Confidential

The Ohio State University Combined Consent and Parental permission to participate in Research and HIPAA Research Authorization

Study Title:	**Using mental imagination to prevent excessive gestational weight gain in overweight and obese pregnant women (*Moms Are Worth It*)**
Principal Investigator:	**Mei-Wei Chang, PhD, RN**
Sponsor:	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

- **This is a consent form and parental permission for research participation.** It contains important information about this study and what to expect if you decide to participate, and if you permit your child to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate and whether or not to permit your child to participate.
- **You and your child's participation and is voluntary.** You or your child may refuse participation in this study. If your child takes part in the study, you or your child may decide to leave the study at any time. No matter what decision you make, there will be no penalty to your child and neither you nor your child will lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you or your child is a student or employee at Ohio State University, your decision will not affect your grades or employment status.
- **You and your child may or may not benefit as a result of participating in this study.** As explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You and your child will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate in this study, and permit your child to participate, you will be asked to sign this form and will receive a copy of the form.

You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The purpose of this intervention study is to help pregnant women make their own personal plans for managing stress or emotion better, healthier eating, and physical activity; thus, to help them reduce their risk for poor maternal and infant health outcomes, for example, gestational high blood sugar, cesarean delivery, and premature birth.

This study will last for 20 weeks and the risk for participating in this study is minimum. We strongly recommend you to stop being physically active including walking, if you experience any shortness of breath or any discomfort. You may want to wear comfortable shoes when you walk. In addition, you may want to consult your health care providers on what physical activity you can or cannot do. If your health care providers tell you that you should be on bed rest, please follow their suggestions.

1. Why is this study being done?

We want to know if a newly developed self-directed, interactive internet-based intervention plus brief individual coaching sessions via Zoom is helpful to pregnant women to better manage stress or emotion, eat healthier and be more physically active. These factors can affect you and your newborn' health. You are asked to help with this research study because you are at or less than 13 weeks of pregnancy with a single fetus, receive prenatal care at OSU-affiliated prenatal care clinics or OSU Ob/Gyn Clinic at McCampbell, and plan to deliver the baby at OSU Wexner medical center.

2. How many people will take part in this study?

Up to 90 pregnant women and 90 newborn babies will take part in this study.

3. What will happen if my child and I take part in this study?

Data collection. After you sign the consent form, you will be asked to do three of following study related activities three times: first time-right after the information session, second time: at 24-27 weeks of pregnancy, third time: at 35-37 weeks of pregnancy.

1. **Online study survey**
   Length. Up to 45 minutes
   How. You will receive a link through your email and text message to do the online survey. You will be asked to click the link to do the survey. You can save the answers and continue to finish later.

2. **Foods you ate or drank during the last 24 hours (24-hour dietary recall).** Total of two random 24-hour dietary recalls at each time point of data collection
   Length. Up to 30 minutes/each recall
   How. We will send you a link, username, and password through your email and text message to do the 24-hour dietary recall. You can save the answers and continue to finish later that day.

3. **Actigraph** (a small device to record your walking steps). Wearing the Actigraph will not harm you or your fetus.
   Length. You are to wear the Actigraph on your non-dominate hand for seven consecutive days with at least 10 hours per day (except when doing water activities including taking shower)
   How. The disinfected Actigraph and wristband will be delivered to your door (without any in person contact). When these items are delivered, we will take a picture then send you the picture via text and/or email to notify you the items being delivered. After you wear the Actigraph for seven consecutive days with at least 10 hours per day, you are asked to text or email the study office to arrange time to pick up the Actigraph. You will be asked to leave the Actigraph in a zip lock bag within a plastic bag by your front door (again, no in person contact). ***The Actigraph is very expensive to the project but has no value to you.*** You are asked to keep the wrist band at the location where you will remember so you can reuse it the second and third times when we ask you to wear the Actigraph. Some women find taking notes in their cell phone or posting a note on the refrigerator door help them remember where they store the wristband.

If you are in the intervention group. You will be asked to complete a phone interview (up to 20 minutes) to let us know areas that the researchers can improve the intervention contents, thus to help more pregnant women in the future**.**

Very important to know. You will be asked to attend the second zoom meeting only if you complete the online survey and two 24-hour dietary recalls, and wear the actigraph for at least five consecutive days with 10 hours per day. The zoom meeting will be recorded (either video or audio per your preference) and must take place at or less than 16 weeks 6 days of pregnancy. This is because we must start the intervention at or less than 17 weeks of pregnancy.

