Study title: The Healthy Moms Study: Comparison of a Post-Partum Weight Loss Intervention Delivered Via Facebook or In-Person Groups

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Informed Consent Form

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Consent Form for Participation in a Research Study

UCONN
UNIVERSITY OF CONNECTICUT

Principal Investigator: Molly E. Waring, PhD

Study Title: The Healthy Moms Study: Comparison of a Post-Partum Weight Loss Intervention Delivered via Facebook or In-Person Groups

Sponsor: National Institutes of Health (NIH)

Introduction

You are invited to participate in a research study to compare a weight loss program for new moms through a private (secret) Facebook group versus in-person group meetings. You are being asked to participate because you are a woman who gave birth between 8 weeks and 12 months ago and are interested in losing weight.

This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks, inconveniences or discomforts that you may have while participating. We encourage you to take some time to think this over and to discuss it with your family, friends and doctor. We also encourage you to ask questions now and at any time. If you decide to participate, you will be asked to sign this form and it will be a record of your agreement to participate. You will be given a copy of this form.

Why is this study being done?

The purpose of this research is to compare two ways to help women lose weight after having a baby. We are testing to see how delivering weight loss counseling in a private (secret) Facebook group compares to weight loss counseling in-person group meetings.

What are the study procedures? What will I be asked to do?

If you decide to participate in this research study, we will ask you to attend a baseline visit and complete an online survey, attend an orientation webinar, participate in a 6-month weight loss intervention, and attend follow-up visits and complete online surveys at 6 and 12 months.

Baseline procedures.
Baseline study visit. We will ask you to attend a 30- to 45-minute study visit. At this visit, we will describe the study and procedures and ask you to provide written informed consent. We will measure your height and weight and ask you to provide your contact information and answer some additional questions to determine whether you are eligible to participate in the intervention. If you have an iPhone, we will show you how to look up how much time you have spent recently

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using the Facebook app using the battery usage statistics. If you have an Android phone, we will ask you to install the free app Rescue Time, which tracks the time you use different apps, and show you how to use it. If you do not want to install Rescue Time, you don't have to; you can still participate in the study without installing this app. We will also encourage you to install the free My Fitness Pal app to help you keep track of what you eat and your physical activity, and will help you set up an account and show you how to use it. If you do not want to install My Fitness Pal, you don't have to; you can still participate in the study without installing the app. After this visit, we will ask your primary care provider or obstetrician/gynecologist to provide approval for you to participate. If your doctor does not provide approval, you will not be able to participate in the intervention.

Baseline survey. After your baseline study visit, we will ask you to complete a survey at home. We will send you a link to the survey via email. In this survey, we will ask you about your experiences and feelings (for example, social support) and behaviors (for example, how you feed your baby). We will also ask you about questions about your reproductive health and past pregnancies (for example, how much you weighed before your most recent pregnancy) and demographics (for example, marital status, education).

Orientation webinar. We will ask you to attend a 60-minute webinar which will include an explanation of what research is, a description of study procedures, and the importance of attending study visits.

Pre-randomization survey. We will email you a link to a short online survey to report your current weight and how much time you spent on Facebook in the past week. During this survey we will also ask you to commit to being in the study (randomization agreement). We expect this survey to take less than 5 minutes.

Once you've completed all baseline procedures, we will determine your final eligibility to participate. In order for us to randomize you, you need to complete the baseline study visit and online survey, we need to receive medical clearance from your primary care provider or obstetrician/gynecologist, you need to attend the orientation webinar, and you need to complete the pre-randomization survey.

Randomization. We will randomly assign you to one of two weight loss interventions. One intervention is online (Facebook) and one is in-person (in-person). Both interventions include the same weight loss intervention content. You have a 50/50 (equal) chance, like the flip of a coin, of being in one group or the other. You should only agree to participate in this study if you are OK with being assigned to either the Facebook intervention or the in-person intervention and don't have a strong preference for either condition.

Weight loss intervention. You will participate in a 6-month weight loss intervention with other women who recently had a baby. You will receive this intervention either through in-person group meetings or a private (secret) Facebook group.

If you are assigned to the **in-person** intervention: During the 6-month intervention you will receive dietary and exercise counseling and tips to help you meet your healthy lifestyle goals via 90-minute in-person groups. These groups will meet weekly for the first four months of the

intervention and then every other week in months five and six. You will receive calorie and physical activity goals to help you achieve a healthy weight loss of 1-2 pounds per week. We will encourage you to track your diet and exercise daily, which will help you stay on goal. Groups will be audiotaped for quality control of the intervention.

If you are assigned to the **Facebook** intervention: During the 6-month intervention you will receive dietary and exercise counseling and tips to help you meet your healthy lifestyle goals via a secret Facebook group. We encourage you to share your progress, ask questions, and talk with the counselor and other women in your weight loss group within this Facebook group. You will receive calorie and physical activity goals to help you achieve a healthy weight loss of 1-2 pounds per week. We will encourage you to track your diet and exercise daily, which will help you stay on goal.

