Using Partners to Enhance Long-Term Weight Loss (Partner2Lose)

Document: Informed Consent Form

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

**Study Title for Participants: Partner2Lose**

**Formal Study Title: Using Partners to Enhance Long-Term Weight Loss (Partner2Lose)**

**Lead Researcher: Corrine I. Voils, PhD**
**600 Highland Ave**
**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 about including domestic partners in a weight management program.

The purpose of this consent and authorization form is to give you the information needed 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."



IRB Approval Date: 2/17/2021
University of Wisconsin – Madison

## Why are researchers doing this study?

Research shows that weight loss, and maintenance of weight loss, improves heart disease risk factors such as blood pressure and cholesterol, the ability to get around, and quality of life. Programs that combine diet and physical activity can lead to significant weight loss.

The purpose of this research study is to compare how people lose weight by participating in a weight management program either with support from a partner or on their own. If you choose to participate in the study, you will be assigned to either the partner-assisted group or participant-only group. Your assignment will be random, like flipping a coin.

This study is being done at the University of Wisconsin-Madison (UW-Madison) in partnership with researchers at Duke University and Research Triangle Institute. A total of about 460 people (230 couples) will participate in this study.

Funding for this study is provided by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

## What will happen in this study?

**Initial Screening Visit**

Once your eligibility is determined by completing the in-person screening measurements (height/weight, memory questions and reconfirmation that you are not pregnant if you are of child-bearing potential), you will be asked to finish the screening visit by completing the following measurements. These will take approximately 1 hour.

- Medical history and demographics – The study team will ask 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, previous weight loss attempts, history of heart disease, diabetes, cancer, liver disease, stroke, and hypertension.

- Dietary intake – You will be asked to complete the National Cancer Institute's Automated Self-Administered 24-hour dietary recall (ASA-24) to provide information on what you ate over a 24-hour period on one weekday and one weekend day. The questionnaire will be completed on a website and you will

receive the link to this website via text message and/or e-mail. You will receive instructions on how to use the website from the study staff during your screening visit and contact information for the study staff if you need help completing the questionnaire.

- Physical activity – A Fitbit™ will be used to measure your physical activity. The study team will provide this to you at your screening visit and instruct you how to use and wear it. You will receive a text message and/or e-mail reminder to wear the Fitbit continuously for 7 days. If you do not attend your first group session, we will ask you to return the Fitbit to the study team.

- Questionnaires/surveys about social support and couple strategies for physical activity and eating habits, the relationship with your partner, pain and COVID-19 will be given at the screening visit. You may skip any question on the questionnaire/survey or during the visit that you do not wish to answer.

**First Group Session**

Within 8 weeks after your initial screening visit, you will attend the first in-person group session by yourself. At that session, you will find out which group you and your partner have been assigned to (participant-only group or partner-assisted group). Your assignment will be random, like flipping a coin.

If you are assigned to the participant-only group, then you will participate in the weight loss program by yourself. If you are assigned to the partner-assisted group, you will participate in the study with your partner.

You will be asked to download the MyFitnessPal™ application to your mobile phone.

**Weight Loss Program: Months 1 – 6**

After the first group session, we ask that you attend an in-person group session every 2 weeks for 6 months, which will be led by a dietitian. Sessions will begin with a weigh-in, followed by dietary education, physical activity demonstration and goal setting. At the third group session, you will set a 6 month weight loss goal with the dietitian. You will be encouraged to participate in the physical activity demonstration, but it is not required. If you are assigned to the partner-assisted group, we ask that your partner attend six of these group sessions. If you are assigned to the participant-only group, then your partner will not attend any of the group sessions. During the first 6 months, you will also receive text messages from the study team three times per week about things you are

learning in the group sessions. Each session will be 1 to 2 hours long. These group sessions might be delivered remotely via a video call if necessary due to public health safety measures.

**Weight Loss Group Sessions: Once a Month in Months 7, 8 and 9**

At the beginning of month 7, there will be an introductory session to explain the transition from the weight loss program to the weight loss maintenance portion of the study. There will be two additional group sessions at months 8 and 9. If you've been assigned to the partner-assisted group, then your partner will attend all three of these group sessions with you. These sessions will last 1 to 2 hours and be similar in format to the first 6 months of group sessions. These group sessions may be delivered remotely via a video call if necessary due to public health safety measures.

