

Consent Form (Information Sheet)

Study Title: Single arm trial of a multi-component commercial digital weight loss

NCT04302389

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Information Sheet for Participation in a Research Study



Principal Investigator: Sherry Pagoto

Study Title: Single arm trial of a multi-component commercial digital weight loss

Sponsor: WW (formerly known as Weight Watchers)

Disclosures: Dr. Pagoto is a paid consultant for WW International, Inc.

Dr. Pagoto advises WW on their suicide risk protocols for their online communities.

Overview of the Research

You are being asked to provide consent to participate in a research study. Participation is voluntary. You can say yes or no. If you say yes now you can still change your mind later. Some key points to consider are summarized in this overview, but you should consider all of the information in this document carefully before making your decision.

- This research is being done to evaluate an updated WW lifestyle modification program. Participation will involve approximately 21-33 hours of your time over the next 7-months.
- The screening process includes a phone call with study staff to give you more details about the study, two surveys, and agreeing to a Non-Disclosure Agreement with WW.
- The possible risks of this study include injury during exercise, exposure of personal information, or discomfort with study procedures. If you feel discomfort during any part of the study procedures, you may withdraw at any time. Risks are described in more detail later in this form.
- There may also be benefits from participation. It is possible you may lose weight by participating in this study, but we cannot promise that. This research may also result in information that leads a societal benefit to deliver more widely available weight loss programs.
- Before making a decision about whether to participate in this research, you should know that there are other options available to you. You may choose not to participate in the study or you may wish to talk to your doctor to review other weight loss options available to you.
- A more detailed description of this research follows.

Introduction

You are being asked to participate because you are interested in losing weight.

Why is this study being done?

The purpose of this study is to test out an updated WW lifestyle modification program to see if this helps with greater weight loss. We're looking for people with a variety of backgrounds who are interested in trying out a new weight loss program. You will be asked to follow the weight loss program for 6 months.

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

This is an online-only study. If you would like to take part in this research, your participation will include 2 online surveys during screening, a screening phone call, signing a Non-Disclosure Agreement, set-up of study materials (scale and app provided to you), a 6-month WW weight loss program, a survey and weigh-in mid-way through the study, and a survey and weigh-in at the end of the study. Your participation will last approximately 7 months.

Screening surveys and phone call:

Screening involves an online survey (starting on the next page), a telephone call with study staff, followed by a second online survey.

Non-Disclosure Agreement:

Because this WW program is new and not yet available to the public, WW will ask you to sign a Non-Disclosure Agreement (NDA) prior to enrolling in the study. An NDA is a contract that promises confidentiality between two parties, typically meant to protect private information. We will send you the NDA before you officially enroll. You will be asked not to share any of the materials you are provided, with anyone else. You will also be asked not to disclose any information regarding any of the materials you use or that you see during the study (e.g., app content, features in the app, the design of the app, information that is provided to you) with anyone else. You can contact the study team or the UConn IRB if you have a concern about this study. You can choose not to sign the NDA if you are uncomfortable with it. However, you will not be able to participate in the study. Please contact us if you have any questions regarding this. Our contact information is at the bottom of this sheet.

Weight Loss Program:

During the 6-month weight loss program, you will use an updated version of the WW app, attend weekly virtual workshops, and be able to receive motivational support from other study members in a private Facebook group. You will be asked to use the app daily for 6-months and participate in weekly virtual workshops. The program weight loss goal is 1-2 pounds per week and includes tracking weight, food, and exercise; making dietary changes; increasing exercise; and preventing weight re-gain.

WW app – The app will guide you through an assessment and then from there you will get a personalized food plan based on expert healthy eating guidelines and the latest nutritional science. You will also receive an activity plan designed to promote regular physical activity and techniques to help you shift towards a helpful mindset for lasting change. You will also be able to track these within the app to monitor your progress throughout the program.

