COMIRB
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Study Title: Balance After Baby Intervention: 2

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about a lifestyle program designed for women with recent gestational diabetes mellitus (GDM). It is designed to help women lose the weight gained during pregnancy and to reduce the risk of getting type 2 diabetes. Women with a history of GDM have a higher risk of developing type 2 diabetes than women who do not have a history of GDM. Studies show that a lifestyle program focusing on healthy eating and physical activity may lead to less type 2 diabetes. This study will test whether a lifestyle program given during the first year after giving birth will lead to a lower risk of getting type 2 diabetes. You are being asked to be in this research study because you had GDM during your most recent pregnancy.

Other people in this study

Up to 277 subjects will take part in this study. 40% of the participants will be in Denver, Colorado and 60% will be in Boston, Massachusetts.

What happens if I join this study?

If you join the study you will participate for 24 months after your delivery. During this time, we will ask you to come to 5 study visits that will each take about 3 hours.

If you agree to participate in this study, you will be randomized (like a flip of a coin) to one of two groups: the lifestyle group or the control group. You and the study doctor will not be able to choose your study group.

Women in both groups will be asked to come to 5 study visits at either the Clinical Translational Research Center (CTRC) at the Anschutz Medical Campus or at Denver Health. The visits will be at 6 weeks, 6 months, 12 months, 18 months, and at 24 months after delivery.

At each of the study visits the following will happen:

- We will ask you not to eat or drink anything, other than water, after midnight the night before each study visit. We will also ask you to skip breakfast the morning of your study visit.
- The study staff will measure your height, weight, waist circumference, and blood pressure.
- The study staff will ask for an update on your medical history
- At each visit we will take up to a little more than a tablespoon of blood from your arm to measure levels of glucose (sugar), cholesterol (level of blood fat), HbA1c (marker for type-2 diabetes), and thyroid stimulating hormone (TSH).
- We will ask you to complete a study questionnaire that will take about 40 minutes to complete. The questionnaire will tell us about your current diet, physical activity levels, mood, and levels of stress. You can skip any questions you do not want to answer. Your answers to this questionnaire will not be shared with anyone outside of the study staff.
- The study visits will each take about 3 hours each.
- In addition, you will be asked to take a urine pregnancy test at the 6, 12, 18, and 24 month study visits. If you become pregnant before the end of the study, you can no longer participate. We will ask your permission to obtain your medical records from your pregnancy.

At three of the study visits (6 weeks, 12 months, and 24 months after delivery), we will also perform an oral glucose tolerance test (OGTT):

- We use this test to find out how well your body uses up glucose (sugar), which is produced when your body digests food. This test is used to diagnose diabetes. The OGTT completed at your 6 week visit will be part of your routine clinical care. The OGTT at 12 and 24 months are for research only.
- You will first have your blood drawn and then will be asked to drink about 1 cup of a sugary drink (“glucola”) over a 5 minute period. This is the same sugary drink you received during your pregnancy to test for gestational diabetes, but the amount is less than what was used in pregnancy. 2 hours after you finish the drink, you will have your blood drawn again.

Schedule of Study Visits

Procedure	Visit 1 (6 wk)	Visit 2 (6 mo)	Visit 3 (12 mo)	Visit 4 (18 mo)	Visit 5 (24 mo)
Height	X				
Medical History Update	X	X	X	X	X
Urine pregnancy test		X	X	X	X
Weight	X	X	X	X	X
Waist circumference	X	X	X	X	X
Blood Pressure	X	X	X	X	X
Fasting Blood Draw	X	X	X	X	X
Oral Glucose Tolerance Test	X		X		X
Questionnaires	X	X	X	X	X

Remember that you will be assigned by chance (like a flip of a coin) to either the lifestyle group or the control group. You will be assigned at your first study visit, around 6 weeks after delivery.

The study procedures for the lifestyle group and control group are described below.

