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 16 weeks, group prenatal care in both groups (COPE-P intervention group and PregnancyPlus attention control group) from 16 $\pm$ 2 weeks 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. Four groups (of at least three 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 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 OSU Total Health and Wellness clinic, for each 18-week time segment, there will be two control groups and two intervention groups. Recruitment at the OSUWMC OB/GYN Clinic is expected to be similar. 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 3 women per group. Participants (18 – 40 years) and will be screened prior to their 16th week of pregnancy and recruited into the study from the antepartum clinics or by contacting research personnel.

If a participant does not screen into the study, she will be thanked for her time and interest and paid a $10.00 gift card 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. If a woman screens into the study, she will not have to repeat the screening tools that were administered to qualify for the study (GAD-7, PSS, EPDS). 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, 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 a $30.00 gift card 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 weeks) 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 weeks, 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 weeks is associated with third trimester labs and the glucose tolerance test. The fifth session at 28 weeks ± 2 weeks and the sixth session at 31 weeks ± 2 weeks 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 hour 45 minutes.

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, breastfeeding, 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

If a woman misses a session, it will be made up one on one. This will be rescheduled at her next visit.

PregnancyPlus Attention Control Group: At each group session, the PregnancyPlus attention control group will receive the prenatal care described under standard care performed by advanced practice registered nurses. 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) Postpartum depression. 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 advanced practice registered nurses and Dr. Melnyk will conduct the training of the intervention group advanced

practice registered nurses. 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. Fitbit data will be collected at each study visit from all participants. COPE-P participants will be asked about use of COPE-P workbook and exercise goals at each intervention session.
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, Healthy Lifestyle Beliefs Scale, and the Group Prenatal Care Acceptability Form. Weight also will be obtained. Both groups will complete program evaluations. In the intervention group, participants will complete the COPE-P Acceptability Form and the COPE-P Program Evaluation. In the attention control group, participants will complete the PregnancyPlus Program 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 with a $30 gift card 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, with the exception of the COPE-P and PregnancyPlus Program Evaluations, at the routine postpartum visit. Participants will receive a $40.00 gift card 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, and COPE-P and PregnancyPlus Program Evaluations). Participants will receive a $50.00 gift card for their participation.
Participants will be sent appointment reminders using their preferred contact method, email or text message, prior to study visits.
Outcome data from charts will be collected by team members blind to group assignment.

In the interest of participant safety during the COVID-19 pandemic, group sessions and timepoint visits may by conducted remotely. Prenatal care will be completed per clinic and provider recommendations for telehealth or in-person visits. Group sessions will take place via CarmenZoom or similar approved OSU platform. Participants will be provided with login information in advance of the session. Efforts will be made to sync Fitbits at in-person prenatal care visits. Study timepoints may also be completed remotely. Gift cards will be provided at scheduled in-person clinic visits, by mail, or by email.

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Sampling. Women will be recruited from the antenatal clinics if they are: between 18 and 40 years old, with an uncomplicated singleton pregnancy of less than 19 weeks and self-identify as either Black or Hispanic and can read and speak English. A 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 and OSUWMC OB/GYN Clinic 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. In order to retain an analytic sample size of 364 and account for an anticipated 30% attrition rate, per initial grant submission, target enrollment is 500 eligible participants.

The Ohio State University Total Health and Wellness Clinic (THWC)
This clinic is a public entity model nurse-managed health center that has been in operation since January 2013. The health center provides primary care that is integrated with behavioral health services and the area served is urban and comprises most of the East and Near East sections of Columbus. Much of the service area is underserved as designated by HRSA. The population in the service area has a higher proportion of Black/African American residents (49.3%) and a somewhat higher proportion of Hispanic (6%) residents than Franklin County (21% and 4.9% respectively). CDC Statistics indicate that in Ohio the percentage of births to women who did not receive prenatal care in the first trimester of their pregnancies was 25.2% and in the service area 30.8% did not receive timely care, a rate almost half again the Healthy People target of 22.1%.

