Log2Lose: Incenting Weight Loss and Dietary Self-monitoring in Real-time to Improve Weight Management Among Adults With Obesity
NCT04770909

PI: Corrine I Voils, PhD, University of Wisconsin, Madison
8/8/2023

University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

Study Title for Participants: Log2Lose

Formal Study Title: Measuring weight loss and dietary self-monitoring in real-time to improve weight management

Lead Researcher: **Corrine I. Voils, PhD**
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K6/100 CSC
Madison, WI 53792-1690
(608)262-9636

Where Lead Researcher works: University of Wisconsin, Department of Surgery

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Invitation

We invite you to take part in a research study to compare different types of strategies to help people build habits for a healthy lifestyle.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information.

Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. Once we have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent."

Why are researchers doing this study?

People who log what they eat and weigh regularly tend to lose more weight and keep it off. Research shows that over time, people tend to do this less often. We are doing this study to compare different strategies that may help motivate people to log their food and weigh themselves regularly.

This study is being done at the University of Wisconsin-Madison (UW-Madison) and Duke University in Durham, NC. About 700 people will participate in this study; of those, roughly half (about 350) will take part in the study at the UW-Madison. Funding for this study is provided by the National Heart, Lung, and Blood Institute.

IRB Approval Date: 8/14/2023
University of Wisconsin – Madison

What will happen in this study?

Initial Screening /Baseline Visit

Once you qualify for the study, we will ask you to complete surveys and have your blood pressure checked. These activities will take about 30 minutes. You may choose to skip any question that you do not wish to answer.

- Demographics – This survey asks you to provide your age, race, ethnicity, gender and birth sex, insurance status, financial stress, education, smoking status, alcohol use, illicit drug use, employment status, stressful life events, and previous weight loss attempts.
- Motivation for weight loss – This survey will ask you questions about things that motivate you to lose weight.
- Medication use - This survey asks if you are taking medications for blood pressure, cholesterol, or type 2 diabetes, and, if so, the names and dosages of those medications.
- Health status – This survey will ask you questions about your general health.
- Delayed discounting and weight loss choice – These surveys will ask about how appealing things are the longer you have to wait for them.
- All or nothing thinking – This survey will ask you questions about all or nothing thinking patterns.
- Blood pressure – We will take your blood pressure on your right upper arm, if possible. If not, then we will take it on your left arm.
- Physical activity and sleep – A Fitbit will be used to measure your physical activity (steps and active minutes) and sleep. The study team will give you instructions on how to use and wear the Fitbit, download the Fitbit app to your smartphone, charge your Fitbit and sync the Fitbit to your phone. You will receive a text message and/or e-mail reminder before group classes begin to wear the Fitbit continuously for 7 days. We ask that you wear it 24 hours per day. You may choose to take it off for showering/bathing, but many people find it more convenient to leave it on. If you do not attend your first group session, we will ask you to return the Fitbit to the study team.

Once you complete the surveys and have your blood pressure taken, you will be randomly assigned (like drawing numbers from a hat) to one of four groups. You will find out which group you are in at the first group class. You must attend the first group class or make arrangements to make it up in order to participate in the study.

Each group will receive different text messages. All groups will receive 3-5 informational and/or motivational texts per week that could help you manage your weight. You will also receive occasional reminders for group classes, phone calls with the dietitian, and study visits. Should you change your cell phone number during the study, we ask that you notify us immediately at 608-265-8758.

Being a part of this study includes a virtual weight program. We have outlined what the program includes below:

Weight Loss Group Classes: Months 1 - 6

We ask that you attend group classes led by the study dietitian via video conference every 2 weeks for 6 months. Classes will cover nutrition, physical activity, and goal setting. Virtual classes will be 1 to 2 hours long.

While you are participating, you will be instructed to weigh yourself and track what you eat and drink regularly. We will give you a digital scale to keep at home. This scale will use cell towers to send a record of your weight to the manufacturer, BodyTrace. BodyTrace will then send your data to our data system at Duke University. If the scale is damaged during the study, it will be up to the discretion of the Lead Researcher to replace the scale.

We will ask you to download Fitbit, an application ("app") onto your smartphone. You will use Fitbit to track your food and drink. Fitbit will send data to our system.

Weight Loss Maintenance Group Classes: Once a month in Months 7, 8 and 9

In month 7, group classes will decrease to once per month and focus on weight loss maintenance. These classes will occur via video conference. They will be 1 to 2 hours long.

You will continue to receive text messages between 2-5 times per week with reminders and other study messages.

Weight Loss Maintenance Telephone Calls: Months 7-18

We will ask you to participate in individual phone calls with the study dietitian that focus on building skills to help you maintain your weight loss. These will occur once per month in months 7-10, and again at months 12, 14, 16, and 18. Calls will last up to 30 minutes.

You will continue to receive text messages between 2-5 times per week with reminders and other study messages.

