Official Title:	Healthy Lifestyle Intervention for High-Risk Minority Pregnant Women: A RCT
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Aims:

Specific Aim 1. Use a RCT to evaluate the short- and more long-term efficacy of the COPE-P program to improve healthy lifestyle behaviors (nutrition and exercise), psychosocial health, and birth and post-natal outcomes in pregnant emotionally distressed minority women as compared to an attention control group.

Hypotheses 1a (primary outcomes). Immediately after the COPE-P program, at 4-6 weeks postpartum (3 months post intervention), and at 6 months postpartum (8 months post intervention), COPE-P participants will report higher healthy lifestyle behaviors, and less anxiety, stress and depressive symptoms than will the attention control participants.

Hypothesis 1b (secondary outcomes). COPE-P participants will demonstrate more appropriate pregnancy weight gain, better birth outcomes (mode of delivery, birth weight, and gestational age), more appropriate postpartum weight loss, and better breastfeeding outcomes than attention control participants.

Specific Aim 2. Examine the role of cognitive beliefs and perceived difficulty in leading a healthy lifestyle in mediating the effects of the COPE-P program on healthy lifestyle behaviors and psychological symptoms in minority pregnant women.

Hypothesis 2 (theory building exploratory). The effects of the COPE-P program on participants' healthy lifestyle behaviors and levels of anxiety, stress and depressive symptoms will be mediated by beliefs about their ability to make healthy lifestyles choices and their perceived difficulty in leading a healthy lifestyle.

Exploratory Aim. Explore characteristics that may moderate healthy lifestyle behaviors, psychosocial health, and birth and post-natal outcomes (e.g., race/ethnicity, income, age, parity, language, level of education, marital status).

Research Question: What is the short and long-term effect of the COPE-P program in high-risk pregnant minority women receiving prenatal care on healthy lifestyle behaviors (nutrition and exercise), psychosocial health (healthy lifestyle beliefs, healthy lifestyle behaviors, anxiety, stress and depression), and birth and post-natal outcomes (gestational age at birth, gender, birth weight, birth length, overall health, mode of delivery, breastfeeding (initiation and duration) versus an attention control group (PregnancyPlus group).

Overview of the design. The study conducted will be a longitudinal randomized block RCT with repeated measures (beginning with screening prior to 19 weeks, group prenatal care in both groups (COPE-P intervention group and PregnancyPlus attention control group) from 16 $\pm$ 2 to 31 $\pm$ 2 weeks and ending at 6 months postpartum). We will block on race/ethnicity to ensure equal numbers of Hispanic and Black women in the COPE-P and PregnancyPlus groups. There will be a total of 30 groups over the course of the study. There will be 22 English speaking groups and 8 Spanish-speaking groups. We will consent and screen up to 700 women, knowing that approximately half will screen out. In order to achieve our target of 182 Black or Hispanic women who complete the study, and accounting for a 30% attrition rate, we will enroll up to 236 women who screen in at Jacobi Medical Center. Four groups (of at least six women per group) will run in each 18-week time segment (COPE-P intervention is six sessions each three weeks apart). The PregnancyPlus group also will have six group prenatal care sessions each three weeks apart. Each session is 1 hour and 30 minutes to 1 hour and 45 minutes in length. Each group within the 18-week time segment will be randomly assigned (using a sealed envelope technique) as either a COPE-P or PregnancyPlus group. At Jacobi Medical Center in Bronx, NY, for each 18-week time segment, there will be two control groups and two intervention groups. The intervention and attention control groups programming will be delivered in Group Prenatal Care methodology which begins in the second trimester consisting of at least 6 women per group. Participants (18 – 40 years) will be screened prior to their 19th week of pregnancy and recruited into the study from the antepartum clinic.

If a participant does not screen into the study, she will be thanked for her time and interest and paid $10.00 for her participation in the screening process.

