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BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
NYC HEALTH & HOSPITALS

SUBJECT INFORMATION AND INFORMED CONSENT FORM

Study Title: Healthy Lifestyle Prenatal Care Study
Protocol #: 1R01MD012770-01A1
Sponsor: Boston College

Principal Investigator: Anne Marie Gibeau, CNM, PhD
Institution: Jacobi Medical Center, NYC Health & Hospitals
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You are being asked to be a subject in a research study. You were chosen because you are a pregnant Hispanic or Black woman between 18 and 40 years old and are less than 19 weeks pregnant. This consent form contains important information about this study and what to expect if you decide to take part. You should ask the study staff all the questions you have before deciding whether or not to take part. Please read this information carefully and feel free to discuss it with your relatives, friends and your doctor. If you choose to be in the study, you must sign this form.

Disclosure of Financial Interest

Boston College, the sponsor of this study, is providing funds to NYC Health + Hospitals on a per subject basis for doing this research study.

Purpose

The purpose of this study is to test the effect of the COPE-P program. We want to learn how the COPE-P program might change the lifestyle behaviors, mental health and birth and post-natal outcomes in pregnant minority women with anxiety, stress, or depressive symptoms.

It will:

- Look at changes in lifestyle overall health and outcome of the delivery.
- Look for trends in order to help improve coping, depression and anxiety.
- Compare the results of the COPE-P with the PregnancyPlus program.

Number of Subjects and Length of Participation

A total of 182 Black or Hispanic women are expected to complete the study at Jacobi Medical Center. In order to achieve this total enrollment, up to 700 women will be screened to participate.

Your participation is expected to last about 12 months.

COPE Program

The COPE program is a cognitive behavioral therapy (CBT) based skills building program for pregnant Hispanic and Black women. This means it is made to help pregnant women

understand how their thoughts and feelings might affect their behaviors. Hispanic and Black women have higher chance for poor birth outcomes than women of other ethnic groups.

The COPE program focuses on skills to connect thinking, feeling, and behaving. It includes teaching women techniques to:

- find triggers to certain behaviors,
- take note of negative thoughts,
- support positive self-talk and self-esteem,
- stay in the moment (concentrate), and
- learn positive coping skills.

The goal of the COPE program is to teach women:

- steps to set goals and make positive changes,
- to notice signs of stress, depression, and anxiety,
- how to problem solve and handle barriers,
- to deal with emotions in healthy ways, and
- how to cope with stressful situations.

Procedures and Tasks

If you sign this consent form, you will then be asked to complete the following three surveys:

- Generalized Anxiety Disorder Scale
- Perceived Stress Scale
- Edinburgh Postnatal Depression Scale

Please answer them to the best of your ability. Once you are done, they will be scored to see if you are able to continue in this study. Depending on your scores, the study staff may have to let your doctor know your scores.

You will be told if you are not able to continue based on your scores.

If you are able to continue, you will be asked to fill out more forms. You will also have your weight measured on a scale in the clinic. You will be given a Fitbit Flex 2 pedometer and directions on how to start using it right away. You should wear it every day to monitor your activity level.

You will be assigned to the next available study group based on how many weeks pregnant you are. Assignment to a study group will be chosen by chance (like flipping a coin) to either a COPE-P group or a PregnancyPlus group. You will be given an appointment for you first group prenatal care session. 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.

Study group prenatal care sessions will be conducted by certified nurse midwives. At each session, standard prenatal care will be provided (weight, blood pressure, urine test, etc.). In addition to standard care, the intervention group will also receive the COPE-P intervention. The PregnancyPlus group will receive standard care prenatal care and discuss a topic related to

pregnancy. At the end of the 6 group sessions, women in both groups will return to receiving one on one standard prenatal care.

Of the COPE-P and PregnancyPlus study groups, there will be 22 English speaking groups and 8 Spanish-speaking groups. Four groups will run in each 18 week segment. Each group will have at least 6 women.

Surveys
If you are eligible to continue with the study, you will complete the following forms today:

- A demographic and personal information form to provide basic information about you (such as where you live)
- A 24 hour diet recall (list of foods eaten in the last 24 hours).
- Healthy Lifestyle Beliefs Scale
- Healthy Lifestyle Behaviors Scale

The surveys ask about your health and well-being. They should take approximately 20 minutes to complete.

Additional Contact
You may be contacted by mail or phone using the information you give the study staff. You may also be contacted in person in clinic. Study staff members, doctors, midwives, and nurses who are part of your care team may contact you.

Study staff members may also contact your medical team, like doctors, midwives, and nurses who are taking care of you and your baby. Study staff members are required to report risky behaviors (thoughts of suicide, drugs, alcohol, or abuse) in pregnant women to their supervisors. Your doctor may talk to you about them and provide, or refer you to, help when needed.

Duration
If you are eligible to take part in the study, your first study visit will be today. There are 4 visits in total. The group prenatal care sessions start around week 16 of your pregnancy and last 18 weeks ending around week 31 of your pregnancy. There are 6 group sessions, 3 weeks apart. They will last between 1 hour and 30 minutes to 1 hour and 45 minutes. At the last group session, you will be asked to complete the study surveys again. At your postpartum check-up, you will be asked to complete the study surveys again and information about your baby's birth will be collected. You will be asked to complete your final study surveys at your baby's 6-month well baby check-up. 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.).