As part of the study, we will audio record all group classes and maintenance telephone calls. The sessions are recorded to ensure the quality of the classes and telephone calls. The audio recordings will be kept for up to 7 years after the study is completed and will be destroyed 7 years after the study is completed. The audio recordings will not be used for purposes outside of the study or in any presentations or publications.

Months 3, 9, and 15

We will ask you to complete surveys about your motivations for weight loss. At month 3, we will ask about the time you spend doing study activities. You will receive a link to the surveys via text message and/or e-mail.

Months 6, 12 and 18

We will ask you to complete study visits at months 6, 12 and 18. At these visits:

- Your weight and blood pressure will be checked. Your blood pressure will be taken on your right upper arm if possible, otherwise your left arm.
- We will ask you to fill out surveys about your motivation for weight loss, time you spend doing study activities, health status, weight loss choice and delayed discounting, other weight loss methods you may have tried outside of the study, your study experience and medication use (medication use only completed at month 18). At month 18, there will also be a survey that asks for your feedback about the study text messages. You will receive a link to the surveys via text message and/or e-mail.
- Physical activity and sleep - You will receive a text message and/or e-mail reminder about when to wear the Fitbit continuously for 7 days.

Months 19-24

- At month 18, the study team will ask whether or not you will allow the study team to continue collecting your weight from the study provided scale for an additional 6 months (months 19-24). This is optional. Collecting this information will help researchers see what happens with your weight after the study has ended.

How we will use your protected health information (PHI)

Protected health information, also called PHI, is information about your physical or mental health that includes information that can identify you, like your name, date of birth, or medical record number. To do this study, we will use the following kinds of PHI:

- Results of tests or procedures done as part of the study (e.g., blood pressure, height, weight)
- Information about your health that you share with the study team
- Specifically, the following PHI will be collected for this study: Name, address, date of birth, phone number, e-mail, audio recordings, web addresses, and/or internet protocol addresses (numeric label that uniquely identifies a specific computer or device connected to a specific network). The internet protocol address will be collected by our study website to track who visits it. Most websites collect internet protocol addresses for this purpose.

How long will I be in this study?

You will be part of the study for about 20 months while you attend group classes, participate in telephone calls, and complete study visits. If you allow the study team to keep collecting your weight from months 19-24, then you will be in the study for up to 26 months.

The researchers may take you out of the study, even if you want to continue, if

- Your health changes and the study is no longer in your best interest and/or it is unsafe for you to continue your participation (e.g., you develop cancer or, if you are of child-bearing potential and you become pregnant)

- You do not follow the study rules or no longer meet the requirements to be in the study
- The study is stopped by the sponsor or researchers

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

Let the researchers know if you choose to leave the study. If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) will last until the research study is done. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to continue taking part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the lead researcher, Corrine Voils, PhD, at
  K6/100 Clinical Science Center
  600 Highland Ave.
  Madison, WI 53792

Will being in this study help me in any way?

- Being in this study may help you lose weight and help you feel better. The study treatment may work better than standard care for your condition, but we cannot promise this will happen. The study treatment might not work at all. Even if the study does not help you directly, your participation in this study may help other people in the future by helping us learn more about how using different types of strategies within the context of a weight management program affect long-term weight loss.

- This study is not a substitute for your regular medical care. You should continue to see your regular medical providers.

What are the risks?

- Dietary changes and/or weight loss can result in low blood pressure or blood glucose levels in participants taking medication for these health problems. You will be instructed on how to recognize and respond to symptoms of low blood pressure and blood glucose levels. Study staff will also be trained how to respond to these symptoms. The study physician will be available to address any of your concerns.

- You may have minor discomfort or bruising at the site of your upper arm from the blood pressure cuff. To prevent this, you will receive the appropriately sized cuff based on the size of your upper arm. If your blood pressure is excessively low or high, the study team will instruct you to follow up with your health care provider.

- You may experience minor skin irritation as a result of wearing the Fitbit wrist-worn device. To reduce the potential for irritation, study staff will provide wear and care tips. If you do experience skin irritation, please stop wearing the Fitbit and reach out to study staff.

- There are small risks of injury or heart problems due to increased participation in physical activity. These risks will be minimized by screening for reasons why it might not be safe for you to do physical activity.

  If you do not want to exercise or feel that you cannot for any reason (during classes or on your own), then you should not do the exercise portion of this study. If you experience any symptoms while exercising, for example, chest pain, difficulty breathing, or dizziness, you should stop exercising and contact your healthcare provider.

- There is a risk that your information could become known to someone not involved in this study. Study staff will take measures to maintain your privacy during group classes. During group classes, you should only share information that you are comfortable sharing publicly. Participants will be asked to not share information about other participants outside of the group classes.

- Sensitive questions about personal issues (e.g., motivations for weight loss) may make participants uncomfortable. You may choose not to answer these questions.

