Official Title: Project Wellness: A Pilot Feasibility Randomized Controlled Trial

NCT Number: NCT04209348

Consent Form Date: 04/26/2021

Consent to Take Part in a Research Study

Title: Project Wellness

Principal Investigator: Samantha F. Ehrlich, PhD MPH

Physicians and researchers at the University of Tennessee Knoxville, the University of Tennessee Graduate School of Medicine, the University of Tennessee Medical Center High Risk Obstetric Consultants (HiROC) are conducting a study called **PROJECT WELLNESS**. This study is to help understand how wellness interventions may improve health outcomes in women with or at risk for Gestational Diabetes Mellitus (GDM), and their babies.

For Study Visit 1, participants will fill out surveys and have their weight and height measured. They will also wear a physical activity monitor (that looks like a wrist watch) for 7 days (i.e., all day and night), and potentially a Dexcom G6 continuous glucose monitor (or CGM, a small device that is worn on your upper arm and continuously records your blood glucose levels) for 7 days. After completing these and returning the surveys and the monitors to study staff, participants will be randomly assigned (by a computer program) to one of two wellness programs: the STEP Up program or the Next Steps program.

Those assigned to the STEP Up program will work with a Lifestyle Coach to increase their physical activity by walking or stepping in place every day; they will be offered a Fitbit to use until they deliver and instructed to use the Fitbit to track their walking/stepping every day. Those in the Next Steps program will also work with a Lifestyle Coach, they will receive educational information on vaccines, baby car seats, and contraceptives following delivery. Both wellness programs include one longer video chat or telephone session (approximately 30-40 minutes) and then at least 4 video chat or telephone sessions (10-20 minutes each) with a Lifestyle Coach (about 1 session per week). Some of the program sessions will be audio recorded for quality assurance.

If you agree to participate, it is important to understand that we cannot guarantee that you will be assigned to one program over the other (since it is done by a computer), so you must be willing to participate in both wellness programs to be in the study.

Regardless of which wellness program you are assigned to, for Study Visit 2 (at about 35 weeks gestation), you will be asked to fill out surveys and measure your weight. You will also wear the physical activity monitor for 7 days, and potentially the Dexcom G6 continuous glucose monitor for 7 days.

All participants will also have a Delivery Visit to measure the baby, and have baby Follow-up Visits at 3 months, 6 months, 9 months and 12 months of age. You will be weighed and fill out surveys and the baby measured at these baby follow up visits. Your will also wear the physical activity monitor for 7 days at these visits. Therefore, you should only agree to participate in Project Wellness if you plan to stay in the Knoxville area through your baby's first birthday.

The greatest risks of this study include the possible loss of confidentiality, and possibly skin irritation and/or infection from the continuous glucose monitor. For those assigned to the STEP Up program, there is also the risk of injury during walking/stepping.

In light of the COVID 19 pandemic, your study visits may be modified, postponed, or canceled, as required by the University of Tennessee, the Knox County Health Department, and/or Centers for Disease Control and Prevention. Study appointments may be conducted remotely via Zoom or cellphone, or in-person with fully vaccinated Project Wellness study staff in a location that is convenient for your (e.g., home or work).

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in a research study. This information is provided to tell you about the study. Please read this form carefully. Your participation is voluntary. Saying no will not affect your rights to health care or services. You are also free to withdraw from this study at any time.

What is the purpose of the study?

The purpose of the study is to help us understand how wellness interventions may improve health outcomes in women with or at risk for Gestational Diabetes Mellitus (GDM) and their babies.

How long will I be in the study?

You will be in the study through the last Follow-up Visit, which will take place near your baby's 1st birthday.

What will happen to me during the study?

All participants will wear the physical activity monitor two times during pregnancy (for 7-days at Study Visit 1 and then again at Study Visit 2), though you will not be able to see any information collected by the physical activity monitor. Those in to the STEP Up program have the option to wear a Fitbit that syncs with their smart phone (and you will be able to see the information collected by the Fitbit). Therefore, at Study Visit 2, those in to the STEP Up program could wear a physical activity monitor on one wrist (the dominant wrist) and the Fitbit on their other wrist (the non-dominant wrist). Women in to the STEP Up program will return the Fitbits to study staff after they deliver their babies.

