The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: Weight Loss Intervention for Mothers with Young Children

Principal Investigator: Mei-Wei Chang, PhD, RN

Sponsor: **The Ohio State University**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide 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.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, 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 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, 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 women make their own personal plans for managing stress or emotions better, healthier eating, and physical activity; thus, to help them with weight loss. This study will last for three weeks and the risk for participating in this study is minimum. During the study 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.

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 mothers of young children to better manage stress or emotions, eat healthier and be more physically active. These factors can affect your health. You are asked to help with this research study because you are between 6 weeks and 5 years postpartum and receive government benefits.

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

Up to 30 women will take part in this study.

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

Data collection. After you agree to participate by providing your electronic, you will be asked to complete online surveys two times: first time-right after the information session, second time: right after you complete the three-week intervention. Also, you will be interviewed via Zoom.

Online study survey
Length. Up to 20 minutes
How. You will receive a link through your email and text message to do the online survey. You can save the answers and continue to finish later.
When. Right after (1) the information session and (2) completing the three-week intervention

Interview via Zoom
Length. Up to 20 minutes
How. You will receive a link through your email and text message to join the Zoom. You will be asked to evaluate the intervention study so that the researchers can improve the intervention contents, thus to help more women in the future
When. Right after completing the three-week intervention

Very important to know. ***You will be asked to attend the second zoom meeting only if you complete the online surveys within three weeks of the first Zoom meeting***. Each zoom meeting will last up to 40 minutes and be recorded (either video or audio per your preference).

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, intervention activities, and other study activities.

The self-directed, interactive web-based intervention. You will be asked to do intervention activities every week for a total of three 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 35 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 must 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. You will write down your dreams and choose three most important personal values (things important to you), ways to help commit to the personal values followed by ways to boost confidence in achieving personal values. Second, you will be asked to select a short-term goal that you look forward to it and like to accomplish. 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. 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 2-3) 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 messages to motivate you to continue to manage stress or emotions 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. During the three-week intervention period, you will be asked to join a total of three 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 20 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 I be in the study?

The length of participation starts from the date that you consent by providing electronic signature.

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

Would you like to be contacted?

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

We will obtain your consent by obtaining your electronic signature during the first zoom meeting.

5. Can 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 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. You may feel some minor discomfort during physical activity. We strongly recommend you to stop being physically active including walking, if you experience any shortness of breath or any discomfort.

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

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 lose weight. In addition, you may have lower risk for type 2 diabetes or cardiovascular disease. Results of this study will help

researchers modify the intervention content for future intervention studies to help women better manage stress or emotions, eat healthier and be physically active.

8. What other choices do I have if I 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 I be paid for taking part in this study?

You will receive up to a total of $30 in the form of electronic gift cards through text and/or your email for providing data for this study.

The researcher and research staff will monitor your survey completion to determine the payment.

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

Activities	Partial complete	100% complete
Online survey (each time point of data collection)	$5.00--do at least 70% of survey but did not complete 100%	$10.00-complete online survey
Interview via zoom (will be either video or audio recorded per your preference) (intervention group)	$5.00- respond to at least two-third of interview questions	$10.00 –respond to all interview questions.
Total	Up to $15	Up to $30

You will be notified via a text message and/or email when we send the electronic gift cards 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 I am 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 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. By signing this form, 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 my de-identified information (and bio-specimens) be used or shared for future research?

Yes.

14. Will my 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 supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

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.

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?

- Your name, birthday, postpartum status, age, and medical diagnosis, for example, diabetes

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?

Signing this authorization also 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.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily 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 combined consent and HIPAA research authorization form**.**

To print or save a copy of this page, select the print button on your web browser.

If you do not wish to participate 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.)

If you do not wish to participate, please close out your browser window.