**Weight Loss Maintenance Telephone Calls: Months 7 – 18**

We ask you to participate in telephone calls with the dietitian or a health educator monthly in months 7-12 and every other month in months 13-18. These telephone calls will focus on building skills to help you maintain your weight loss. These calls will last up to 30 minutes. If you are in the partner-assisted group, your partner will also participate in the calls in months 7-9, month 12 and month 18. The calls that your partner receives with you will be up to 15 minutes longer.

You will continue to receive text messages from the study team, two times a week during months 7-9, one time per week during months 10-12, and every 2 weeks during months 13-18. These text messages will be about weight loss maintenance.

**Months 6, 12, and 18 Visits**

We ask you to return at months 6, 12 and 18 for in-person measurement visits. These visits may occur remotely via a video call if necessary due to public health safety measures. At these visits, the following information will be collected: weight, dietary intake (you will be sent a link to complete this via text message and/or e-mail), physical activity via a Fitbit (you will be sent a text and/or e-mail reminder about when and for how long to wear it), and questionnaires/surveys. The questionnaires/surveys will be about social support and couple strategies for physical activity and eating habits, the relationship with your partner, pain, weight loss methods and COVID-19. You will have the option of the completing the questionnaires/surveys at home, on your own. You will receive a link to the questionnaires/surveys via text message and/or e-mail. If you do not finish the surveys beforehand, this visit will last 30-45 minutes. Otherwise, they will only take 5-10 minutes.

**Months 3, 9, 15 and 21**
We will ask you to complete the questionnaires/surveys about social support and couple strategies for physical activity and eating habits and the relationship with your partner, and COVID-19 in months 3, 9, 15 and 21. You will receive a link to the questionnaires/surveys via text message and/or e-mail so that you can complete them at home, on your own. These will take you about 30 minutes.

During months 19 - 24, contact from the dietitian will stop.

**Month 24 Visit**
We ask you to return at month 24 for a final in-person measurement visit. This visit may occur remotely via a video call if necessary due to public health safety measures. At this visit, the following information will be collected: weight, surveys (weight loss methods and COVID-19), dietary intake (you will be sent a link to complete this via text message and/or e-mail) and physical activity via a Fitbit (you will be sent a text and/or e-mail reminder about when and for how long to wear it). If you do not finish the surveys beforehand, this visit will last 30-45 minutes. Otherwise, it will only take 5-10 minutes.

If you were assigned to the participant-only arm, your partner and you will be invited to attend two of the weight loss program group sessions after you complete your 24-month visit. Each session will last 1.5 to 2 hours and include dietary education, physical activity demonstration and goal setting.

As part of the study, we will collect audio recordings of all group sessions andmaintenance program telephone calls. The sessions are being 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.

## Protected health information (PHI) we will use for this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your 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., 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, medical record number, 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 up to 28 months (up to 2 months for screening, 24-month program, and an optional 2 months at the end of the program if you were assigned to the participant-only group).

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's 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 (e.g., unable to reach you by telephone)
- The study is stopped by the sponsor or researchers

## How is being in this study different from my regular health care?

People with obesity usually have access to commercial weight loss programs or can be referred to a dietitian by their doctor. Some people decide to try to lose weight on their own. People in this study will take part in a comprehensive weight management program in addition to the regular healthcare they receive from their doctor.

## 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 want to leave the study, you can do so by contacting the lead researcher, Dr. Corrine Voils, at (608)262-9636 or Partner2Lose@surgery.wisc.edu or by notifying one of the research team members in-person.

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 take 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 600 Highland Ave, K6/100 CSC, Madison, WI 53792-1690.

## What are my other choices if I do not take part in this study?

You do not have to be in this research study to achieve weight loss. If you decide not to take part in the study, you have other choices.

For example:

- You may choose to take part in a different study, if one is available
- You may choose to get a consult from your primary care physician or specialist
- You may choose to see a dietitian
- You may choose a commercial weight loss program

## Will being in this study help me in any way?

- Being in this study may not help you directly, but your participation in the study may benefit other people in the future by helping us learn more about treatment options for those with weight problems.

- You may learn skills that help you reduce weight by following dietary recommendations and participating in regular physical activity.

- Additionally, you may notice a positive change in your relationship with your partner.

## What are the risks?

- There are minimal 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 have questions or any new health problems or symptoms that arise during your participation, the study physician will be available to address them.