Groups can be created on Facebook and with the use of privacy settings we can determine who can see the posts and who can participate. We will have the privacy settings on Facebook group in this study set to "secret" which means that people can only join if they are invited by the study team and posts in the group are only viewable by invited members. Your Facebook friends will not be able to see that you are a member of this group, and posts in this group, or any comments you make on them, will not show up in your Facebook friends' newsfeeds. It is always a possibility that other group members could screenshot content and share the screenshots or to discuss what is happening in the group with other people, but we will ask all participants to in no way share any content in the group with anyone. Please be advised that since Facebook controls its privacy settings, they may update or change these settings at any time.

We will download data from the Facebook group including posts, comments, and reactions from the weight loss counselor, you, and other people in your group so that we can study this data to better understand how people participate and how much response our posts garnered from the group. We will not download any data from your Facebook profile or any post to your feed – just your posts, comments, and the posts/comments you reacted to in the study Facebook group. Facebook may ask you to indicate (for example, by clicking on a button) that you are OK with us collecting these data from Facebook.

Weekly email reports. Regardless of which intervention condition you are in, each week, we will email you a link to a short online survey to report your current weight and how much time you spent on Facebook that week. This survey should take less than 5 minutes each week.

6-month follow-up procedures. At 6 months, we will ask you to complete an online survey and attend a group study visit. We will email you a link to an online survey. The survey will ask you about your thoughts and feelings (for example, stress, mood, social support) and behaviors (for example, how you feed your baby, how much of the time you spend sitting, sleep habits). We will ask you to tell us what you thought of the intervention (for example, whether you would recommend it to a post-partum friend) and about other things you may have done to lose weight (for example, joining another weight loss program). We expect that the survey will take 30 minutes. At the in-person study visit, we will weigh you. The study visit will also include a group discussion (focus group) with other women in your weight loss group about what you liked and didn't like about the intervention. We will audiotape this discussion. We expect that the study visit will take about 1.5 hours.

12-month follow-up procedures. At 12 months (about 6 months after the end of the intervention), we will ask you to complete an online survey and attend a study visit. We will email you a link to an online survey. The survey will ask you about your thoughts and feelings (for example, mood, social support) and behaviors (for example, how you feed your baby). We expect that the survey will take about 30 minutes. At the in-person study visit, we will weigh you. We expect that the visit will take about 15 minutes.

What other options are there?

Instead of being in this research study, you can choose to not participate. Your doctor may be able to suggest other options to help you lose weight.

What are the risks or inconveniences of the study?

Possible risks related to this research study include: injury during exercise and psychological discomfort while completing surveys. We try to avoid injuries by encouraging you to avoid exercise that could result in discomfort, pain, or injury.

If you report that you are a safety concern to yourself or someone else we will need to release your confidential information for emergency care purposes. At the beginning of the study and at 6 and 12 months, you'll answer some questions about your mood (i.e., depressive symptoms). If we find that answers on the form are concerning, we will ask you to consult with your primary care provider or obstetrician/gynecologist to discuss your symptoms. The study team will also contact your primary care provider or obstetrician/gynecologist and give her/him your results. We may also determine that you need psychiatric care immediately and we'll make arrangements for you, and also consult with your primary care provider or obstetrician/gynecologist. We also encourage you to talk to your weight loss counselor or your primary care provider, obstetrician/gynecologist, or another health care provider if you feel depressed or experience any unexpected mood changes at any point during the study.

One of the risks of being in this study is that your personal information could be lost or exposed. To minimize this risk, we will do everything we can to make sure that your information is protected. We describe how we will protect your information below. If you do not wish to answer any of the questions on the survey, you may leave it blank. If you feel discomfort during any part of the study procedures you may withdraw at any time.

If you are randomly assigned to the Facebook condition, information you share in the Facebook group is subject to Facebook's terms of use and privacy policy, including terms of use for their website and mobile application. We encourage you to re- review these terms and the privacy policy. Facebook may be able to collect, store and use information about you, such as personal information, location data, shared information, photographs, and more. During the study, if the research team becomes aware of any changes made to Facebook's privacy policy, we will notify you that Facebook's policy has been updated and will encourage you to review your Facebook privacy settings. The Facebook group is private ("secret") and posts are only available to group members. We ask that you not use locations or contact information, when talking to other study participants. We will also ask not to disclose that you are in a research study to protect

confidentiality of other participants and not to share posts from the Facebook group with people not in the group. The research team will not download (save) any photographs you share in the Facebook when we download engagement data. Online social interactions will be monitored by study staff to help ensure the protection of privacy. We will delete the Facebook group 6 months after the last post or comment.

