long and you will be compensated $30. Up to 15 women will be invited to participate in an interview. Due to COVID-19, the trial will be run two times; a remote pilot of the trial will be run in the Fall of 2020 (n=30), followed by a larger in-person trial (pending COVID-19) in the Spring of 2021 (n=70)
Interviews with participants will be conducted after the pilot trial (Fall 2020) in addition to after the full trial (Spring 2020).

B. Description of Population to be Enrolled:

We anticipate eligibility screening for pregnant women (6 through 12 weeks) to take approximately 5-10 minutes to complete. The time window for gestational age recruitment was selected based on our formative work [25] [26] that suggests that in order to impact EGWG early intervention is critical. The first 4 weeks of the intervention will consist of educational materials as women may not want to participate in physical activity until near the end of first trimester when their risk for miscarriage drops and the mother tends to feel better physically. The experiential component (i.e., walking and yoga) will start in week 5. In order to extend our recruitment window, we will create rolling recruitment opportunities with women entering into the program from weeks 1 through weeks 6 (weeks 1-4 electronic materials; weeks 5-6 zoom sessions begin). All women will receive the electronic materials for weeks 1-4 before starting the zoom group sessions in week 5. For those women who start the zoom sessions in week 6, they will receive an additional session (material from original week 5) at the end to ensure all women receive 16 sessions (8 weeks of zoom sessions). Women will be recruited from the University of Colorado Clinics, clinics in Denver Metro and surrounding areas as well as social media (e.g. facebook and instagram). We will work with providers to help with recruitment of women in need of intervention for EGWG.

Sample Size. In terms of intervention effects on EGWG, results have been variable across studies, with average intervention effects being small to moderate. In terms of physical activity, our preliminary work with the original MBMM showed an effect roughly equivalent to Cohen's d = 0.69. This effect falls into the moderate range, similar to higher-impact interventions on EGWG [27]. Based on these two effect ranges, we estimated effect size to detect effects of $d > .63$, a medium effect, for the proposed MBMM+ intervention. Using this effect size, $\alpha = .05$, and $1-\beta = .80$, a sample size of 40 per arm (80 total) would be adequate to detect medium effects in EGWG, exercise, and other outcomes. We propose enrolling 50 per arm to account for up to 20% attrition and to allow for power to detect potentially smaller effects for EGWG. This level of power is expected to also be adequate for detecting changes in mediators, which have previously been observed to be more powerfully affected by the MBMM intervention than physical activity.

Due to COVID-19, the trial will be run two times; a remote pilot of the trial will be run in the Fall of 2020 (n=30), followed by a larger in-person trial (pending COVID-19) in the Spring of 2021 (n=70)

C. Study Design and Research Methods

Intervention Group:

The MBMM+ intervention is designed to promote the engagement in physical activity and takes into account barriers among pregnant women cited in our formative work such as lack of knowledge and skills, body changes and discomfort, feeling limited, and lack of social support [24]. Uniquely, the MBMM+ program also targets sleep hygiene and mood to further support regular physical activity engagement. Over the years of working with pregnant women, we have observed that once women notice how their regular physical activity helps their mood and sleep patterns they are often more likely to continue engaging in regular physical activity. During the first four weeks of the MBMM+ program, participants will receive electronic informational handouts covering topics on weight management (content will be based in part on Co-I Downs' Healthy Mom Zone intervention such as informing on benefits and guidelines of healthy GWG, tips on healthy eating, energy balance, and sleep quality) [26] as well as the benefits and safety concerns related to prenatal physical activity. Starting week 5 of the 12-week intervention, participants will attend two virtual, group sessions per week with each session lasting approximately 30 minutes and will be held remotely via zoom. Sessions will be held on weekday evenings and weekend mornings as these times were preferred by pregnant women. Given that pregnant women often express a lack of knowledge about safe physical activities during pregnancy, preventing them from engaging in physical activity, each session will include both didactic and experiential components to increase knowledge and skill building. Sessions will begin with a didactic component covering overcoming barriers to physical activity, goal setting, self-monitoring, problem solving, topics related to mood (stress management, family/work balance, wellness wheel), sleep hygiene (setting routines, avoiding stimulants, environmental supports), and additional physical activity topics (e.g., managing physical activity in postpartum, overcoming relapses). Participants will be given educational materials in print and electronic form based on their preferences. Participants will then be encouraged to complete the experiential component (i.e., physical activity) on their own for 30 minutes in duration and involve primarily walking, at a moderate intensity, based on national recommendations [28] coupled with yoga. Yoga classes will be led remotely four times throughout the program. For these sessions, the online class will last 60 minutes; 15 minutes of didactic followed by 45 minutes of yoga. Our formative work suggests that mothers prefer walking and find it more enjoyable in the form of groups. We have chosen to also include yoga to provide options for ways to be active that also positively impact sleep and mood [16] [29] and pregnant women report desiring prenatal yoga [30]. All didactic sessions will be facilitated by the peer leaders (see below). The yoga sessions will be taught by an experienced prenatal yoga instructor residing in Denver, CO.