If a woman does screen into the study, she will provide further baseline data at this point. In addition to the screening tools, baseline data will include: demographic and personal information, weight from clinic scale, a 24 hour diet recall, the Healthy Lifestyle Beliefs Scale and the Healthy Lifestyle Behaviors Scale. A participant will then be assigned to the next available group based on fetal gestational age (groups having been scheduled and previously randomized as intervention or control as described above). In the event that group prenatal care is not feasible, the group sessions can be conducted as virtual visits (Zoom or Facetime etc.) or content can be provided in a 1:1 patient to provider setting. Participants will then be given an appointment for their first group prenatal care session and a Fitbit Flex 2, instructions on how to immediately begin using the Fitbit (to provide baseline data that will be uploaded at the first group session) and a Fitbit number (for confidentiality) so that they can compare with other pregnant women. All participants will receive $30.00 for at the baseline visit (**T0**).

All women in this study will receive 6 sessions of group prenatal care beginning at 16 weeks gestation (± 2 week) and ending at 31 weeks (± 2 week). At 16 weeks gestation, women receive care every three weeks. The timing of our group prenatal care is designed around prenatal testing to decrease participant burden. We will begin at 16 weeks when all women in care have alpha-fetal protein screening drawn. The second session is at 19 ± 2 week, when women are normally receiving an anatomy sonogram. The third session is 22 ± 2 weeks, which is not associated with any specific prenatal care milestones. The fourth session is 25 ± 2 week is associated with third trimester labs and the glucose tolerance test. The fifth session at 28 weeks ± 2 week and the sixth session at 31 weeks ± 2 week are not associated with specific prenatal care milestones. Therefore, 3 of the 6 sessions have standard prenatal testing associated with them (encouraging attendance).

COPE-P intervention group: The COPE-P intervention group will receive the COPE-P Intervention over the 6 sessions of group prenatal care. Each session lasting for 1 and a half hours.

Session 1 of COPE-P focuses on the thinking, feeling and behaving triangle, and the ABCs (A=Antecedent or Activator event, B=Belief that follows the event, C=Consequence: how you feel and how you behave). The thinking, feeling and behaving triangle and the ABCs are reinforced throughout the program and examples for use are based on peer input.

Session 2 of COPE-P focuses on self-esteem and positive self-talk, including ways to build self-esteem and the group provides examples of how to change unhealthy habits into healthy ones. Signs of poor and healthy self-esteem are discussed. Discussion of healthy eating and active living is integrated throughout Session 2. Nutrition content includes information on reading labels. Skills building activities for Session 2 include changing an unhealthy habit into a positive one.

Session 3 of COPE-P focuses on stress and coping during pregnancy. Physical and emotional responses to stress are discussed along with healthy snacking. Examples of healthy ways to cope with typical stresses are solicited. Signs of depression and anxiety are elicited and the group problem solves positive strategies to deal with depression, anxiety, and stress. This skills building session focuses on recognizing unhealthy ways of coping and examples of how to unhealthy coping into healthy coping strategies.

Session 4 of COPE-P focuses on planning, goal setting and the 4-step problem solving process, including overcoming barriers related to eating. The skills building activity for Session 4 focuses on developing strategies for overcoming barriers and problem solving a current challenge.

Session 5 of COPE-P focuses on dealing with emotions in healthy ways through positive thinking and effective communication. Women practice regulating their emotions along with mental and guided imagery. Positive self-control strategies for emotions and unhealthy eating are explored. The skills building activities in this session focus on practicing mental imagery and monitoring for emotional triggers with a response plan.