Virtual Workshops – The virtual workshops will be online-based meetings. These workshops will be conducted through Zoom (a video conferencing app). They will be held on a weekly basis during the 6-month intervention and will last between 30-60 minutes. A trained WW coach will be leading the group. During these workshops, you will receive group support from participants. You will also have the opportunity to discuss progress and setbacks, troubleshoot challenges, receive help with goal setting, and discuss and learn about various topics surrounding promoting a healthy lifestyle. You may call into these meetings if you prefer. We ask that once you pick a workshop time, you agree you can commit to that time for the duration of the program. The virtual workshops will not be recorded.

Facebook Group – You will have the option to join a private Facebook group with other study participants that gives members an opportunity to receive motivational support from each other. You can share your journey through photos, videos, and comments, encourage others, and ask questions to other participants. The moderators of the group will not be posting intervention content or provide coaching, but will be there to monitor the group.

Milestone Charms – You will have the opportunity to receive charms for achieving a weight loss milestone. WW will send you a small keychain if you hit a weight loss goal milestone of: 5lbs, 10lbs, 15lbs, 20lbs, 25lbs, 30lbs, 40lbs, 50lbs, 75lbs, 100lbs, 125lbs, 150lbs, 175lbs, and 200lbs during the program. Weight loss is reviewed on a weekly basis and if you have hit a weight loss milestone, UConn staff will let WW know, and they will ship the charms out to you. You can opt-out of receiving charms at any time.

Market Research – After the study is over, you will be asked by WW to participate in a market research focus group. They will ask you if you are interested during your final workshop. Your participation is voluntary, you can say yes or no. WW is interested in gaining more understanding about the user experience with the app and program. Participating in the market research focus group is not a part of this research study and will be solely between you and WW. It will also not affect your participation or your status as a participant in this study in any way.

We ask that all participants in the study to not disclose to others that you in a research study. As is the case with any online activity, it is always possible that other members in a virtual workshop or the Facebook group could screenshot content and share the screenshots or to discuss what is happening in the group with other people. Be cautious about what you post about regarding your name, location, or other personal information. We will receive the information that you enter in these platforms so that we can study this data to better understand how people participated. Specifically, we will collect what you enter for your diet, weight, exercise, and other app features you may use your attendance to virtual workshops, and your posts, comments, views, and reactions in the Facebook group.

Weekly Weigh-ins:

You will receive a WW Bluetooth scale so we can keep track of your weight throughout the study. Once we determine that you are eligible, we will confirm your mailing address and WW will process and ship the scale to you directly. Once you receive the scale, we can help you set it up. To set it up, you will need your phone and to download a separate WW app that is specifically used for the scale. We ask for participants' weights at the beginning of the study throughout the program, and at the 3-month and 6-month assessments so that we have a measure of how people are doing. It is important that you weigh yourself at these time points in the morning with no clothing and before eating or drinking so that we can get an accurate measure of weight for everyone. Weight is uploaded directly from the scale to the WW scale app and then synchronizes to the WW app. At the end of the study, the scale is yours to keep. In the event you have issues with your weights uploading to the WW apps, we will have you report your weight via a private survey link. On the survey, you can upload a screenshot of your weight displayed on the scale. Study staff will record your weight in our database and then permanently delete the screenshot.

Follow-up:

We will ask you to complete surveys mid-way through the program (at 3-months; about 20 minutes) and at the end of the program (at 6-months; about 40 minutes). The surveys will include a repeat of what you complete during the screening process as well as a feedback survey. We will also collect your weight at these time points as well.

Data Collection:

During this study, we will collect your study data in these ways: 1) the surveys you complete at the beginning, middle, and end of the study, 2) your WW app entries, 3) the virtual workshop attendance) your posts, comments, and reactions in Facebook and 5) your weight from the study scale. This information is very important to our study and necessary to answer our study questions. If you are uncomfortable with the study team accessing this data, you may choose not to participate in the study.

We use a software program called Grytics to collect engagement data (posts, comments, reactions) from the Facebook group. When you join the Facebook group, you'll be asked to click a link to "opt in" to the Grytics software so we can collect your engagement (posts, comment, reactions) from the group; this process is voluntary and not required for participation in the study. The study team Grytics account is password protected and only members of the study team will be able to view and download the engagement data collected by Grytics.