  If you have severe spine degenerative disk disease and/or a history of compression fractures, you should not participate in the physical activity portion of the intervention. During the exercise portion of the group sessions, if you do not want to exercise or feel that you cannot for any reason, then you should not do the exercises. If you experience any symptoms while exercising, for example, chest pain, difficulty breathing, dizziness, you should stop exercising as these symptoms might mean that you are working too hard. You should also follow-up with your healthcare team if you experience any of these symptoms during exercise.

- If you are taking blood pressure medication, changes to your diet and/or weight loss can result in low blood pressure. You will be instructed on how to recognize and respond to symptoms of low blood pressure. Study staff will also be trained how to respond to these symptoms. The study physician will be available to address any of your concerns.

- There is a risk that your personal information could become known to someone not involved in this study. If this happens, it could result in damage to your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job. Study staff will take

measures to maintain your privacy during in-person sessions. During group sessions, you should only share information that you are comfortable with sharing publicly. Participants will be asked to not share information about other participants outside of the group sessions.

- This study uses a mobile health platform, called Prompt, to collect data from the Fitbit device and application ("app"). Prompt is a web-based software application developed by colleagues at Duke University. Prompt uses a company called Amazon S3 to store data, which will include your cell phone number, study ID, and data generated from the Fitbit device and app. Prompt is password-protected, and only approved research team members at the UW or Duke University will have access to the software and participant data.

- Your Fitbit data and study ID will be exported from Prompt to secure, firewall-protected electronic folders at the Duke University School of Nursing for analysis.
- Following completion of the study, your data will removed from Prompt, and you will be instructed to delete your Fitbit account and remove the app.

- Fitbit data will be transferred from your Fitbit smartphone app to the Fitbit company servers; however, these data will not be identifiable (e.g., by your name or contact information). These data will be stored by Fitbit indefinitely.

- You will receive text messages as part of this study. These messages will be sent from a software program at Duke University called REDCap. REDCap is a password-protected and secure software tool that will connect with a company called Twilio. Twilio provides the ability to send text messages to your phone. You are not able to opt-out of the text messages.

- Study staff will direct you to not share information from the Fitbit and MyFitnessPal apps with third-party services (e.g., social media). You should read the privacy statement for the apps if you decide that you want to share information with any third-party services; however, we discourage you from doing so.

- Data about what you eat and drink will be collected by the ASA-24 system, which was developed jointly by the National Cancer Institute (NCI) and Westat (a social science research consulting group). Neither the NCI nor Westat will have access to any identifiable information (e.g., your name or contact information).

- If any of the listed companies or their business partners further disclose these data, then the data may no longer be covered under privacy protections.

- The audio recordings of group classes and telephone calls will be shared with Dr. Laura Porter (the study psychologist) at Duke University, who may listen to them for quality assurance. The recordings will only have your study ID, not your name or contact information. The recordings will be stored in secure electronic folders at the UW-Madison and Duke University.

- Sensitive questions about your personal information (e.g., quality of your relationship) asked during the questionnaires and/or interactions with the research staff may make you feel uncomfortable. You may choose not to answer these questions.

  You may also experience some emotional distress during group visits or telephone calls. If the study staff notices that you experience notable emotional distress, they may discuss it with Dr. Laura Porter (the study psychologist). If you are experiencing emotional distress, you should contact your physician or other healthcare provider, such as a mental health professional.

- E-mail is generally not a secure way to communicate sensitive or health-related information as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. 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 email, please contact the study team at 608-890-2917.

- OnceHub is an online scheduling tool that you will use to schedule your measurement visits at months 6, 12, 18 and 24. You will only enter your name and email into OnceHub.

## Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures.

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

Payment will be provided via check at the end of each measurement visit (Months 6, 12, 18 and 24). If you complete all of these visits, you will receive $180 total. Your partner would also receive $180 if each measurement visit is completed. If you choose to leave the study or we take you out of the study for any reason, you will only receive payment for the visits that you completed. You will get to keep the Fitbit (if you attend the first group session), receive a resistance exercise band, and dietary resource book.

| Visit | Payment |
|---|---|
| Month 6 | $40 each/$80 per couple |
| Month 12 | $40 each/$80 per couple |
| Month 18 | $40 each/$80 per couple |
| Month 24 | $60 each/$120 per couple |

## 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 healthcare 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). The lead researcher's (Dr. Voils) research team will have access to your health information, your name, address, phone number, and other information that can identify you. They will assign you a study ID to protect your identity and maintain the link between your study ID and protected health information. This link will be stored securely in the tracking system stored on the UW Department of Surgery's computer systems behind the UW School of Medicine and Public Health firewall. Your information will be stored securely; any of the study data that are on paper will be stored in a locked file cabinet within a locked office. Any of your data that are stored on a computer will be stored in secure, firewall-protected UW Department of Surgery electronic folders. Researchers at Duke University will only store your study ID and phone number. 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 and to the study sponsor responsible for monitoring this study.