For the remote pilot trial in the Fall of 2021, each session will have one lead Peer Leader and one additional peer leader to help facilitate the sessions and support goal setting. Our MBMM formative work and expertise in community-based physical activity interventions suggests participants prefer peer group leaders because they foster a sense of community and social support within the group setting [23]. Peer leaders will be compensated for their time working with the MBMM+ program and will be peer mothers from the community who are recent mothers (< two years postpartum) who successfully engaged in regular

physical activity during a previous pregnancy. Peer leaders will be identified by our research team, recreation center directors, and health care provider partners. At the end of every didactic session, participants will check in with an assigned peer leader to discuss in small groups their weekly logs. The team will use the 'breakout room' feature in zoom to divide the larger group into their smaller groups for these discussions. Peer leaders will note the discussions that occurred amongst the participants in their group, describe barriers that were identified, problem-solving strategies that were suggested and used, and future goals/recommended action steps. This group work will help participants to learn ways to fit physical activity into their lifestyle and overcome barriers by receiving feedback from their peer leader and other group members. It will also ensure that the intervention is conducted and received in the way intended as the peer leaders and program manager/PI will review these small group progress notes each week and monitor intervention delivery.

Peer leader training and fidelity: Weekly, the research team will have phone calls with the group peer leaders to debrief and address any issues that may arise. At least one member of the research team will participate in all sessions to ensure quality control of intervention delivery and data collection efforts by peer leaders. The PI will conduct a training session delivered remotely before the onset of the intervention with the peer group leaders to cover topics including how to engage in safe and effective physical activity during pregnancy, an overview of behavioral change theory and the behavioral skills that the intervention is targeting, ways to garner social support and leadership skills. The PI has been extensively trained by the Cooper Institute in Prenatal-Postnatal Physical Activity. The yoga instructor will have been extensively trained in prenatal yoga.

Control Group:
Women randomized to the control group will complete a similarly structured 12-week program; electronic materials related to various prenatal topics including preparation for birth, birthing options, and responsive parenting will be distributed twice a week for the first 4-weeks of the program. Starting week 5 of the 12-week intervention, participants will attend two virtual, group sessions per week with each session lasting approximately 45 minutes. Sessions will be held remotely via zoom. Sessions will be held on weekday evenings and weekend mornings as these times were preferred by pregnant women.

The Intervention-group Table of Contents and Control-group Table of Contents displays all key topics presented throughout the 12-week intervention and control groups. Please find study materials for intervention and control arms in the Appendix.

D. Description, Risks and Justification of Procedures and Data Collection Tools

Recruitment and Informed Consent. Participants for this study will be recruited from obstetric clinics located in the Aurora and Denver Metro and surrounding areas, as well as facebook and instagram. The investigators and study staff have completed NIH-approved training for human subject-based research, and are experienced at consenting subjects according to federal guidelines. Up to 100 pregnant participants will be recruited to

complete this study (two trials; remote pilot in the Fall of 2020 with 30 participants followed by larger trial in the Spring of 2021 with 70 participants).