We encourage you to track what you eat and your physical activity throughout the study period, and we suggest My Fitness Pal as a tool to help you with tracking. If you have an Android phone, we will ask you to download the Rescue Time app and report to us throughout the study how much time you are spending on Facebook. Information you enter into an app or website or allow an app or website to access from your phone (such as My Fitness Pal or Rescue Time) is subject to that company's terms of use and privacy policy. You should review these terms and the privacy policy carefully before choosing to download and use the app or the website. My Fitness Pal may be able to collect, store and use information about you, such as personal information, location data, shared information, photographs, and more. During the study, if the research team becomes aware of any changes made to their privacy policy, we will notify you that this has occurred and will encourage you to review your privacy settings. For any app or website, we encourage you to choose a password that includes a mix of lowercase letters, uppercase letters, numbers, and symbols, and does not include your username, the app/website name, or other easily-guessable information about you. We also encourage you to not use the same password across different accounts, and to not share your passwords with others.

There may be unforeseen risks involved in taking part in this study. A possible inconvenience is the time it takes to participate in this study.

What are the benefits of the study?

It is hoped that you will benefit (losing weight) by participating in this study. However, we cannot promise a benefit. Additionally, results of this study may help other women in the future.

Will I receive payment for participation? Are there costs to participate?

Facebook, My Fitness Pal, and Rescue Time (Android) do not cost any money to use. We encourage you to check your data usage plan to ensure you are using the appropriate settings on your phone to minimize the use of your data so you don't incur any charges due to any increased use of apps during participation in the study.

You will receive a $20 gift card after completing the baseline assessment (study visit and online survey) and a $40 gift card after completing follow-up assessments at 6 months and 12 months (study visit and online survey), for a total of $100. You will be reimbursed up to $5 for parking or bus fare for each study visit or intervention meeting, as needed.

This research may lead to the development of a commercial product. This product may have economic benefit to UConn. If such a product is developed, UConn do not intend for you to share in the economic benefit.

How will my personal information be protected?

The following procedures will be used to protect the confidentiality of your data. The researchers will keep all study records (including any codes to your data) locked in a secure location. Research records will be labeled with a code. The code will be derived from a number that reflects how many people have enrolled in the study.

When we transcribe (type) the audio recordings of the focus group discussions at the 6-month study visit, we will remove your name and type in your study code instead. After transcription, we will delete the audio recording. If you are randomized to the Facebook condition, we will download data from Facebook that includes all the posts and replies posted in the intervention group. We will remove your name and others' names from these data and replace your name with your study code.

A master key that links names and codes will be maintained in a separate and secure location. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. Data that will be shared with others will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee 100% confidentiality. Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties. As described above, if you are randomly assigned to the Facebook condition, the Facebook group will private ("secret") and posts are only available to group members, but use of Facebook is governed by Facebook's terms of use and privacy policy, including what Facebook can do with any information you post on their website or through their mobile app.

Data that we collect from you may be shared with other researchers in the future, but only after your name and all identifying information have been removed.

If you choose to stop participating in this study, data that has already been collected will remain part of the study database and may not be removed in order to maintain the integrity of the research. However, any identifiable information will be destroyed so that no one can tell the data belonged to you.

If, during the course of this research study, a UConn employee suspects that a minor (under the age of 18) has been abused, neglected, or placed at imminent risk of serious harm, it will be reported directly to the Department of Children and Families (DCF) or a law enforcement agency.

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.

You should also know that the UConn Institutional Review Board (IRB) and Research Compliance Services may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

What happens if I am injured or sick because I took part in the study?

In the event you become sick or injured during the course of the research study, immediately notify the principal investigator or a member of the research team. If you require medical care for such sickness or injury, your care will be billed to you or to your insurance company in the same manner as your other medical needs are addressed. There are no funds available to reimburse you for this medical care.

However, if you believe that your illness or injury directly resulted from the research procedures of this study, you may be eligible to file a claim with the State of Connecticut Office of Claims Commissioner. For a description of this process, contact Research Compliance Services at the University of Connecticut at 860-486-8802.

Can I stop being in the study and what are my rights?

You do not have to be in this study if you do not want to. You do not have to answer any question if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate. If you are assigned to the Facebook intervention and you decide to stop your participation, you may leave the Facebook group or request that we remove you from the Facebook group.

You will be notified of all significant new findings during the course of the study that may affect your willingness to continue.

You will be withdrawn from the study if: you become pregnant, you disrupt in-person groups, or you post inappropriate content on Facebook.

Whom do I contact if I have questions about the study?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this study or if you have a research-related problem, you may contact the principal investigator, Dr. Molly Waring, PhD at 860-486-1446. If you have any questions concerning your rights as a research participant, you may contact the University of Connecticut Institutional Review Board (IRB) at 860-486-8802.

Documentation of Consent:

I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.

_____	_____	_____
Participant Signature	Print Name	Date
_____	_____	_____
Signature of Person Obtaining Consent	Print Name	Date