### 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
- The study sponsor, National Institute of Diabetes and Digestive and Kidney Diseases
- Collaborating lead researchers outside of UW-Madison, including researchers at the Duke University School of Nursing and School of Medicine and the Research Triangle Institute

- Companies or groups performing services for the research team, such as Prompt, Twilio, Fitbit, Amazon S3, the National Cancer Institute, Westat, OnceHub (Please refer to page 9 and 10 to see which data these companies will have access to and how they will be protected.)

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.

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.

To help us protect your privacy, a Certificate of Confidentiality will automatically be granted from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of harm to self or others.

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. If you have any questions about your rights as a research participant or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research participants to address concerns about research participation and assist in resolving problems.

## Agreement to participate in the research study: Partner2Lose

You do not have to agree to participate in this study. If you refuse to particpate, however, you cannot take part in this research study.

If you agree to participate in this study, 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.

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****You will receive a copy of this form****

Study #: 2018-1400
Version: 2/9/2021

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

**Study Title for Participants: Partner2Lose**

**Formal Study Title: Using Partners to Enhance Long-Term Weight Loss (Partner2Lose)**

**Lead Researcher: Corrine I. Voils, PhD**
**600 Highland Ave**
**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 about including domestic partners in a weight management program.

The purpose of this consent and authorization form is to give you the information needed 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."



IRB Approval Date: 2/17/2021
University of Wisconsin – Madison

## Why are researchers doing this study?

Research shows that weight loss, and maintenance of weight loss, improves heart disease risk factors such as blood pressure and cholesterol, the ability to get around, and quality of life. Programs that combine diet and physical activity can lead to significant weight loss.

The purpose of this research study is to compare how people lose weight by participating in a weight management program either with support from a partner or on their own. If you choose to participate in the study, you will be assigned to either the partner-assisted group or participant-only group. Your assignment will be random, like flipping a coin.

This study is being done at the University of Wisconsin-Madison (UW-Madison) in partnership with researchers at Duke University and Research Triangle Institute. A total of about 460 people (230 couples) will participate in this study.

Funding for this study is provided by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

## What will happen in this study?

**Initial Screening Visit**

Once your eligibility is determined by completing the in-person screening measurements (height/weight and memory questions), you will be asked to finish the screening visit by completing the following measurements. These will take approximately 1 hour.

At the screening visit, we will collect the following information from you:

- Medical history and demographics – The study team will ask 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, previous weight loss attempts, history of heart disease, diabetes, cancer, liver disease, stroke, and hypertension.

- Dietary intake – You will be asked to complete the National Cancer Institute's Automated Self-Administered 24-hour dietary recall (ASA-24) to provide information on what you ate over a 24-hour period on one weekday and one weekend day. The questionnaire will be completed on a website and you will

receive the link to this website via text message and/or e-mail. You will receive instructions on how to use the website from the study staff during your screening visit and contact information for the study staff if you need help completing the questionnaire.

- Questionnaires/surveys about social support and couple strategies for physical activity and eating habits, the relationship with your significant other, pain, and COVID-19 will be given at the screening visit. You may skip any question on the questionnaire/survey or during the visit that you do not wish to answer.

Your significant other will attend the first in-person group session by herself/himself. At that session, s/he will find out which group both of you have been assigned to (participant-only group or partner-assisted group). A process like flipping a coin will determine which group you are assigned to. If you are assigned to the participant-only group, then you will not participate in the weight management program (only your significant other will). If you are assigned to the partner-assisted group, you will participate in the study with your significant other.

Regardless of whether you are randomly assigned to the participant-only group or partner-assisted group, you will return at months 6, 12, 18, and 24 for in-person measurement visits. These visits may occur remotely via a video call if necessary due to public health safety measures. At the month 6, 12 and 18 visits, the following measurements will be done: weight, dietary intake, a weight loss methods survey and the questionnaires/surveys as described above. You will have the option of the completing the questionnaires/surveys at home, on your own. You will receive a link to the questionnaires/surveys via text message and/or e-mail. At the month-24 visit, weight, surveys (weight loss methods and COVID-19) and dietary intake will be collected. If you do not finish the surveys beforehand, these visits will last 30-45 minutes, otherwise, they will only take 5-10 minutes. We will call you to schedule them.