Session 6 of COPE-P focuses on coping with stressful situations commonly encountered during pregnancy while continuing to reinforce the thinking, feeling, and behaving triangle. Influences on healthy eating are explored. In skills building activities, women practice positively dealing with challenging situations **PregnancyPlus Attention Control Group:** At each group session, the PregnancyPlus attention control group will receive the prenatal care described under standard care performed by certified nurse midwives. Additionally, each week for six weeks, they will discuss a pamphlet designed for patient education by ACOG. These six pamphlets are: 1) Nutrition during pregnancy 2) Exercise during pregnancy 3) Obesity and pregnancy 4) Exercise after pregnancy 5) Breastfeeding your baby 6) Routine Tests during Pregnancy. At each group prenatal care session, routine obstetric assessment (blood pressure, pulse, weight, BMI, urinalysis for glucose and protein, auscultating fetal heart tones, and uterine size assessment) will be performed. Routine discomforts of pregnancy, smoking cessation, and danger signs of pregnancy will be discussed. Women will return to receiving individualized standard prenatal care at the end of the 6 sessions. Dr. Gennaro will conduct the training of the attention control group midwives and Dr. Melnyk will conduct the training of the intervention group midwives. The same protocol for assessing fidelity will be used for COPE-P and PregnancyPlus.

Different care providers will run the COPE-P and PregnancyPlus groups, assuring that there is no carryover effect of the intervention into the control group.

In addition to baseline assessments, at the end of the 18-week timeframe and at their last group prenatal care session, all women will complete the GAD-7, PSS, EPDS, a 24 hour diet recall, the Healthy Lifestyle Behaviors Scale and the Healthy Lifestyle Beliefs Scale. Fitbit data and weight also will be obtained. In the intervention group, participants also will complete the COPE-P evaluation. This data will be **T1**, and will be collected at approximately 31 weeks gestational age. For women who miss this visit, data will be collected at the next scheduled prenatal visit. Participants will be compensated $30 for their study participation.

Three months after the intervention (approximately 4-6 weeks postpartum - **T2**), all women will be contacted and will once again complete all measures, as well as an infant data form, at the routine postpartum visit. Participants will receive $40.00 for their participation.

At eight months post intervention (**T3** - six months postpartum at the six-month well baby visit), all women will once again be contacted and complete all measures (including weights taken on available pediatric clinic adult scales –same model as prenatal scales). Participants will receive $50.00 for their participation. Outcome data from charts will be collected by team members blind to group assignment.

If study visits cannot be conducted face-to-face, data will be collected through telehealth methods such as via phone or video call (Zoom or Facetime etc.).

Sampling. Women will be recruited from the antenatal clinic if they are: between 18 and 40 years old, in their first trimester with an uncomplicated singleton pregnancy of less than 19 weeks, and self-identify as either Black or Hispanic and can read and speak English or Spanish. A completed sample size of 182 Black and Hispanic women from JMC in the Bronx and 182 Black and Hispanic women from OSU Total Health and Wellness clinics will be required to meet the determined sample size of 364 total (at 4 data collection points for each, resulting in ~1,450 observations). This will have greater than 80% power to detect small to moderate effects (i.e. 25 or greater) between group differences in healthy lifestyle behaviors, psychosocial health, and outcomes testing at alpha = .05 for all proposed models. The sample of 364 will have > .80 to detect a small to medium mediated effect. The sample of 364 will have > .80 to detect a small to medium mediated effect.

Setting. Jacobi Medical Center is part of New York City Health + Hospitals (NYC H + H), the largest municipal hospital system in the United States. New York City Health + Hospitals oversees the public health care system in all the five boroughs that comprise New York City. It provides one-fifth of the total number of discharges and more than one-third of the emergency services and hospital-based clinic visits in all of New York City. Jacobi Medical Center is an academic affiliate of the Albert Einstein College of Medicine. Jacobi Medical Center is located in the Bronx. As one of the largest health care delivery facilities in the Bronx and in New York City, Jacobi Medical Center has developed a world- wide reputation of distinction. It is renowned for its primacy in

the delivery of emergency and trauma services, has developed an image of excellence as a provider of choice subspecialty care, and is widely recognized for its devotion to the health care needs of the large and diverse community it serves. The Bronx population represents a wide range of racial and ethnic diversity with 43.4% of the population being African-American and 55% of the population being Hispanic, adding up to more than 100% as Hispanics may be of any race and are also included in the applicable race category by the U.S. Census Bureau (2015). Jacobi Medical Center is an urban medical center, which serves a population of 1.3 million. The Obstetrics Division serves the region as demonstrated by over 12,000 clinic visits as well as approximately 2,000-plus hospital discharges per year. There were 1960 live births at Jacobi Medical Center during 2015 with 1373 of these births to Black and Hispanic women.