Randomization (like flip a coin).
You will be randomly assigned to an intervention (the self-directed, interactive web intervention and brief individual coaching sessions via aoom plus usual prenatal care) or usual prenatal care group during the second zoom meeting.
If you are in the usual prenatal care group, you will not have access to the intervention website or receive any individual coaching sessoin via zoom during the 20-week intervention period.

Self-generation of reminders. All participants will be asked to self-generate 3-5 messages to motivate and remind them to do the data collection activities. If you are in the intervention group, you will be asked to self-generate 3-5 messages to motivate and remind you to do the intervention activities.

Study newsletters. All participants will receive a study newsletter every other month via email. The newsletter will cover general information on, for example, over-counter medications that you should not take during pregnancy.

The self-directed, interactive web-based intervention: intervention group only. You will be asked to do intervention activities every week for a total of 20 weeks. The intervention has two parts: Part I (Becoming a Better Me) and Part II (Self-Care Booster). You **must use the same device** (such as smart phone or internet-connected computer) and the **same browser for a designated week** to do the parts I and II activities. You can do the intervention activities at the time and location that are convenient to you. You will be asked to do most activities using a dropdown menu. Also, you will be asked to type in short answers for some activities. You can save your responses and finish later the day.

Part I: Becoming a better me.

Length. Up to 25 minutes
When. Each week. You will be asked to do the “becoming me a better me activity” on the days 1-4 of the intervention week.
How. Each week, we will send you the intervention web link through both email and text messages. You will be asked to click the link and use your first and last name and birthday to log in. First, you will be asked to select one of four faces to represent how you have felt and how you want to feel. Also, you will write down your dreams and choose three most important personal values (thigs important to you), ways to commit to the personal values followed by ways to boost confidence in aching personal value. Second, you will be asked to select a short-term goal that you look forward to it and like to accomplish this week. After that, you will be asked to respond to Five Ws (WHAT, WHY, WHEN, WHERE, and WHO), review example plans for accomplishing your chosen goal and respond to HOW—these activities will help you make personal plans. Third, you will be asked to select three daily challenges to implement the plans for accomplishing your goals, three solutions to each of the three chosen challenges, and benefits for overcoming the chosen challenges. Finally, you will receive a summary of “Becoming A Better Me.” You will be asked to save the summary in

PDF in your device to review. You will also be asked to picture your plans for accomplishing your goal two to three times a day until you accomplish the goal.

Please note that during the **second Zoom meeting** you will be asked to use your personal device to complete the part I intervention activity. You will do part I activities for the rest of weeks (weeks 2-20) at any time and convenience location.

Part II: Self-Care Booster

Length. Up to 5 minutes
When. After you accomplish your chosen goal. You will be asked to do the activity on the days 5-7 of the intervention week.
How. You will be asked, for example, how your chosen goal, personal values, stress management, healthier eating, and physical activity went. Then, you will receive tailored messages to motivate you continue manage stress or emotion better, eat healthier, or be more physically active. At the end, you will receive a summary of the "Self-Care Booster." You will be asked to save the summary in PDF in your device to review at any time.

The individual coaching sessions via zoom: intervention group only. During the 20-week intervention period, you will be asked to join a total of 10 individual coaching sessions via Zoom. Each coaching session will be recorded (either audio or videos per your preferences). The recording will be transcribed and be analyzed to help us revise the individual coaching sessions for future studies.

Length. Up to 15 minutes
When. Within two days of completing Part I: becoming a better me.
How. The research staff will schedule the coaching session at your convenient time. S/he will send you the zoom link to join the coaching session. During the coaching session, a research staff will ask you about your chosen goal for the week and your plans for accomplishing your chosen goal. She will also help you problem solve as needed so you can accomplish your goal.

4. How long will my child and I be in the study?

The length of participation starts from the date that you consent providing electronic signature for participation after you deliver the baby.

After completion of the study, we may contact you to ask your interest in participating in other studies or serve on the peer advisory group for other studies

Would you like to be contacted?

- ○ Yes, I would you like to be contacted in the future to potentially participate in other studies.
- ○ No, I do not want to be contacted after completion of this study.

If you agree, we will obtain your consent by asking you to provide your electronic signature during the first zoom meeting.

5. Can my child and I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can my child and I expect from being in the study?

The risk for participating in this study is minimal. You may feel uncomfortable about answering some questions. If you do not wish to answer a question, you may skip it and go to the next question.