At months 3, 9, 15 and 21, we will ask you to complete the questionnaires/surveys about social support and couple strategies for physical activity and eating habits, the relationship with your partner, and COVID-19. You will receive a link to the questionnaires/surveys via text message and/or e-mail so that you can complete them at home, on your own. These will take you about 30 minutes to complete.



IRB Approval Date: 2/17/2021
University of Wisconsin – Madison

The following procedures will apply **only** if you are randomly assigned to the ***partner-assisted group***:

**Weight Loss Program: Months 1 – 6**

If you are assigned to the partner-assisted group, during the first 6 months, we ask that you attend an in-person group session once a month (6 sessions total) with your significant other. The first session you will attend will be an orientation to the study and your role as a partner in the study. You will have the option to download the MyFitnessPal™ app on your mobile phone. Following sessions will focus on dietary/physical activity education, goal setting, and communication with your significant other. You will be encouraged to participate in the physical activity demonstration, but it is not required. During the first 6 months, you will also receive text messages from the study team three times per week about things you are learning in the group sessions. Sessions will be led by a dietitian and last 1 hour, 30 minutes to 2 hours. These group sessions might be delivered remotely via a video call if necessary due to public health safety measures.

**Weight Loss Group Sessions: Months 7, 8 and 9**

In months 7, 8, and 9, you will attend a group session once per month where you will learn about weight loss maintenance and your role to help your significant other. These group sessions might be delivered remotely via a video call if necessary due to public health safety measures.

**Weight Loss Maintenance Program Telephone Calls – Months 7-18**

You will participate in monthly telephone calls with your partner and the dietitian or health educator during months 7, 8, 9, 12, and 18. These calls will last up to 45 minutes.

You will continue to receive text messages from the study team, two times a week during months 7-9, one time per week during months 10-12, and every two weeks during months 13-18. These text messages will be about weight loss maintenance.

During months 19-24, all contact from the dietitian will stop.

If were assigned to the participant-only group, your significant other and you will be invited to attend two weight loss program group sessions after both of you complete your 24-month outcome assessments. Each session will last 1 to 2 hours long and include dietary education, physical activity demonstration and goal setting.

As part of the study, we will collect audio recordings of all group sessions you attend and maintenance program telephone calls. The sessions are being audio 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.

## Protected health information (PHI) we will use for this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your 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., 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, web addresses, and 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 up to 28 months (up to 2 months for screening, 24-month program, and an optional 2 months at the end of the program if you were assigned to the participant-only group).

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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's unsafe for you to continue your participation (e.g., you develop cancer)
- You do not follow the study rules or no longer meet the requirements to be in the study (e.g., unable to reach you by telephone)
- The study is stopped by the sponsor or researchers



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## How is being in this study different from my regular health care?

People with obesity usually have access to commercial weight loss programs or can be referred to a dietitian by their doctor. Some people decide to try to lose weight on their own. If you are assigned to the partner-assisted group, you will have access to a comprehensive weight management program. If you are not assigned to the partner-assisted group, then being in this study will not be different from the regular health care you receive from your doctor.

## 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 want to leave the study, you can do so by contacting the lead researcher, Dr. Corrine Voils, at (608)262-9636 or Partner2Lose@surgery.wisc.edu or by notifying one of the research team members in-person.

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 take 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 600 Highland Ave, K6/100 CSC, Madison, WI 53792-1690

## What are my other choices if I do not take part in this study?

You do not have to be in this research study to achieve weight loss. If you decide not to take part in the study, you have other choices.

## Will being in this study help me in any way?

- Being in this study may not help you directly, but your participation in the study may benefit other people in the future by helping us learn more about treatment options for those with weight problems.
- You may also learn skills that help you reduce weight by following dietary recommendations and participating in regular physical activity.
- Additionally, you may notice a positive change in your relationship with your partner.

## What are the risks?

- There are minimal 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 have questions or any new health problems or symptoms that arise during your participation, the study physician will be available to address them.

  If you have severe spine degenerative disk disease and/or a history of compression fractures, you should not participate in the physical activity portion of the intervention. During the exercise portion of the group sessions, if you do not want to exercise or feel that you cannot for any reason, then you should not do the exercises. If you experience any symptoms while exercising, for example, chest pain, difficulty breathing, dizziness, you should stop exercising as these symptoms might mean that you are working too

hard. You should also follow-up with your healthcare team if you experience any of these symptoms during exercise.