Obstetrical care is provided by 22 licensed midwives at Jacobi Medical Center as well as by over 40 obstetricians. There are adequate numbers of bilingual licensed midwives to work with Co-Investigator Anne Gibeau, PhD, CNM, RN to provide group prenatal care. There is an excellent working relationship between obstetrical and pediatric care providers and both obstetrical and pediatric care providers are interested and supportive of this study.

Jacobi Medical Center offers a number of other resources to its obstetrical patients receiving care in the Women's Health Practice. There are two Women's Health Patient Educators, who provide a weekly class series, with a new curriculum each month covering topics like childbirth education, infant safety and postpartum care. Women are encouraged to attend all of them starting in the 7th month of pregnancy. The Midwifery staff offer monthly Childbirth Education classes. There are two full-time IBCLC-certified Lactation Consultants available to patients in both the group and individual setting to assist with the initiation and continuation of breastfeeding. Jacobi has a specialized Adolescent Obstetric Practice to meet the needs of young mothers-to-be and Family Planning Services. Pregnant women and new mothers, who meet income eligibility criteria, are assessed by a healthcare professional for WIC eligibility which would provide them access to nutrition advice, breastfeeding support, nutritious food, and other services.

The Research Center of the NBHN is located at Jacobi Medical Center and has demonstrated its proficiency in sound, meticulous, efficient and ethical clinical investigation. Presently running more than 40 protocols funded by the National Institutes of Health, numerous private foundations, and many industry and trade organizations, including the largest Pediatric HIV clinical trial group in the country, the Center meets its mission of finding new and better ways to help patients through world-class clinical research and will provide support for this current application. The Center is presently conducting investigations by more than 30 researchers representing every clinical specialty area offered by the NBHN Network. It employs two full time regulatory affairs managers who maintain strict adherence to the most stringent submission requirements and deadlines, and twelve full-time Research Coordinators. A unique arrangement with two approved Investigational Review Boards facilitates the review and approval process. A research coordinator with experience in obstetrical research and the ability to speak Spanish will be hired to participate in data collection.

Inclusion and Exclusion Criteria:
Women will be recruited from the antenatal clinic if they are:

Inclusion criteria.
- Between 18 and 40 years old
- In their first trimester with an uncomplicated singleton pregnancy of less than 19 weeks
- Self-identify as either Black or Hispanic
- Speak and read English or Spanish

Exclusion criteria
Women will be excluded if they have:
- Chronic medical conditions (e.g., hypertension, or diabetes)
- Currently receiving treatment or therapy for a psychiatric diagnosis

- Have participated in this study with a prior pregnancy
- Obstetrical complications, such as preeclampsia, gestational diabetes, or fetal abnormalities
- Do not speak and read English or Spanish

Recruitment. Research team members will approach women in the antenatal clinic who may be eligible for the study based on their chronological age and fetal gestational age and verbally explain the study. Gestational age is based on the ultrasound dating or last menstrual period when ultrasound is not available. If a woman self identifies as Black or Hispanic, a participant informed consent form will be provided and consent obtained. A copy of the participant informed consent form will be given to the participant. She will then be screened for study eligibility.