This may help to explain the fact that data indicates that, compared to state rates of 8.5% and 7.6 per 1,000 and the Healthy People targets of 7.8% and 6.0/1,000, 10.6% of babies in the service area were born at a low birth weight and the infant mortality rate was 10.2 per 1,000 live births. The interprofessional and team service model is the integration of primary care, behavioral health care, and prenatal clinic. From its inception, the OSU THW has had both family practice primary care NPs, a psychiatric NP funded by the Wexner Medical Center, a LCSW who serves part-time as a mental health counselor and part-time doing case management, and two nurse midwives.

The Ohio State University Wexner Medical Center OB/GYN Clinic (OSUWMC OB/GYN)
This well-established hospital-based ambulatory clinic provides a combination of advanced practice registered nurse and physician care at The Ohio State University Wexner Medical Center, including obstetrics and gynecology resident training. The clinic provides obstetric and gynecologic care that is integrated with social work to residents of Columbus, Ohio, and the surrounding area. Approximately 78% of patient visits are utilize publicly funded or subsidized insurance. The population in the service area has a higher proportion of Black/African American residents (45%) and a somewhat higher proportion of Hispanic residents than Franklin County. The clinic provides comprehensive obstetric & gynecologic care, including ultrasound, with access to multiple specialties.

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

- Between 18 and 40 years old
- An uncomplicated singleton pregnancy of less than 19 weeks (based on ultrasound or last menstrual period when ultrasound is not available)
- Self-identify as either Black or Hispanic
- Speak and read English as there are not enough Spanish-speaking women to warrant conducting groups in Spanish.
- Eligible for APRN care per clinic guidelines

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
- An answer of 2 or 3 on item 10 on the EPDS scale
- Have participated in this study with a prior pregnancy
- Obstetrical complications, such as preeclampsia, gestational diabetes, or fetal abnormalities (women who have a history of pre-term birth will still be allowed to participate)
- Do not speak and read English
- Participation in Moms2B support group after consent date

Recruitment.
Electronic Health Records of obstetric patients will be regularly reviewed. Working off of the clinic schedules, those who pre-screen as potentially eligible will be approached in person and informed of the study. Eligibility will be assessed among interested individuals, with reasons for ineligibility recorded. The reason for decline will also be recorded among uninterested individuals. The potential participant may be enrolled on the day of recruitment or we will ask permission to record their contact and pertinent scheduling information (see “Contact Card”) to allow for follow-up. Participants may also provide verbal approval for contact to study staff. To reduce potential participant burden, promote autonomy, and promote just subject selection, we will combine recruitment efforts among active College of Nursing (CON) OB/GYN studies recruiting at the same location (primarily OSUWMC OB/GYN). When CON OB/GYN research is

presented, potential participants will have the opportunity to indicate all CON OB/GYN studies in which they are interested. REDCap will be used as a central site to track potential participants, recruitment activities, contact information, interest, eligibility, and follow up (see "CON OB/GYN Clinic Recruitment" REDCap Tracking Form). Each study participating in combined CON OB/GYN clinic recruitment will have all aspects of the recruitment process approved by the IRB under their respective IRB protocol before being included on the recruitment materials or in the recruitment process. Studies will be included on recruitment materials only after they have been approved and will be removed from recruitment materials when no longer recruiting. All staff members involved in combined CON OB/GYN recruitment will be listed and approved by the IRB under each respective study for which they contribute to recruitment. We will maintain logs of declining individuals and potential participants. Declining individuals will not be approached again during this pregnancy. We will follow up with potential participants at the clinic and/or through their provided methods of contact (up to ten separate attempts, with contacts and attempts recorded) to determine continued interest and plan for enrollment. Once no longer needed for recruitment and scheduling purposes among all studies, paper copies of these recruitment materials will be shredded and contact information of potential but unenrolled participants will be deleted from the study files. If a potential participant indicated that they were interested in our "Contact List (to hear about future studies from our teams)" (see "Contact Card"), we will transfer their contact information to our research programs' contacts lists.