Recruitment and Informed Consent. The proposed study will utilize recruitment strategies that were found to be effective during formative work and are described in the research plan. Participants will be recruited actively via clinicians at obstetric clinics. An informational flyer will be shared with all potentially eligible women and women will sign-up during check-out if they are interested in the program. Program staff will contact interested women and ask pre-screening questions to assess eligibility. Participants will also be recruited passively via informational flyers; these flyers will contain research team contact information and will be displayed in public spaces at clinics and in community settings and on listservs/internet sites. Potential participants can email or call a member of the research team to learn more about the study and participate. We are confident that we will be able to recruit the necessary sample to conduct the proposed work based on our working relationship with local clinics. All eligible participants will need to sign a HIPPA waiver with the doctor to enable medical information to be released to the study team as well as a waiver stating that they are cleared for physical activity. All eligible participants will be asked to complete a consent form and baseline survey (comprised of all T1 tools mentioned above) remotely. Once this is completed, participants will receive a Fitbit and a scale and complete the 7-day Fitbit assessment period. They will take their weight (three times) one day during this period and send an email or text to the Study Coordinator. The consent form describes the purpose of the study, criteria for participation, confidentiality measures, incentive details, and contact information for the principal investigator. Contact information will be stored separately from the surveys such that it could not be linked to survey responses. Upon completion of the baseline survey (T1) and the 7-day Fitbit assessment period, participants will be randomly assigned to either the intervention (MBMM+ program) or control arm (i.e. health education program) using computer generated numbers and assigned from a pre-generated table.

Inclusion criteria – The population of interest includes English-speaking, pregnant (<13 weeks gestation; or 13-16 weeks gestation and has gained less than 10 lbs in total for women of normal pre-pregnancy weight or less than 5 lbs for overweight/obese) primiparous women, aged 18-46 years, reside in Denver, CO and have medical clearance to exercise during pregnancy. Exclusion criteria include multiparous and having conditions that preclude them from exercising (i.e. HCP has restricted patient from engaging in exercise according to AGOG's absolute contraindications to exercise (e.g. haemodynamically significant heart disease, restrictive lung disease, incompetent cervix/cerclage, persistent second or third trimester bleeding, placenta previa after 26 weeks gestation, premature labor during the current pregnancy, ruptured membranes, and pregnancy induced hypertension).

Protection Against Risk. Every effort will be made to ensure the protection of participants against risk. First, participation is voluntary and participants may refuse to participate or withdraw from the study at any time. Second, participants do not waive any legal rights by consenting to the study. Third, the Principal Investigator and program manager will be

available to participants throughout the study to answer any questions or concerns they may have. All information collected from participants will be kept strictly confidential in accordance with the study protocol and protected within the limits of the law. Any identifying data will be destroyed at the end of the study. De-identified information learned from the study could be used in reports, presentations, and publications but no participant will be personally identified. Risks pertain to psychological discomfort related to completing questionnaires on mood. Additional risk pertains to discomforts pregnant women may experience while engaging in physical activity during the intervention and control arms of the study such as mild muscle soreness with a small possible risk of injury to muscles, ligaments, and tendons of the body. To minimize these risks, the study staff has extensive expertise in designing physical activity programs for pregnant women and will closely monitor all activity sessions to reduce this risk. Also, study staff who will be working with the participants in the intervention will be knowledgeable about basic First Aid. A Data Safety Monitoring Plan (DSMP) will also be in place to ensure the safety of all participants. The DSMP will include a Data Safety Monitoring Board (DSMB) and comprise the following specialties: obstetrics, exercise physiology, psychology and biostatistics and will meet periodically to review any adverse events, data, and procedures. Please see DSMP for details.
In order to minimize psychological risk of harm, we will include detailed information about possible risks in the informed consent form and process, which illustrates the most sensitive types of questions about which subjects will be asked. Participants will also be instructed that they are free to not answer any questions they do not wish to answer on the questionnaires. All participants will also receive information on local mental health resources upon completion of each assessment. This resource sheet has types of clinical care offered on sliding fee basis as well as free access to various hotlines and community resources.