Measures

General Anxiety Scale (GAD-7): is a 7-item, 4-point Likert-type scale ranging from (0) Not at all to (3) Everyday, that assesses the participants' level of anxiety over the last 2 weeks. Scores range from 0 to 21, with higher scores indicating greater functional impairment related to the patient's experience of anxiety. The scale's reliability and validity have been tested across clinical care settings. It has been found useful in monitoring symptom severity and changes across time. Brevity of the GAD-7, (it can be completed in 5 minutes or less) helps to minimize patient burden. In our COPE-P pilot work, the Cronbach's alpha was .89.

Perceived Stress Scale (PSS): is a widely used, standardized measure of global stress designed to elicit the degree to which respondents find their lives unpredictable, uncontrollable, and overloading (three central components of stress). Concurrent and predictive validity were supported by comparing the PSS with depression scores and life-event scales in college samples. The PSS has demonstrated internal consistency reliability of .84 to .86 with young adult populations and .80 with pregnant minority women and takes about 5 minutes to complete. Cronbach's alpha in the COPE-P pilot was .80.

The Edinburgh Postnatal Depression Scale (EPDS)**:** is a 10 item self-report perinatal depression questionnaire. The scale asks participants to describe how they have felt in the previous week. Unlike other depression screening tools, the EPDS excludes questions regarding somatic symptoms of pregnancy and has been found to be equivalent to a structured interview in determining prevalence of depression. Scores range from 0-30 with higher scores signifying higher severity of depressive symptoms. ACOG supports the EPDS as a depression screening tool in pregnant women because of its brevity, readability and scoring ease. As will be indicated in participant informed consent forms, if a woman answers item 10 (self-harm) with a 1,2, or 3 she will be accompanied to a mental health provider for immediate care. Women with high scores will be referred to their primary care provider and we will monitor to assure follow up. The EPDS takes 5 minutes to complete.

24 Hour Adult Nutrition Log: Nutrition will be examined by conducting a 24 hour diet recall for each participant at each data point. Food models and pictures will be used to accurately identify portion sizes and participants will be asked brand names of food. The target day for the diet recall will be 24 hours in advance of the data visit. Information from the diet histories will be analyzed using the Food Processor database that contains over 2400 foods. Nutrient values are in accord with information provided by the United States Department of Agriculture and over 550 other research sources. Fast foods are included as are over 1182 convenience food items. he database is updated annually.

Healthy Lifestyle Beliefs Scale: The HLBS is a 16-item scale adapted from other belief scales used by Co-PI Melnyk in prior studies and takes 5 minutes to complete. This scale taps beliefs about various facets of maintaining a healthy lifestyle (e.g., "I believe that I can be more active" and "I am sure that I will do what is best to lead a healthy life"). Subjects respond to each item on a five point Likert-type scale that ranging from 1 strongly disagree to 5 strongly agree. Construct validity of the scale has been supported through factor analysis with over 1000 young adults. Cronbach's alpha from the COPE-P pilot was .91.

Healthy Lifestyle Behaviors Scale: Healthy lifestyle behaviors will be measured with the Healthy Lifestyle Behaviors Scale developed for use in multiple prior studies. Subjects respond to each of the 15 items (e.g., I exercised regularly; I talked about my worries) on a 5-point Likert-type scale that ranges from 1 strongly disagree to 5 strongly agree. Construct validity has been supported through factor analysis from data obtained in our prior work. Cronbach's alpha in the COPE-P pilot was .86 and took 5 minutes to complete.

Exercise: During pregnancy, spring loaded pedometers have been found to be inaccurate due, to the pedometer being tilted away from the vertical plane such that the spring suspended lever arm does not register

all steps. This is particularly true for overweight or obese pregnant women so an accelerometer measure of step counts is much more accurate. However, accelerometer type measures of physical activity may over count steps especially when participants are involved in motor vehicle traffic and most especially on bumpy roads. Devices, such as the Fitbit Flex 2, combine accelerometer and pedometer features to improve accuracy and have the advantage of being worn on the wrist like a bracelet so women are less likely to forget to use it, a common problem with devices that necessitate being affixed to clothing.