As needed, we may also distribute recruitment materials to community members at physical locations (e.g., OSU Practice-based Research Network-affiliated locations, obstetric offices, community fairs and events, libraries, daycares, churches, community centers, health centers, Center for Science and Industry, see Appendix A for additional) and through online and social media outlets (e.g., ResearchMatch.org, StudySearch, 293-HERO, Facebook, Twitter, LinkedIn, Craigslist, Meetup Groups, email listservs) likely to be frequented by pregnant women. Flyers may also be distributed by community members to pregnant women (e.g. StepOne). We may also email women who have indicated to our team that they are interested in hearing about research opportunities. Participants will be provided with recruitment materials to share as they see fit. Interested individuals will have the opportunity to contact our office or complete a REDCap screening survey (see "CON OB/GYN Community Recruitment") to determine eligibility, with reasons for ineligibility recorded. As above, we will we will combine efforts across CON OB/GYN Studies, with approvals granted separately for each study under their respective IRB. We will maintain logs of and follow-up with potential participants contacting our office as described above. Once no longer needed for recruitment and scheduling purposes among all studies, paper copies of these recruitment materials will be shredded and contact information of potential but unenrolled participants will be deleted from the study files. If a potential participant indicated that they were interested in our contacts list (to hear about future studies from our teams), we will transfer their contact information to our research program's contacts list.

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 referred to a mental health provider for immediate care. If a woman answers item 10 with a 2 or 3, in addition to being accompanied to a mental health provider for immediate care, she will be excluded from the study. If a woman scores a 1, she will not automatically be excluded from the study. 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 from 8:00am the day prior to the data visit to 8:00am on the day 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.

Primary Care PTSD Screen: The PC-PTSD is designed to detect PTSD in busy primary care and other medical settings. Higher scores indicate high risk. A score of two or more suggests the presence of PTSD, though it should be considered “positive” if the person answers “yes” to three or more items.

SOPA: The SOPA is a 6-item measure adapted from both the PC-PTSD screen and the Jellinek-PTSD (J-PTSD) screen. The SOPA includes an additional question about contact with the police and/or law enforcement. It also includes a definition of traumatic events and asks participants to indicate the ones they have experienced if they check yes; then they will indicate if they experienced any of the eight adverse childhood experiences – ACEs. Participants also circle “yes” or “no” to five questions about PTSD symptoms, including one question about future plans or hopes from the J-PTSD.

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: Measures group care model acceptability in less than 5 minutes at a 6th grade reading level.

Program Evaluation: Separate forms for intervention and attention control that address qualitative data regarding participant experience in study program as well as delivery method, virtually or in-person in less than 5 minutes.

Goal Setting & Self-Monitoring Log: COPE-P participant manual pages, similarly titled, will be copied at the conclusion of the 18 week intervention. These logs include a secondary set of exercise and nutrition data, as well as self-reported information regarding health behaviors, emotions, goals, and barriers to goal achievement.

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
	COPE-P Goal Setting-& Self-Monitoring Log	T1
Weight Gain/Loss, BMI	Scale	T0, T1, T2, T3
Perceived Sleep Quality	COPE-P Goal Setting & Self-Monitoring Log	T1
Goal Setting & Barriers	COPE-P Goal Setting & Self-Monitoring Log	T1
Exercise	Steps Fitbit Flex 2 Accelerometer	T0 (given at screening T1, T2, T3)
	COPE-P Goal Setting & Self-Monitoring Log	T1
Psychosocial Health		
Anxiety	GAD7	T0, T1, T2, T3
Depressive Symptoms	EPDS	T0, T1, T2, T3
	COPE-P Goal Setting & Self-Montioring Log	T1
PTSD	PC-PTSD, SOPA	T0
Perceived Stress	PSS	T0, T1, T2, T3
Birth and Post-Natal Outcomes		
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) Program Evaluation (COPE-P or PregnancyPlus, per randomization)	T1 and T2 T1 and T3
Group Prenatal Care Experience	Group Prenatal Care Acceptability Form	T1

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 a $10.00 gift card for her participation in the screening process. Participant may be offered participation in the COVID Cohort study at this time. See cohort protocol below, Appendix B.