Time Commitment:

See the table below for the expected time commitment for participating in the study.

Study Phase	Time
Initial Screening Survey (5 min)	5
Telephone Screening (30 min)	30
Baseline (65 min total) Scale/app set-up (15 min) Online survey (40 min) NDA acknowledgement (10 min)	65

Intervention Pilot (24 wks)/15 min/day Virtual workshops (24 wks) 30-60min/week	1,080-1,800
Follow-up surveys: 3-month online survey (20 min) 6-month online survey (40 min)	60
Total	1,240-1,960minutes (approx. 21-33 hrs)

What other options are there?

You may choose not to participate in the study or you may wish to talk to your doctor to review other weight loss options available to you.

What are the risks or inconveniences of the study?

Possible risks related to this research study include injury during exercise. We try to avoid injuries by avoiding exercise that could result in discomfort, pain, or injury. Another possible risk 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. Confidentiality will be maintained by the use of network secured database and locked file cabinets only accessible to study staff.

Information you share in the WW app (including weights uploaded from the study scale), is subject to WW's terms of use and privacy policy, for their website and mobile application. Information you share in the virtual workshops is subject to WW's terms of use and privacy policy, as well as Zoom's terms of use and privacy policy. Information you share in the private Facebook group is subject to Facebook's terms of use and privacy policy, for their website and mobile application. You should review these terms and the privacy policies carefully before participating and downloading the app. WW, Zoom, and 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 WW's, Zoom's, or Facebook's privacy policy, we will notify you and will encourage you to review the applicable privacy settings. We cannot guarantee confidentiality, though, we do everything we can to protect it. To help protect yourself, please do not share your location or contact information in the group. The research team will not download any photographs you share in the Facebook group when we download engagement data. Online social interactions will be monitored by WW staff to ensure the protection of privacy and will be brought to our attention if necessary.

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.

If you feel discomfort during any part of the study procedures, you may withdraw at any time.

What are the benefits of the study?

It is hoped that you will receive a benefit (weight loss) by participating in this study, however we cannot promise a benefit. Benefits to society include providing evidence to support more widely available weight loss programs.

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

We will provide \$20 compensation for completing the screening procedures (telephone screening, NDA signature, and survey), \$50 for completing the 3-month survey and weighing-in, and \$50 for completing the end-of-study survey and weighing-in. Compensation will be in the form of an online Amazon gift card e-mailed to you after you provide weight and complete the survey at each assessment. You can also keep the scale.

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. At the end of the study, we will remove your name and contact information from the research records and replace with a code. The code will be a three digit number that reflects how many people have contacted the study team to express interest in the study. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. The app and virtual workshop data sent to UConn by WW will also be sent in a secured file transfer. Any computer hosting files will have password protection to prevent access by unauthorized users. Only the members of the UConn 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 and WW 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.

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. 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 this website at any time.

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. 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.

On the other hand, UConn reserves the right to withdraw you from participation if it becomes known that weight loss could harm you (e.g., you become pregnant) or post inappropriate content on the online community (e.g., attacking other participants, discriminating against others, consistent explicit language).

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 project or if you have a research-related problem, you may contact the principal investigator, Dr. Sherry Pagoto (sherry.pagoto@uconn.edu, 860-486-2313) or the research coordinators (mhealthstudy@uconn.edu). If you have any questions concerning your rights as a research subject, you may contact the University of Connecticut Institutional Review Board (IRB) at 860-486-8802.

NEXT STEPS

If you are interested in learning more about this research and participating, proceed to the next page and begin the initial screening survey. In this survey, the only personal contact information we will collect is your e-mail address. If you are eligible to proceed with the study, we will collect your name and contact information. The questions in this survey will ask questions to determine your eligibility. Some of these questions are related to your health. We will retain this information for our data analysis. All data will be de-identified after the study is over.