Lifestyle Group: If you are assigned to the lifestyle group, you will take part in a web-based lifestyle program, designed for new mothers. Lifestyle participants will need access to a computer connected to the internet. This lifestyle program includes 12 weekly internet-based video sessions held over a period of 12 weeks. Each session will take about 5-10 minutes to watch on-line. Each of the sessions is designed with new mothers in mind. The sessions will help you with healthy eating, engaging in physical activity, and problem-solving to overcome difficulties you might face. As you watch the videos you will be asked to enter some information into the website. You will also be asked to enter information about your weight and your exercise.

You will have access to a lifestyle coach during the time you are in the study. Your lifestyle coach will help you make changes to your diet, increase your physical activity levels, and help you with possible difficulties that may stop you from reaching your goals. We will suggest that you have contact with the lifestyle coach at least once each week during the first 3 months of the program. You can contact her by email or phone**.** You may have more contact if you or the lifestyle coach decides that you need more

help to reach your goals. Between 3 and 6 months we will suggest that you connect with the lifestyle coach at least once every other week. Once you have been in the study for 7 months, we will suggest you check in with the lifestyle coach at least once each month.

You will also be able to get extra support for your goals from the other new mothers in the lifestyle group. On the *Balance after Baby* website you can give and receive support from other new mothers. You will have access to a secure blog where you can post questions and communicate on-line with other new mothers. In addition, you can use the website to communicate privately with your lifestyle coach.

Subjects in the lifestyle group will receive a pedometer, a small tool that counts the number of steps you take. This will help keep track of physical activity goals.

Control Group: If you are assigned to the control group, you will have the same 5 study visits as the lifestyle group. However, you will not have access to the Lifestyle program.

What are the possible discomforts or risks?

Blood Draws

In this study we will need to get a little less than 7 tablespoons of blood from you over the course of the entire study. We will get blood by putting a needle into one of your veins and letting the blood flow into a glass tube. You may feel some pain when the needle goes into your vein. A day or two later, you may have a small bruise where the needle went under the skin.

Oral Glucose Tolerance Test

The sugary drink ("glucola") has a very sweet taste, and may possibly cause nausea, or, rarely, vomiting.

Questionnaire

The questionnaire may be tiring to fill out or make you feel uncomfortable, but you will be given as much time as you need to complete it. Also you can skip any questions you feel uncomfortable answering.

Weight loss

This program encourages weight loss. There are risks associated with making changes in your diet. The most common side effects associated with reduced calorie diets are likely to be hunger and fatigue. Occasionally people can experience constipation, nausea, abdominal discomfort, or diarrhea when changing their usual diet. It is possible you could

develop headaches, trouble sleeping, change in your mood, or psychological stress. The most serious but very rare side effect of reduced calorie diets is gallstone formation, which usually only occurs with extremely low fat diets.

This program encourages exercise. There are risks associated with exercise. Exercise may cause sweating, fatigue, or feeling out of breath. These effects are normal. It is also possible that you could develop soreness or injuries (most commonly in your feet, knees, legs, hips, or back) during the study. Exercise can rarely cause abnormal heartbeats, chest pain, passing out, heart attack, stroke, or death. These are extremely rare events.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

The study staff and doctors working on this study will monitor you closely during your time in the study and have years of experience performing the study procedures, so the anticipated risk to all subjects from this study is minimal.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about a lifestyle program designed to lower risk for type 2 diabetes for women with recent gestational diabetes mellitus (GDM). This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Are there alternative treatments?

Women with a history of gestational diabetes can engage in a healthy lifestyle outside of this study. An OGTT may be performed by your regular doctor around 6 weeks after delivery as part of routine care. If you have any further questions about gestational diabetes, please talk to your doctor.

Who is paying for this study?

- This research is being sponsored by the Centers for Disease Control.

- The sponsor will only pay for procedures not considered standard of care. The oral glucose tolerance test (OGTT) at 6 weeks is considered standard of care.

Will I be paid for being in the study?