An optional study procedure is wearing the Dexcom G6 continuous glucose monitor (CGM) for 7 days at Study Visit 1 and Study Visit 2. The Dexcom G6 CGM is a patch device, about the size of a quarter that is applied to the skin of the arm and contains a small sensor probe that remains a ½ inch beneath the skin to measure glucose levels. The sensor probe is a platinum/silver wire about the width of 2 human hairs. The CGM is designed for people with Type I and Type II Diabetes and is safe to use, but not yet approved for clinical use in women with or at risk for GDM (i.e., so your doctor/nurse will not use it to monitor glucose levels for your prenatal care). You may experience skin irritation or redness around the device's adhesive patch. There is also the possibility of an infection. You will need to: keep your CGM receiver (i.e., a device smaller than the size of a cell phone that records the glucose values measured by the sensor probe) within 20 feet of yourself (e.g., carry it in your purse), spend no more than 2 hours apart from the CGM receiver, and charge the receiver's battery every 3 to 5 days. Please note that sensor deployment failures have been reported in the Dexcom G6 CGM, participants in the Project Wellness study have experienced this malfunction as well. A sensor deployment failure means

that the piece of equipment used to apply the sensor does not disengage from the sensor after it is applied to the skin. If this happens, we would remove the sensor and you would decide whether or not you want to try again. The CGM is optional, so you do not have to wear the CGM to participate in the study.

One or more of your sessions with the lifestyle coach may be audio recorded for quality control purposes. Your coach will obtain your permission prior to recording any session.

Study staff will access your electronic medical records to collect information about your pregnancy and delivery. If you are being seen by HiROC for your clinical care, study staff will make photocopies of your purple blood glucose pamphlets on file there.

At Study Visit 2, you will be asked to sign a medical release form for study staff to access your baby's medical record and gather information on his/her weight, height and head circumference through 1 year of age.

Your weight will be measured and your baby will have several measurements at 3 months, 6 months, 9 months and 12 months following delivery. If possible, we also try to measure the baby at delivery (if you deliver at UTMC and we are able to come see you and baby in the hospital, or soon after delivery at your home). There are no risks to the babies by taking these measurements. They include measuring your baby's body weight, length or height, and head, abdominal and arm circumferences (i.e., using a tape measure). In addition, your baby will have his/her skinfolds measured at the hip, thigh, arm and back. You can hold your baby for the skin folds measurements. Although there is no risk of harm from these measures, your baby may briefly experience a very mild discomfort resulting from the light pinch of skin with the caliper. This pinching sensation is about as uncomfortable as if you were to lightly take a pinch of skin between your fingers.

What side effects or risks can I expect from being in the study?

The potential risks to you include the possibility that someone could find out you were in this study or see your study information (but we believe this risk is unlikely because of the procedures we use to protect your information).

You may experience skin irritation or redness around the continuous glucose monitor's adhesive patch. There is also the possibility of infection from wearing the continuous glucose monitor. The continuous glucose monitor is optional.

If you are assigned to the Step Up program, it is possible you could injure yourself while walking or stepping (this risk is rare but could be serious).

Are there benefits to taking part in the study?

The potential benefits to you from this study, depending on which program you are assigned to, include increased physical fitness or improved readiness for the weeks following your delivery.

The possible benefits to society may include information on whether wellness programs improve health outcomes in women with or at risk for GDM and their babies.

What other choices do I have if I do not take part in this study?

If you choose not to participate in Project Wellness, your medical care will not be affected.

How many people will be in the study?

Up to 48 people will be in this study.

What will it cost me to be in the study?

It will not cost you anything to be in the study.

Will I be paid for taking part?

You will receive gift cards to Walmart for your participation in Project Wellness.

The most you will be paid for completing Study Visit 1, Study Visit 2, and the Delivery Visit is $280.00. Specifically, you will receive $80 for completing Study Visit 1, $100 for completing Study Visit 2, and $100 for completing the Delivery Visit.

The most you will be paid for completing all of the baby follow up visits is $210.00. You will receive $50 for completing the 3-month visit, $50 for completing the 6-month visit, $50 for completing the 9-month visit, and $60 for completing the 1-year visit.

If the study were to end early, you would not be asked to complete (and would not be paid for) your remaining visits.

Is the Investigator paid to do this study?

No, the investigator is not being paid to enroll people in this study.

What if I am injured in this study?

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

IRB NUMBER: 4547
IRB APPROVAL DATE: 05/14/2021
IRB EXPIRATION DATE: 08/17/2021

It is important that you tell the study investigator, Samantha Ehrlich, if you feel that you have been injured because of taking part in this study. You can tell her in person or call her at (865) 974-4663, or email her at sehrlich@utmck.edu.