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. The woman will not have to repeat the GAD-7, PSS, or EPDS.
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 a $30.00 gift card for at the baseline visit, **T0**. Participants will be given the choice between receiving study reminders by text message or email.
All women in this study will receive 6 sessions of group prenatal care beginning at 16 weeks gestation (± 2 weeks) and ending at 31 weeks (± 2 weeks) according to previously described randomization into COPE-P intervention group or PregnancyPlus attention control group. 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. Dr. Gennaro will conduct the training of the attention control group advanced practice registered nurses and Dr. Melnyk will conduct the training of the intervention group advanced practice registered nurses. 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, the Healthy Lifestyle Beliefs Scale and the Group Prenatal Care Acceptability form. Fitbit data and weight also will be obtained. Both groups will complete program evaluations. In the intervention group, participants will complete the COPE-P Acceptability Form and the COPE-P Program Evaluation. In the attention control group, participants will complete the PregnancyPlus Program 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 asked to sign a medical release form in case they choose to visit an off-site pediatrician following the birth of the baby so that the necessary follow-up information is still accessible. This data will be extracted by a study team member. Participants will be compensated a $30 gift card 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 a $40 gift card for their study participation at this visit. All measures will be collected, with the exception of the Program Evaluation

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 a $50 gift card for their participation. All measures will be collected, including the Program Evaluation. After completion of T3, participant may be offered participation in the COVID Cohort study. See cohort protocol below, Appendix B.

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.

For virtual group sessions or study timepoints, efforts will be made to complete all data collection. Surveys will be completed and data directly entered into pre-existing REDCap forms. The 24-Hour diet recall will be reviewed verbally. The diet recall form will be completed electronically by study staff during the visit and saved electronically on the College of Nursing R: drive. Weights will be obtained by patient report and chart review. Fitbits will be synced at scheduled in-person visits with study staff. Participants will be mailed medical record release forms to sign and return to retrieve off-site records. Study staff will track if sessions or timepoints were completed in-person or virtually.
At each of the timepoints, participants will receive a physical gift card or an emailed gift card in the appropriate denomination.

Analysis plan.
Data management: Screening and enrollment data will be collected using a combination of paper and pencil data collection, REDCap software, and Excel spreadsheets stored on the OSU College of Nursing Research Server. 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 collected by Fitabase. Fitabase use will be connected to participant ID numbers using their "anonymous data collection" method described below. There will be Fitbit chargers at the visits to encourage women to charge the Fitbits during the visit and at home. Data from the 24 hour diet recalls will be manually entered at each site into the software Food Processor and then exported into an Excel file for data analyses. REDCap software will be used to store the data. 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.
The College of Nursing provides secure file storage for research projects.

- This server runs Windows Server 2012R2 and is only used to host research files. No unnecessary services are running. (No IIS, SQL, MS Office, FTP. Details available upon request.)
- The Windows operating system is kept up to date by automatic updates from Microsoft.
- The physical server is housed in a secure room within Newton Hall. Only pertinent IT staff and the building coordinator have keys to access this room.
- Electronic access to the research server is restricted to the college LAN or VPN by a Cisco ASA 5510 firewall. Access from the Internet without VPN is not allowed.
- Electronic access is further restricted by the on-host Windows Firewall.
- User access is tightly controlled, by request only. New users must be cleared by the College of Nursing Associate Dean for Research.
- Permissions to individual folders and subfolders are managed individually. Users only have access to folders of projects in which they are directly involved. All changes are submitted in writing.
- Permissions are audited annually by IT in collaboration with the Associate Dean for Research and Director of Data Commons.
- The administrator account for the server has a non-standard password and has been disabled.
- All user accounts connecting to the server are domain accounts and are authenticated through a domain controller. Accounts are automatically locked out for 30 minutes after 5 invalid attempts.
- User access and system information is logged and exported to a central event-logging server, which is auditable.
- Backups of the server are encrypted using military grade encryption.

Data collected via REDCap survey tool and will be kept confidential. REDCap Survey Software is a powerful, flexible, and easy to use online survey software tool for creating professional surveys and questionnaires. Best in class features such as custom email invitations, logic and events based functionality, and an online reporting and data export module to SPSS, SAS, Excel and CSV make online survey creation and management practically effortless. Only authenticated users can log in to create surveys or view the responses. Additionally the users can be assigned to roles in order to limit which authenticated user can view/modify your survey questions or view the responses.

Fitabase

Security and Privacy Information: As a research platform that collects data from internet connected consumer devices, we take security and privacy seriously. Fitabase is a fully hosted, cloud-based software solution that implements robust industry standards to maintain secure databases and keep data private.