You will receive a $500 stipend for completing all study visits. This stipend will help cover childcare and transportation costs. You will receive $100 following completion of the 6 week visit and $100 following the completion of the 12 month visit. $80 following completion of the 6 month visit and $80 following the completion of the 18 month visit, and $140 following the 24 month visit. We will pay for the costs of parking at all study visits. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

It is important to know that payments for participation in a study is taxable income.

Will I have to pay for anything?

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

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Jacinda Nicklas. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Nicklas at 303-724-9028. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Jacinda Nicklas with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

You may also talk to a Subject Advocate at the Clinical and Translational Research Center (CTRC). The number there is 720-848-6662.

Optional Consent for Data and Specimen Banking for Future Research

Dr. Jacinda Nicklas would like to keep some of the data and blood that is taken during the study but is not used for other tests. If you agree, the data and samples will be kept and may be used in future research to learn more about gestational diabetes, type 2 diabetes, and heart disease. The research that is done with your samples is not designed to specifically help you. It might help people who have gestational diabetes, type 2 diabetes, and other diseases in the future. Reports about research done with your data and samples will not be given to you or your doctor. These reports will not be put in your health records. The research using your data and samples will not affect your care.

The choice to let Dr. Nicklas keep the data and samples for future research is up to you. No matter what you decide to do, it will not affect the care that you will receive as part of the study. If you decide now that your data and samples can be kept for research, you can change your mind at any time and contact your study doctor to let him or her know that you do not want *Dr. Nicklas* to use your data and samples any longer, and they will no longer be used for research. Otherwise, they may be kept until they are used up, or until Dr. Nicklas decides to destroy them.

If your data and samples are given to other researchers in the future, *Dr. Nicklas* will not give them your name, address, phone number or any other information that will let the researchers know who you are.

Sometimes data and samples are used for genetic research (about diseases that are passed on in families). Even if your data and samples are used for this kind of research, the results will not be told to you and will not be put in your health records. Your data and samples will only be used for research and will not be sold. The research done with your data and samples may help to develop new products in the future, but there is no plan for you to be paid.

The possible benefits of research from your data and samples include learning more about what causes diabetes and other diseases, how to prevent them and how to treat them. The greatest risk to you is the release of your private information. *Dr. Nicklas* will protect your records so that your name, address and phone number will be kept private. The chance that this information will be given to someone else is very small. There will be no cost to you for any data or sample collection and storage by Dr. Nicklas.

Please read each sentence below and think about your choice. After reading each sentence, circle "yes" or "no." If you have questions, please talk to your doctor or nurse. Remember, no matter what you decide to do about the storage and future use of your data and samples, you may still take part in the study.

I give my permission for my data and blood to be stored at the University of Colorado for future use by the study investigators:

1. I give my permissions for my data and blood to be kept by Dr. Nicklas for use in future research to learn more about how to prevent, detect, or treat diabetes or heart disease.

   ☐ Yes ☐ No _____Initials

2. I give my permissions for my data, blood and tissue samples to be used for research about other health problems (for example: causes of osteoporosis).

   ☐ Yes ☐ No _____Initials

3. I give my permission for my study doctor (or someone he or she chooses) to contact me in the future to ask me to take part in more research.

   ☐ Yes ☐ No

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include

- University of Colorado Denver
- University of Colorado Hospital

- Denver Health

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Jacinda Mawson Nicklas, MD, MPH, MA
University of Colorado Denver
Mailstop C263
12348 E. Montview Blvd.
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- The Centers for Disease Control who are sponsoring this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. [To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed].

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make *all or some* of the following health information about you collected in this study available to: Brigham and Women's Hospital and Westat who is the coordinating agency for this research study.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Your social security number (for the purpose of providing you with payment)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records

What happens to Data and Blood that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data and blood collected from you during this study are important to this study and to future research. If you join this study:

- The data, and blood given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data or blood collected from you.
- If data or blood are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

HIPAA Authorization for Optional Additional Study Procedures

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Witness Signature: _____ Date:_____

Witness Name: _____ Date: _____

Investigator: _____ Date: _____
Investigator must sign within 10 days