Birth and Post-Natal Outcome Data: will be abstracted from clinic charts by team members blinded to treatment group and from the Demographic and Personal Information Form (DPI) completed at T0-T3.

COPE-P Acceptability: Measures acceptability in 5 minutes at a 6th-grade reading level.

Group Prenatal Care Acceptability: The Group Prenatal Care Acceptability asks participants to describe aspects of their Group Prenatal Care experience on a scale of 1-5 and if they found it helpful. It takes 3-5 minutes to complete.

COPE-P/PregnancyPlus Program Evaluation: The Program Evaluation will collect open-ended responses from participants evaluating their experience with the COPE-P and the PregnancyPlus program. The survey will take approximately 5-7 minutes to complete.

Table 1. Study Variables, Measures and Timing

Variables	Measures	Timing
Demographic Characteristics Age, Height Education Level, Relationship Status, Race/Ethnicity, Language Spoken, Income, Parity, Medications, Mental Health Referral/Rx post screening	Demographic and Personal Information (DPI) Form	**T0** =Baseline (screening visit) **T1** = 31 weeks **T2=** 6-8 weeks postpartum visit **T3**=6 months well baby visit
Healthy Lifestyle Behaviors	Healthy Lifestyle Behaviors Scale[132]	T0, T1, T2, T3
Healthy Lifestyle Beliefs	Healthy Lifestyle Beliefs Scale[141]	T0, T1, T2, T3
Nutrition	24 Hour Nutrition Log/Food Processor	T0, T1, T2, T3
Weight Gain/Loss, BMI	Scale	T0, T1, T2, T3
Exercise	Steps Fitbit Flex 2 Accelerometer	T0 (given at screening T1, T2, T3)
Psychosocial Health		
Anxiety	GAD7	T0, T1, T2, T3
Depressive Symptoms	EPDS	T0, T1, T2, T3
Perceived Stress	PSS	T0, T1, T2, T3
Birth and Post-Natal Outcomes	Infant Data Form	
Gestational Age at birth, Gender	Chart review	Post delivery
Birth Weight, Birth Length, Overall Health	Chart review	Post delivery
Mode of Delivery (C/S, Vaginal, Forceps/Vacuum)	Chart review	Post delivery
Breastfeeding (initiation and duration)	DPI Form	T2, T3
COPE-P Acceptability	Index (COPE-P group)	T1 and T2
Group Prenatal Care Acceptability	Group Prenatal Care Acceptability	T1
Program Experience	COPE-P/PregnancyPlus Program Evaluation	T1 and T3

Procedure.

After meeting inclusion criteria for the study, she will be given screening tools (General Anxiety Scale – GAD-7, Perceived Stress Scale – PSS, and the Edinburgh Postnatal Depression Scale – EPDS) to determine study participation.

If a potential participant scores:

- Greater than or equal to 10 on the General Anxiety Disorder 7-item scale (GAD-7)
- Or greater than or equal to 20 on the Perceived Stress Scale (PSS)
- Or a cut-off score of 10 on the Edinburgh Postnatal Depression Scale (EPDS)

They will be eligible to participate in the study. For the GAD-7 a score of $\geq$ to 10 indicates moderate anxiety and maximizes sensitivity and specificity, for the PSS, a score of 20 or greater is the high-stress cut-off and a cut-off score of 10 on the EPDS is suggested to indicate moderate depressive symptoms in pregnant women.

If a **participant does not screen** into the study, she will be thanked for her time and interest and paid $10.00 for her participation in the screening process.

If a **participant does screen into the study**, she will provide further baseline data at this point which includes: demographic and personal information, weight from clinic scale, a 24 hour diet recall, the Healthy Lifestyle Beliefs Scale and the Healthy Lifestyle Behaviors Scale.