Where Data is Stored: Fitabase code and databases physically reside on the Microsoft Azure platform (www.windowsazure.com). We rely on the robust security, both physical on- premise guarding, and over network, provided as part of that platform. From Microsoft (http://www.windowsazure.com/en-us/support/trust-

center/security/): Windows Azure runs in data centers managed and operated by Microsoft Global Foundation Services (GFS). These geographically dispersed data centers comply with key industry standards, such as ISO/IEC 27001:2005, for security and reliability. They are managed, monitored, and administered by Microsoft operations staff that have years of experience in delivering the world's largest online services with 24 x 7 continuity. In addition to data center, network, and personnel security practices, Windows Azure incorporates security practices at the application and platform layers to enhance security for application developers and service administrators.

Compliance: See information on Microsoft's extensive compliance at: https://azure.microsoft.com/en-us/support/trust-center/compliance/ Offsite Backup Handling In addition to the primary copies of our databases, Small Steps Labs LLC maintains snapshot archives of database for disaster recovery purposes. Backup copies reside on hardware only accessible to Small Steps Labs LLC and our employees. Our backup copies are encrypted and password protected. See information on Microsoft's extensive compliance at: https://azure.microsoft.com/en-us/support/trust-center/compliance/

Encryption & Secure Connections Fitabase uses Secure Sockets Layer (SSL) for all authentication (logins), billing, and administration of the site. The user's browser establishes the authenticity by requesting an SSL certificate that verifies the identity of Fitabase. Once that SSL certificate is recognized, a Secure Sockets Layer (SSL) connection is established for security, encrypting data transmitted between browser and web server.

Passwords: Fitabase stores passwords in encrypted form. When an administrator attempts to log in to Fitabase.com, their attempted password is encrypted and if matched, the user is allowed in to the site. This practice prevents unauthorized usage of the site. If the database were to be compromised, passwords would not be retrievable.

Usage Logging: Fitabase logs all site usage, including attempts to access restricted data, or log in to accounts of others. We maintain security policies to block / freeze accounts that appear to be compromised until we are able to make contact via the email address used to set up the administrator account.

Optional Anonymous Data Collection: Fitabase allows groups wishing to collect data anonymously the option to do so by associating device data with their own alphanumeric identifiers. To best accomplish this, groups should setup the Fitbit.com account that corresponds with each device using an anonymous email address not linked to a real person. Fitabase does not collect personally identifiable information beyond what it is provided by Fitbit.com. Additionally, Fitabase does not collect IP addresses from synced participant devices.

Remind

Remind uses Amazon Web Services (AWS) and other third-party services within the AWS environment to host and operate its databases. AWS is an industry-leading cloud service platform that provides Remind with nondescript facilities, professional security staff, controlled access, video surveillance, intrusion detection, and other security features. All data is separated from outside connections, and access is limited to select, current members of the Remind team.
• Remind stores its data within an AWS region that is FedRAMP compliant.
• Remind's main database and all backups are encrypted at rest.
• The AWS cloud infrastructure has been designed and managed in compliance with regulations, standards, and best-practices, including HIPPA, SOC 1/SSAE 16/ISAE 3402 (formerly SAS70), SOC 2, SOC 3, PCI DSS Level 1, ISO 27001, FedRAMP, DIACAP and FISMA, ITAR, FIPS 140-2, CSA, and MPAA.
Software Security
Remind's infrastructure is built on industry-tested technology and security practices.
• Remind uses encryption, firewall, and network security software.
• Remind uses single sign-on (SSO) and twofactor authentication (TFA).
• Any VPN access to Remind systems requires SSO and TFA. VPN access is required for many services, including remote access (through SSH) to production servers and

management tools.
• Logging into confidential parts of company systems requires time-limited SSH keys generated by classified users. All SSH requests are logged for auditing.
• Low-level auditing software is run on all systems to record potentially malicious actions that may take place.
• Remind runs periodic penetration tests, then logs and resolves discovered issues.
• All Remind clients use TLS/SSL when communicating with our servers.
• Remind has a host-based intrusion detection system to detect unauthorized access to production hosts.
• Audit logs are sent to a central location for storage and analysis. Access to production servers and interaction with production systems is audited and logged.