7. What benefits can my child and I expect from being in the study?

If you are in the intervention group, you may find the intervention helpful to better manage stress or emotion, eat healthier and be more physically active. It is possible that you will gain appropriate weight during this pregnancy and may have lower risk for gestational diabetes, gestational hypertension and cesarean delivery. In addition, you may have lower risk for delivering your baby at or before 37 weeks gestation and delivering a larger or smaller size baby.

If you are in the usual care group, there are no direct benefits to you for taking part in this study. However, you may become more aware of your stress and emotion, eating behavior, and physical activity.

Results of this study will help researchers modify the intervention content for future intervention studies to help pregnant women better manage stress or emotion, eat healthier and being physical activity.

8. What other choices do my child and I have if we do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There is no cost of taking part in this study.

10. Will my child and I be paid for taking part in this study?

You will receive up to a total of $155 in the form of Amazon electronic gift cards through text and/or your email Table 1 presents incentives for data collection at each time point.

The researcher and research staff will monitor your survey completion, 24-hour dietary recall completion, and duration of wearing the Actigraph to determine the payment.

Table 1. Incentive distribution at each time point of data collection

Activities	Partial complete	100% complete
Online survey	$5.00--do at least 70% of survey but did not complete 100%	$10.00-complete online survey
Two 24-	$ 5.00-complete at least one	$15.00-

hour dietary recalls	24-hour dietary recall but partially complete the second dietary recall	complete two 24-hour dietary recalls
Actigraph	$5.00—wear the Actigraph for four consecutive days with at least 10 hours per day.	$15.00-wear the Actigraph for seven consecutive days with at least 10 hours per day
Innterview via zoom (will be either video or audio recorded per your preference) (intervention group)	$2.00- respond to at least two-third of interview questions	$5.00 –respond to all interview questions.
Total	Up to $17	Up to $45

If you complete the All required data collection activities (such as online survey [100%]complete and two dietary recalls and wear the Actigraph for the seven consecutive days with at least 10 hours/day on your non-dominate hand) at each time point of data collection, you will receive a bonus of $30 at the completion of the study.

You will be notified via a text message and/or email when we send the electronic gift card to you via email and/or text. You can expect to receive the electronic gift card within 3 months of completing data collection at each time point.

By law, payments to participants are considered taxable income.

11. What happens if my child and I are injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my child and I rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. Providing electronic signature to participating in the study, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that

may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects' research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will our de-identified information be used or shared for future research?

No.

14. Will our study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor NICHD, supporting the study, their agents or study monitors

We will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you. Your data will be protected with a code to reduce the risk that other people can view the responses.

If we find information that significantly affects your health, we **will not** share it with you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

Pre-screening data elements	During the course of the study	Post-delivery data elements
Name	Gestational diabetes diagnosis	Date of delivery
Birthdate	Gestational hypertension diagnosis	Gestational age
Gestational age	Body weight at each prenatal visit	Mode of delivery
Date of ultrasound	Lab results of glucose testing	Apgar score
Number of fetuses	Results of ultrasound	Baby weight
Current physical disease (e.g., heart disease, cancer, or renal disease)	Hospital admission-during pregnancy and post-delivery: mother	Length of labor
History of miscarriages (≥ 3)	Pregnancy termination	NICU admission
Diagnosis of eating disorder	Other medical diagnoses	Blood lost
Diagnosis of type 1 or 2 diabetes	Medications	Other medical diagnoses
Diagnosis of hypertension	Blood pressure at each prenatal visit	Medications
Body weight at the first prenatal visit		
Date of the first prenatal visit		
Body weight at the first prenatal visit		
Date of the first prenatal visit		
Height		
Pre-pregnancy weight		
Other diagnoses		
Medications		
Email address		
Mailing address		
Phone number		

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
- working for or with the sponsor; or
- owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;

- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. 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 researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Providing consent for participating in the study means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact

Mei-Wei Chang, PhD, RN
Associate Professor
The Ohio State University College of Nursing
342 Newton Hall, 1585 Neil Avenue, Columbus, OH 43210
Phone: 614-247-7211

Email: Chang.1572@osu.edu.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact Dr. Mary Beth Happ at (614) 292-8336 or happ.3@osu.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If my child or I are injured as a result of participating in this study or for questions about a study-related injury, you may contact Mei-Wei Chang, PhD, RN, 614-247-7211 or Chang.1572@osu.edu.

Please click the "Add signature" link to the right to sign with your mouse or finger. _____

Please enter the date and time you completed this consent form.

(You may click the "now" button to autofill the date and time.) _____