A participant will then be assigned to the next available group based on fetal gestational age (groups having been scheduled and previously randomized as intervention or control as described above). Participants will then be given an appointment for their first group prenatal care session and a Fitbit Flex 2, with instructions on how to immediately begin using the Fitbit (to provide baseline data that will be uploaded at the first group session) and a Fitbit number (for confidentiality) so that they can compare with other pregnant women. All participants will receive $30.00 for at the baseline visit, **T0.**

All women in this study will receive 6 sessions of group prenatal care beginning at 16 weeks gestation (± 2 week) and ending at 31 weeks (± 2 week) according to previously described randomization into COPE-P intervention group or PregnancyPlus attention control group. In the event that group prenatal care is not feasible, the group sessions can be conducted as virtual visits (using programs such as Zoom, WebEx, Facetime etc.) or content can be provided in a 1:1 patient to provider setting. Different care providers will deliver the COPE-P and PregnancyPlus content, assuring that there is no carryover effect of the intervention into the control group. Dr. Gennaro will conduct the training of the attention control group midwives and Dr. Melnyk will conduct the training of the intervention group midwives. The same protocol for assessing fidelity will be used for COPE-P and PregnancyPlus. Dr. Melnyk will train the research team to assess fidelity of the intervention with the intervention fidelity checklist. Fidelity will be assessed by having research team members observe 2 of the 6 sessions for each intervention group. Inter-rater reliability of 90% will be established and observer drift monitored and corrected throughout the trial. Feedback will be provided immediately after the session to interventionists if they are not adhering to the intervention as intended to be delivered.

At the end of the 18-week timeframe and at their last group prenatal care session, all women will complete the GAD-7, PSS, EPDS, a 24 hour diet recall, the Healthy Lifestyle Behaviors Scale and the Healthy Lifestyle Beliefs Scale. Fitbit data and weight also will be obtained. In the intervention group, participants also will complete the COPE-P evaluation. This data will be **T1**, and will be collected at approximately 31 weeks gestational age. For women who miss this visit, data will be collected at the next scheduled prenatal visit. Participants will be compensated $30 for their study participation.

Data collection at the 3 month post intervention follow up visit, **T2**, will occur at the normally scheduled 4-6 weeks regular postpartum visit. Participants will be compensated $40 for their study participation at this visit. All measures will be collected.

The 8 month post-intervention visit, **T3**, will be the final data collection point and will occur at a routinely scheduled 6 month well baby visit. Participants will receive $50 for their participation. All measures will be collected.

A research team member will administer the post-intervention follow-up study questionnaires for each data collection point (T0 – T3). It will be noted how many sessions were completed by the participant. Outcome data from charts will be collected by team members blind to group assignment.

Analysis plan.

Data management: Survey data will be obtained using paper and pencil surveys and at each site all surveys will be scanned using Remark software to ensure accuracy and avoid the necessity of double data entry. Fitbit data will be uploaded using Bluetooth technology at each data point (with T0 baseline data being collected between screening and the first group prenatal care session) and entered into an Excel database. Data from the 24 hour diet recalls will be manually entered at each site into Food Processor and then exported into an Excel file for data analyses. At each visit, weights will be recorded. Obstetrical chart data will be extracted at each site. Dr. Szalacha will merge the Ohio and New York data files, perform data cleaning, construct analytic variables, assess psychometrics and conduct both interim and final analyses.

Data Analysis: Preliminary analyses: Statistical analyses of these data must not only demonstrate the efficacy

of the COPE-P intervention, but also map the trajectories of group differences over time, and identify subgroup differences. Analysis will begin with characterization of the sample with descriptive statistics that identify differences between the COPE-P and PregnancyPlus groups 1) evident at baseline, despite randomization and 2) between groups due to differential attrition. Data will be screened for normality, outliers, and homogeneity. Appropriate nonparametric analyses will be considered in situations of irresolvable heterogeneity. We will evaluate the psychometric qualities (reliability, convergent and discriminant validity) of the scales, employing both exploratory factor analyses and SEM measurement models. Descriptive statistics will be used to summarize the sample characteristics and distribution of each variable. Missing Data. All data analyses will be completed as intention to treat analyses (i.e., individuals analyzed by group according to original random assignment, without regard to adherence to the intervention). Missing data will be imputed, when appropriate, using multiple imputation in SAS v9.4 PROC MI.