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,153-154 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.155 Models with more than one mediator are simply extensions of the single-mediator case.156 In our multilevel models, we will investigate mediation effects within the different levels of analysis and across levels.157 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).

Appendix A

Potential Advertising Locations
Local Churches
OSU CarePoint East Family Medicine
OSU Resident Clinic
OSU Parking Garages
Columbus Public Health
Step One mailings
Franklin County Public Health
Heart of Ohio
Whitehall Community Health Action Team (CHAT)
Council on Healthy Mothers and Babies (COHMAB)
Pregnancy Care Connection (PCC)
Lower Lights
Grant Mobile Units
Healthcare Collaborative of Greater Columbus (Access Health Columbus)
Medicaid Managed Care Plans
Ohio Hispanic Coalition
Ohio Latino Affairs Commission
St. Vincent Family Center
'Que' Pasa, OSU? (magazine)
CAP4Kids Monthly newsletter (Children's Advocacy Project cap4kids.org/Columbus)
Physicians CareConnection
Women's Care Center
Pregnancy Decision Health Centers
Planned Parenthood
The Women's Clinic of Columbus

Appendix B: A separate cohort study will also be conducted for a limited number of participants who have agreed to participate in the Healthy Lifestyle Prenatal Care Study-OSU. The following protocol addresses this cohort study. The technical aspects of data management, described above, will be utilized unless otherwise stated below.

Minority Women's Experiences of Pregnancy during the COVID 19 Pandemic: COVID Cohort Study

Purpose

Describe the effects of the COVID-19 outbreak on social determinants of health among Black and Hispanic pregnant women consented for the Healthy Lifestyle Prenatal Care Study-OSU.

Aim

Explore how the COVID-19 pandemic was experienced by minority pregnant women in the following areas:

1) Lifestyle behaviors (nutrition, exercise, sleep)
2) Mental/emotional health (stress, depression, anxiety, how I cope)
3) Healthcare utilization (prenatal, pediatric, preventative and health promotion)
4) Life and family (economic, employment, living situation)

Overview of Study Design

A mixed methods approach collecting survey data on levels of anxiety, stress, and depression and interviews will be conducted to determine how COVID-19 has impacted family life and health among Black and Hispanic pregnant women. Data will be collected from two cohorts of participants in the Healthy Lifestyle Prenatal Care Study-OSU (HLPCS). Quantitative data on anxiety, stress and depression is already being collected as part of the larger study. A paper and pencil tool will be used to collect select demographic information about the participant. If visit is conducted virtually, responses will be directly entered into REDCap by research staff. Individual experiences on the impact of COVID-19 will be collected using semi-structured audio-recorded interviews and medical record review.

Recruitment and Sample

Data will be collected until saturation of themes in the transcripts is achieved. We anticipate a minimum of 20 and maximum of 30 participants will complete this study cohort.

As in the HLPCS, Cohort 1 will be recruited from the antenatal clinic if they are: between 18 and 40 years old, with an uncomplicated singleton pregnancy of less than 19 weeks, and self-identify as either Black or Hispanic and can read and speak English. Cohort 1 will complete the informed consent process either in-person or remotely. If in person, participants will sign the COVID Cohort 1 Consent Form and be provided with a copy. If completed remotely, the process will utilize Signet to complete electronic signature and provide the participant with a copy of the consent form. Cohort 2 will include participants who previously met these criteria and are now approximately 6 months postpartum and have completed Timepoint 3 for the HLPCS. These participants will be approached at the completion of the timepoint for participation in the additional study. If interested, they will complete the COVID Cohort 2_T3_Verbal Consent form. They will be provided with a Contact Card after completion of verbal consent, either a paper card or via email.

Inclusion and Exclusion Criteria:

Women will be recruited from their appointments in the corresponding clinic (antennal or pediatric).

Inclusion criteria.

- Consented for HLPCS

Exclusion criteria

- Not able to read or speak English.