- If you are taking blood pressure medication, changes to your diet and/or weight loss can result in low blood pressure. You will be instructed on how to recognize and respond to symptoms of low blood pressure. Study staff will also be trained how to respond to these symptoms. The study physician will be available to address any of your concerns.

- There is a risk that your personal information could become known to someone not involved in this study. If this happens, it could result in damage to your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job. Study staff will take measures to maintain your privacy during in-person sessions. During group sessions, you should only share information that you are comfortable with sharing publicly. Participants will be asked to not share information about other participants outside of the group sessions.

- You will receive text messages as part of this study. These messages will be sent from a software program at Duke University called REDCap. REDCap is a password protected and secure software tool that will connect with a company called Twilio. Twilio provides the ability to send text messages to your phone. You are not able to opt-out of the text messages. Twilio will have access to limited personal information (phone number).

- If you decide to download the MyFitnessPal™ app, study staff will direct you not to share information with third-party services (e.g., social media). You should read the privacy statement for the app if you decide that you want to share information with any third-party services; however, we discourage you from doing so.

- Data about what you eat and drink will be collected by the ASA-24 system, which was developed jointly by the National Cancer Institute (NCI) and Westat (a social science research consulting group). Neither the NCI nor Westat will have access to any identifiable information (e.g., your name or contact information).

- If any of the listed companies or their business partners further disclose these data, then the data may no longer be covered under privacy protections.

- The audio recordings of group classes and telephone calls will be shared with Dr. Laura Porter (the study psychologist) at the Duke University, who may listen to them for quality assurance. The audio recordings will be only have your study ID, not your name or contact information. This information will be stored in secure electronic folders at UW-Madison and Duke University.

- Sensitive questions about your personal information (e.g., quality of your relationship) asked during the questionnaires and/or interactions with the research staff may make you feel uncomfortable. You may choose not to answer these questions.

- You may also experience some emotional distress during group visits or telephone calls. If the study staff notices that you experience notable emotional distress, they may discuss it with Dr. Laura Porter (the study psychologist). If you are experiencing emotional distress, you should contact your physician or other health care provider, such as a mental health professional.

- E-mail is generally not a secure way to communicate sensitive or health-related information as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. 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 email, please contact the study team at 608-890-2917.

- OnceHub is an online scheduling tool that you will use to schedule your measurement visits at months 6, 12, 18 and 24. You will only enter your name and email into OnceHub.

## Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures.

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

Payment will be provided via check at the end of each measurement visit (Months 6, 12, 18 and 24). If you complete all of the study visits, you will receive $180 total. Your significant other would also receive $180 if each measurement visit is completed. If you choose to leave the study or we take you out of the study for any reason, you will only receive payment for the visits that you completed.

| Visit | Payment |
|---|---|
| Month 6 | $40 each/$80 per couple |
| Month 12 | $40 each/$80 per couple |
| Month 18 | $40 each/$80 per couple |
| Month 24 | $60 each/$120 per couple |

## 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). The lead researcher's (Dr. Voils) research team will have access to your health information, your name, address, phone number, and other information that can identify you. They will assign you a study ID to protect your identity and maintain the link between your study ID and health information. This link will be stored securely in a tracking system which is stored on the UW Department of Surgery's computer systems behind the UW School of Medicine and Public Health firewall. Your information will be stored securely; any of the study data that are on paper will be stored in a locked file cabinet within a locked office. Any of your data that are stored on a computer will be stored in secure, firewall-protected UW Department of Surgery electronic folders. Researchers at Duke University will only store your study ID and phone number. 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 and to the study sponsor responsible for monitoring this study.

### 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
- The study sponsor, National Institute of Diabetes and Digestive and Kidney Diseases
- Collaborating lead researchers outside of UW-Madison, including researchers at Duke University School of Nursing and School of Medicine, and the Research Triangle Institute

- Companies or groups performing services for the research team, such as Twilio, the National Cancer Institute, Westat, OnceHub. (Please refer to page 8 and 9 to see which data these companies will have access to and how they will be protected.)

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.

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.

To help us protect your privacy, a Certificate of Confidentiality will automatically be granted from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of harm to self or others.

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. If you have any questions about your rights as a research participant or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research participants to address concerns about research participation and assist in resolving problems.

## Agreement to participate in the research study: Partner2Lose

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

If you agree to participate in this study, 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.

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****You will receive a copy of this form****



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