Hypothesis-driven analyses. Various bivariate tests (e.g., independent and dependent t-tests, correlations, ANCOVA and repeated measures analyses of covariance) will be used to evaluate differences and longitudinal patterns of change across time and between relevant subgroups (e.g., intervention groups, language groups) for each significant outcome in the preliminary bivariate analyses, (primary outcomes are healthy lifestyle behaviors, anxiety, stress, and depressive symptoms). For secondary outcomes (appropriate weight gain during pregnancy, birth and post-natal outcomes (e.g., mode of delivery, birth weight/length, gestational age, postpartum weight loss and breastfeeding practices) we will fit a series of longitudinal multilevel growth models to the data.

For all continuous outcomes, such as anxiety, the basic model, to which we can add our controls and predictors. The level 1 submodel estimates how each participant's anxiety changes over the four data collection periods. The level 2 submodel will relate the inter-individual differences to intervention group and other time-invariant predictors and controls, such as medication (i.e., antidepressants) and have begun therapy (i.e., in usual care for mental health diagnoses), and will estimate a participant's initial anxiety level and rate of change in anxiety. Anxiety will be modeled in terms of random subject effects (intercept and time trends) to account for individual differences in how participants change over time. We will begin with a linear model for time but will investigate nonlinear effects as suggested by the data. Subsequent models will contain time-varying covariates (i.e., dose of intervention, weight, exercise) and thus will focus on within-participants effects, that is, whether within-participant differences in the covariates are associated with within-participant differences in anxiety. We will examine the potential of cognitive beliefs and perceived difficulty in leading a healthy lifestyle in mediating the effects of the COPE-P program on healthy lifestyle behaviors and psychological symptoms. Rather than detecting mediated effects with the causal steps approach of Baron and Kenny, we will use the Joint Significance Test established by MacKinnon, which assesses the statistical significance of the X to M relation, α path, and then the M to Y relation, β path. If both are statistically significant, there is evidence of mediation. Models with more than one mediator are simply extensions of the single-mediator case. In our multilevel models, we will investigate mediation effects within the different levels of analysis and across levels. Finally, we will explore characteristics that may moderate healthy lifestyle behaviors, psychosocial health, and birth outcomes (e.g., race/ethnicity, age, parity, language spoken, level of education, income, marital status) in the above models. The proposed examination of mediators and moderators should allow for increased understanding of mechanisms underlying any intervention effect and different responses among the participants. The most appropriate covariance structure for the residuals εij will be determined after data collection and the correlation of responses over time is estimated. Several covariance structures will be examined and the resulting models compared for fit using the quasi-likelihood independence model information criterion (QIC) fit using SAS 9.4 (Proc MIXED).

Should any of the outcomes need to be dichotomized (i.e., present vs. absent), we will fit a multi-level random effects logistic regression models with time-varying covariates. The basic model, to which we will add our controls and predictors, can be written: where i indexes participants, t indexes time, COPE-P is an indicator of the intervention group, COPE-P x Time is the intervention by time interaction, Xk is a set of time-varying covariates measured for each participant I at time t and ui is participant-specific error term. The interaction term COPE-P x Time is the test of the effectiveness of the COPE-P program. If successful, the regression coefficient will be negative, indicating that the modeled probability of psychological symptoms declined more

rapidly with time in the COPE-P group than they did in the PregnancyPlus group. We will fit these models using SAS 9.4 (Proc NLMIXED).