Cohort 1 will consist of women who consented but were screened ineligible to participate in the HLPCS on the GAD-7, the PSS, and the EPDS. Participants in Cohort 1 will complete a demographic form as this information is not collected from participants who screen out of HLPCS. Cohort 2 consists of women who have completed all study

requirements for the HLPCS, so as not to confound the data collected as part of their participation. As such, all of the participants in Cohort 2 previously met the same inclusion and exclusion criteria but have since given birth and will be approximately 6 months postpartum when participating in this cohort.

Data management

Quantitative

Demographic data will be obtained using paper and pencil surveys and entered in REDCap. For participants completing visit virtually, demographic data questions will be directly entered by research staff into REDCap. Birth outcome data will be obtained from medical record review and entered into REDCap. REDCap is a secure, web-based application that stores all the data for the HLPCS and it provides an intuitive interface to enter data and enforces real time validation rules at the time of entry.

Qualitative

Data collection may take place in-person or remotely over the phone. To maximize privacy and minimize noise, in-person data collection will take place in a reserved private conference room near the antenatal clinic. Participants will be asked a series of questions under each of the 4 categories and asked to answer as many as they are able to in 60 minutes. Their responses will be audio-recorded digitally. Audio files will be uploaded to REDCap immediately following the interview. Audio files will be downloaded from REDCap onto a secure server for transcription. All audio files will be deleted after transcription of the files. Copies of each completed and de-identified transcript will be encrypted and stored on an OSU College of Nursing Research Server. Standardized procedures will be employed to maintain privacy and confidentiality of the data. These include keeping all hard copies in a locked drawer in a key-locked room and allowing only authorized study staff access to the raw data, using subsisting codes for identifiable information, coding the data using individual identification codes, and not storing names with identification codes.
Data collection and analysis will be undertaken concurrently. Transcribed interviews will be reviewed and coded for themes.

Data Analysis

Quantitative: All of the quantitative data will be analyzed using descriptive statistics by the study statistician. The exploratory design will allow us to use the quantitative data to inform our use of the qualitative data and assess whether anxiety, depression, stress, and health behaviors are changed by the impact of COVID-19. Additionally, data from participants in the larger study, prior to the COVID-19 pandemic will be compared to post-COVID-19 data.

Qualitative: We will use thematic analysis to analyze the qualitative data.[1] Thematic analysis is a widely applied method of organizing and richly describing qualitative data through identification, analysis, and reporting of patterns and themes within each case and across cases – it is commonly employed to analyze descriptive qualitative data.[2-4] The aim of thematic analysis is to provide a rich, detailed description of the data set that represents the 'reality' of the participants as accurately as possible – to shed light on the experiences of the participants.

We will follow a detailed, six-phase approach to thematic analysis – a well-described and systematic method of analyzing qualitative data. Members of our study team have extensive experience conducting thematic analyses. The procedure will be as follows: (1) read transcripts to begin to identify patterns of meaning in the data; (2) begin open coding in ATLAS.ti™ (or other suitable qualitative analysis software program) to generate initial codes from 5 to 7 transcripts; (3) compare codes, and through discussion, reach coding agreement; (4) generate a final codebook; (5) code a sub-group of transcripts and achieve coding agreement (Cohen's Kappa); (6) complete coding of transcripts.

After all of the data have been coded, codes will be sorted into patterns and then potential themes and subthemes. The themes will be further refined by adding, collapsing, expanding, and revising the codes and exemplar quotations. We will use member checking with those conducting the COPE-P sessions to solidify themes and subthemes. Subsequently, we will examine how themes and subthemes may combine into overarching themes. Once a thematic map is generated, the researchers will conduct a detailed analysis of each individual theme and will determine how each theme fits into the overall understanding of the experience of how the COVID-19 pandemic was experienced by minority pregnant women in the Midwest.

We will incorporate multiple strategies to improve methodological trustworthiness and strengthen the meaning of findings. The criteria for determining validity in qualitative research as outlined by Whittemore, Chase, and Mandle[5] will guide this study, including establishing credibility, authenticity, criticality, and integrity.

Integrative: The third objective is to integrate the quantitative and qualitative data and findings. We will create a matrix displaying the prevalent themes among the participants with their depression, anxiety and stress groupings in

order to compare and contrast descriptions of their experiences of COVID 19 while pregnant within and across groups. The goal is to determine whether there are differences in their experiences depending on their mental health.

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