- Some participants could become uncomfortable during group classes or telephone calls. If you experience distress, you should contact your physician or other healthcare provider, such as a mental health professional.

- Information from your cellular scale (Body Trace) and dietary app, Fitbit will be transmitted to the research team's mobile health software, which is stored at Duke University. The software is password-protected, and only approved research team members at the UW or Duke University will have access to the software and participant data. The software will store your phone number, Study ID, name, zip code, and data from the scale and diet apps.

  Information collected by devices (cellular network-connected scales) and mobile apps is subject to their terms of use, which you should read carefully. Many apps make claims that they are secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and neither the UW nor Duke can guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your phone or what information from your phone may be stored outside of Duke.

  Fitbit now requires all users to link a Google account and Gmail email address. You must have a Google account and Gmail email to participate in this study. All information linked to this account is accessible by Google. The study team will provide instructions for deleting this account at the end of participation in the study. You can still use your preferred email address to communicate with the study team and others.

  These apps may send/receive information with other mobile apps, including social networking apps or websites. If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully. Similarly, there are potential security risks with the cellular scale.

  We recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges.

  At the conclusion of the study, we will provide you instructions on how to remove the mobile apps from your device.

  As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

We are not asking you to make any health decisions based on the use of these devices or mobile apps. You should discuss health decisions directly with your healthcare provider.

- You will receive text messages as part of this study. These messages will be sent from a mobile health platform at Duke University that will connect with a company called Twilio. Twilio provides the ability to send text messages to your phone. You cannot opt-out of the text messages because they are an important part of the study.

- E-mail is generally not a secure way to communicate sensitive or health-related information because there are many ways for unauthorized users to access e-mail. You should avoid sending sensitive, detailed personal information by e-mail. E-mail should also not be used to convey information of an urgent nature. If you need to talk to someone immediately or would prefer not to receive study communication by e-mail, please contact the study team at 608-265-8758.

- OnceHub is an online scheduling tool that you will use to schedule your study visits. You will only enter your name and e-mail into OnceHub.

- The audio recordings of group classes and telephone calls will be stored with your study ID only, not your name or contact information. The recordings will be stored in secure electronic folders at Duke University. Only members of the study team will have access to these recordings.

Will being in this study cost me anything?

- There will be no cost to you for any of the study activities or procedures.
- You will have to pay for basic expenses like any childcare, food, parking, or transportation related to study activities.

Will I be paid or receive anything for being in this study?

- We will pay you $40 for the study visit at Month 6, $25 for study visit at Month 12 and $35 for the study visit at Month 18. Payment will be provided at the end of each visit. If you choose to leave or we take you off the study for any reason, you will receive the amount earned for study visits you have attended.
- You will receive a cellular scale, Fitbit watch, debit card, educational booklet and exercise band.

What happens if I am injured or get sick because of this study?

Being injured during this research is very unlikely. However, accidents can happen.

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact your regular health care provider.
- Call the lead researcher, Corrine Voils, PhD, at 608-262-9636 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

How will the researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your health information, your name, address, phone number, and other information that can identify you. We will also store this information securely. The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information or biospecimens that may identify you in a legal proceeding or in response to a legal request without your consent. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. This includes access to your medical records so that study monitors, auditors, the Institutional Review Board and regulatory authorities can verify study procedures and/or data. These groups will maintain your confidentiality. By signing this consent form, you are authorizing this access to your records. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections

- Collaborating researchers outside UW-Madison, including researchers at Duke University
- Companies or groups performing services for the research team, such as Amazon, Twilio, BodyTrace, Fitbit, OnceHub, U.S. Bank and their business associates
- After the study is complete, study data will be transmitted to and stored at the Duke Data Repository, for use by other researchers including those outside of the study. These data will not include any of your identifying information.

Will information from this study go in my medical record?

None of the information we collect for this study will be put in your medical record. Authorizing the research team to use your PHI means that we can release it only to the people or groups listed above, and only for the purposes described in this form. However, once your health information is released outside UW-Madison or UW Health, it may not be protected by privacy laws and might be shared with others.

Also, if ALL information that can identify you is removed from the health information collected in this study, then it is no longer PHI and this authorization will no longer limit how the remaining information can be used. This means the information could be used or shared for reasons other than the ones described in this form, such as a research study about another kind of disease. It also means that the information could be shared with researchers working at institutions that are not listed above.

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.

What if I have questions?

If you have questions about this research, please contact the lead researcher, Corrine Voils, PhD, at 608-262-9636 or the research team (log2lose@surgery.wisc.edu). If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

_____

Typed Name of [Participant]

_____

E-Signature of Research [Participant] Date

_____

Signature of Person Obtaining Consent and Authorization Date

Optional Permissions:

I give my permission to have my name and contact information kept, and to perhaps be contacted regarding future research participation opportunities. [Check yes or no]

****You will receive a signed and dated copy of this form****