Visit 0	1st Prenatal care appointment
Visit 1	Last group prenatal care session
Visit 2	Postpartum check-up
Visit 3	6-month well-baby check-up

Risks

There are minimal risks for you or your baby connected with the study, although some risks may be unknown at this time. There is a risk that you may become upset by the questions on the surveys. If this occurs the study staff will notify your doctor for follow up. You do not have to answer any question you do not want to.

Benefit
There is no guarantee that you will benefit as a result of your participation in this study. If you have certain emotional problems during your pregnancy, these conditions may improve, stay the same or get worse. However, your feedback may provide knowledge and information about the COPE intervention that may help minority women in the future cope with pregnancy.

Alternative
You do not need to agree to be in this study to receive pregnancy care. Your alternative to being in this study is not to take part in it.

New Information
If any new information is learned about this study that might change your willingness to stay in this study, you will be told about it promptly.

Reimbursement
If you consent to participate but are not able to continue with the study because of your screening scores, you will receive $10 in cash for your time.

If you are able to continue with the study, you will receive $30 in cash when you complete your baseline visit, including screening tools and surveys. At the end of your 6 group sessions, you will receive another $30 in cash for completing the study visit 1, including another set of surveys, a weight measurement, and the collection of your Fitbit data. You will receive $40 in cash after you have completed the study surveys at your postpartum visit, and $50 in cash after you have completed the study surveys 6 months after your baby is born for the final visit. You will need to sign a receipt to confirm the money you received. If you leave the study early, you will be reimbursed only for each visit you complete.

Tax law may require the NYC Health + Hospitals Finance Department to report the amount of payment you receive from NYC Health + Hospitals to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally this reporting would take place if you receive payments that equal $600 or more from NYC Health + Hospitals in a calendar year. You would be responsible for the payment of any tax that may be due.

Costs
You and/or your medical insurance will be responsible, in the usual way, for the costs of your pregnancy and your standard care that you would have even if you were not in this study.

Injury Compensation
For medical emergencies please call 911. Because this study involves only collecting information and requires no specific tests or treatments, no research-related injuries are expected. No financial compensation will be offered by the sponsor, NYC Health & Hospitals or the

Biomedical Research Alliance of New York. NYC Health & Hospitals will treat subjects even if they are not able to pay.

You are not waiving any legal right to seek compensation through the courts by signing this form.

Voluntary Participation and Withdrawal
Your participation is voluntary. This means you may decide not to join the study. If you choose to take part in the study, you may stop at any time. Whatever your decision, there will be no penalty, your care will not be altered and you will not lose benefits you would have if you were not in this study. You should tell the study doctor if you want to stop being in the study.

You may be withdrawn from the study for any reason at any time without your consent by your study doctor, the study sponsor, the FDA or other regulatory authorities. Reasons this may happen include: if it is believed to be in your best interest, if you do not follow the study instructions, the study is stopped or for other administrative reasons. NYC Health + Hospitals may end this study or your participation in this study at any time.

Medical Records
The research records will be kept private and your name will not be used in any written or verbal reports. Your research records and medical records may be inspected by members of the research team, the sponsor, and other institutions that participate in this study. Support for this study is provided by Boston College Connell School of Nursing. The researcher and research staff will review your medical records and will keep the information private. The research records will be kept in a secured manner and computer records will be password protected. The people who reviewed this research study as members of the Biomedical Research Alliance of New York Institutional Review Board, Jacobi Medical Center, and NYC Health + Hospitals may also review your research study records. All of these groups have been requested to keep your name private.

Confidentiality
Your name will not appear in any written or verbal reports about the study. Your responses to the questionnaires will be kept in a locked file cabinet at Jacobi Medical Center.

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries where the study product may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor's representatives and may be looked at by the FDA and other regulatory agencies, the Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required

by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results
- Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history
- Billing records

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration
- Department of Health and Human Services agencies
- Governmental agencies in other countries
- Biomedical Research Alliance of New York (BRANY)
- The Institutional Review Board
- Accrediting agencies
- Data safety monitoring boards
- Health insurers and payers
- NYC Health + Hospitals research staff members

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The

information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Notice Concerning HIV-Related Information: HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor, but will not be shared with others without your authorization, unless federal or state law requires the disclosure. You have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights or New York City Commission on Human Rights. These agencies are responsible for protecting your rights.

Certificate of Confidentiality: This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project or for information that must be disclosed in order to meet the requirements of the U.S. Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

Contacts and Questions
If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Anne Marie Gibeau at 718-918-6326.
, you may contact [

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

Signatures - Consent
I have read this form and I know that I am being asked to take part in a research study. I have had a chance to ask questions and have had them answered. I freely agree to participate in this study. I am not giving up any legal rights by signing this form. I will be given a copy of this signed form to keep**.**

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Subject: Print Name Signature Date

I have explained the research to the subject before requesting the signature above. A copy of this form will be given to the subject.

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P**erson obtaining consent:** Print Name Signature Date