Participants who experience miscarriage will be withdrawn from the study. During the study, results on clinical measures may be shared with health care providers to ensure participant safety. This will be explained in the informed consent form. Finally, with respect to potential physical risks to an embryo or fetus, all participants will be informed that "This study may include risks to an embryo or fetus that are currently unforeseeable." The Data Safety Monitoring Board will monitor delivery and birth outcome data. Please see below for more information on the DSMP.

If it is discovered that a participant is engaging in behavior which endangers her infant in any way, or if there is evidence that any participant is a victim of domestic violence, this will be brought to the attention of her healthcare provider who may need to contact legal authorities. Any suspicion of child abuse arising from information collected in this study will result in study staff immediately notifying authorities.

Potential Benefits

Pregnant women in the MBMM+ intervention may have improved health from increased levels of physical activity, improved mood and sleep hygiene and weight management.

Participants in the control arm (health education group) may experience enhanced knowledge related to pregnancy and child health topics.

Importance of Knowledge to be Gained

The MBMM+ program is designed to enhance participants' knowledge, confidence, and support to increase their likelihood of engaging in regular physical activity to ultimately reduce the likelihood of excessive gestation weight gain. Given the beneficial effects of physical activity on many maternal and child outcomes, there is a definite need to promote engagement in regular prenatal physical activity. Moreover, given the detrimental effect of excessive gestational weight gain (EGWG) there is a critical need to develop and test interventions aimed at reducing EGWG.

E. Potential Scientific Problems:

Throughout the course of this study, we will provide for protection of human subjects. All protocols will be submitted for review and approval to the Colorado Multiple Institution Review Board (COMIRB). All personal data will be kept secure with personal identifiers and study identification numbers maintained in separate, secure, databases. Only the PI and Co-Is will have access. The proposed study is designed to women and overall, the findings of this study may potentially impact the health and wellbeing of women and children.

We have also designed the assessment procedures to minimize burden on participants. . Participants will be compensated $30 per survey completion (T1and T3; $60 total/participant). Participants will also receive tickets for a random drawing and chance to receive free diapers for their participation in T2 data collection. Pregnant participants in the MBMM+ intervention group will also receive a yoga mat and pedometer, and both control and intervention groups will receive drawings for free diapers. These types of incentives and amounts are consistent with our other studies at UCH. In addition to the yoga mat and pedometer, the intervention group participants will have the opportunity to keep a Fitbit. If participants attend all sessions 8-16, they will get to keep a Fitbit at the end of the program following post-data collection. If participants in the intervention program attend all but two sessions from sessions 8-16, they will be entered into a raffle for a Fitbit to keep at the end of the program following post-data collection.

F. Data Analysis Plan:

We will use latent growth curve models to separately examine intervention effects on 1) moderate-intensity exercise assessed by the Fitbit and 2) EGWG. These models will then be expanded to examine secondary outcomes (e.g., physical activity, mood, sleep quality, delivery outcomes) and mediators (e.g., exercise self-efficacy, social support, and behavioral skills). For all models, we will control for patient age, ethnicity, parity, risk status, and SES. Primary analyses will be conducted as intent-to-treat, although exploratory as-treated analyses may also be used. Analyses will be conducted primarily using SAS Version 9.2 and Mplus Version 6.0. In closing, the study's proposed approach

is scientifically sound using a tight, randomized controlled trial framework to reduce study bias and increase likelihood of reproducibility.

G. Summarize Knowledge to be Gained:

This is an important and fundamental study that needs to be conducted to meet the need for effective, sustainable community-based interventions to reduce EGWG. Because pregnancy is an opportune time to adopt healthy behaviors such as physical activity, there is a definite need for intervention at this time. The MBMM+ intervention has been designed based on feedback from pregnant women from recent formative and pilot work to develop an intervention that is attractive and unique to this population. The intervention includes a strong social support component as our formative work and extant literature clearly demonstrate lower levels of attrition in interventions providing social support. Moreover, the addition of the small group interaction after each session will provide further opportunity to build rapport and strengthen interpersonal support and a sense of group membership. Third, self-regulation techniques that support maintenance of physical activity and its interrelatedness of mood and sleep will be used. All of these supports can show successful community-based interventions to reduce EGWG.