You are not waiving any legal rights or releasing the University of Tennessee or its agents from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee does not have funds budgeted for compensation either for lost wages or for medical treatment.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who do I call if I have questions about the study?

Questions about the study:

Samantha F. Ehrlich, PhD MPH
Office Phone: (865) 974-4663
Cell Phone:
Email: sehrlich@utmck.edu

Project Wellness study staff may also be reached at:
Phone: (865) 297-3350
Email: ProjectWellness@utmck.edu

Questions about your rights as a research subject: You may contact the UT Graduate School of Medicine Institutional Review Board (IRB) at 865-305-9781. The IRB is a group of people that reviews studies for safety and to protect the rights of study subjects.

Can I stop being in the study?

You may withdraw from the study at any time. Your treatment, payment or enrollment in any health plans or eligibility for benefits will not be affected if you decide not to take part.

If you choose to withdraw from the study, you would not be asked to complete (and would not be paid for) your remaining visits.

Could I be removed from the study?

You may be withdrawn for the study for any of the following reasons:

- The sponsor may stop the study.
- If you do not keep your appointments as scheduled you may be removed from the study.
- If the study ends early.

If the study were to end early, you would not be asked to complete (and would not be paid for) your remaining visits.

Identifiable private information:

Identifiers will be removed from the identifiable private information collected for Project Wellness and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Will my medical information be kept private?

All reasonable efforts will be made to keep your protected health information (PHI) private and confidential. PHI is health information that is, or has been, collected or maintained and can be linked back to you. Using or sharing ("disclosure") of such information must follow federal privacy guidelines. By signing the consent document for this study, you are giving permission ("authorization") for the uses and disclosures of your personal health information. A decision to take part in this research means that you agree to let the research team use and share your PHI as described below, for the purpose of this research.

As part of the study, Dr. Samantha Ehrlich and her study team may share the results of your blood glucose tests. These may be study or non-study related. They may also share portions of your medical record, with the groups named below:

- The Federal Government Office for Human Research Protections,
- The University of Tennessee Graduate School of Medicine Institutional Review Board,
- The National Institutes of Health

Federal privacy regulations may not apply to these groups; however, they have their own policies and guidelines to assure that all reasonable efforts will be made to keep your personal health information private and confidential.

The sponsor may give your personal health information, not containing your name, to others or use it for research purposes other than those listed in this form. In handling your personal health information, the sponsor, Dr. Samantha Ehrlich and associated staff will keep your information in strict confidence, and shall comply with any and all applicable laws regarding the confidentiality of such information.

The study results will be retained in your research record and stored in Dr. Ehrlich's office after the study is completed. Research information (without your name and contact information) will be kept electronically on the University of Tennessee Knoxville's secure computer network. Any research information entered into your medical record will be kept indefinitely.

Unless otherwise indicated, this permission to use or share your PHI does not have an expiration date. If you decide to withdraw your permission, we ask that you contact Dr. Samantha Ehrlich in writing and let her know that you are withdrawing your permission. The mailing address is:

Samantha F. Ehrlich, PhD MPH
1914 Andy Holt Ave, HPER room 369
Knoxville TN, 37996

At that time, we will stop further collection of any information about you. However, the health information collected before this withdrawal may continue to be used for the purposes of reporting and research quality.

CERTIFICATE OF CONFIDENTIALITY:

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.

We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly
- To the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others

CLINICALTRIALS.GOV:

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.

CONSENT OF SUBJECT TO PARTICIPATE IN PROJECT WELLNESS:

I have read or have had read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts and side effects as well as the possible benefits of the study. I will receive a copy of this form after it is signed.

I freely volunteer to take part in this study and give permission for my baby to take part in this study.

_____	_____
Printed Name of Subject	Printed Name of Baby (X if unknown)
_____	_____
Signature of Subject	Date & Time

_____	_____	_____
Printed name of person Obtaining Consent	Signature of person Obtaining Consent	Date

CONSENT OF SUBJECT TO BE CONTACTED AND INVITED TO PARTICIPATE A FUTURE RESEARCH STUDY:

The investigators may decide contact Project Wellness participants in the future to invite them to participate in a follow up research study.

I give permission to be contacted and invited to participate in a follow up research study in the future.

_____	_____
Signature of Subject	Date & Time