Collaborate2Lose: Collaborating with romantic and non-romantic support persons to improve long-term weight loss

NCT05448313

July 3, 2023

Participant Name: _____ Date: _____

Title of Study: Collaborate2Lose: Collaborating with support persons to improve long-term weight loss

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: Corrine I. Voils, PhD

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the VA Health Services Research and Development Service. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this research study is to compare weight loss between Veterans who participate in a weight management program with or without a support person (an adult they are living with). If you choose to participate, you will be in this study for up to 80 weeks (up to 8 weeks for screening and a 72-week program).

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

- You are comfortable talking in small groups about weight management and effective communication.
- You are comfortable having someone who lives with you be closely involved in the weight management program.
- You want to learn skills that help you lose weight by changing how you eat and getting regular exercise.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

- You are not interested in losing weight.
- You don't want to talk about weight management or communication strategies in small groups with people you don't know.
- You want to lose weight but you don't want to work closely with someone in your household to do it.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer or change your mind later.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is [insert name] at the [insert site]. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, their contact information is: [insert name and phone number].

Participant Name: _____ Date: _____

Title of Study: Collaborate2Lose: Collaborating with support persons to improve long-term weight loss

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: Corrine I. Voils, PhD

DETAILED INFORMATION ABOUT THE STUDY

WHY AM I BEING ASKED TO PARTICIPATE?

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

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 4 years. Your individual participation in the study will take 80 weeks (up to 8 weeks for screening and a 72-week weight management program). A total of 300 participants will participate in the study.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Consent (30 minutes)

At this visit via video call, study staff will review the consent with you. If you decide to participate, an electronic version of the consent will be emailed to you for your electronic signature.

Initial Surveys (30 minutes)

You will be emailed a link to complete surveys online. These surveys are about:

- Demographic information, including age, gender, sex, race, ethnicity, education, employment status, travel distance to VA, weight-related diseases, previous weight loss attempts, and pregnancy status (if of childbearing potential)
- Support from people in your life around eating and exercise
- Strategies for changing your eating and exercise habits

You may skip any question on the surveys you do not wish to answer.

Initial Weight (15 minutes)

At this visit via video call, study staff will ask you to weigh yourself on a scale we will send to you. You will then be asked to share a photo of the weight displayed on the scale.

First Group Class

Within 8 weeks of consenting to be in the study, you will attend the first online group class. At this class, you will find out if you will participate in future classes with your support person or on your own. Your assignment will be random, like flipping a coin.

Weight management program (22 group classes)

This program will involve 22 online group classes via a video call led by a member of the research team. The classes will be held every other week until week 30, then every 4 weeks (at weeks 34, 38, and 42), and then every 8 weeks (at weeks 50, 58, and 66). Each class will take up to 2 hours. At these classes, you will learn about nutrition, exercise and goal setting. You will be invited to participate in an optional 10-15 minute exercise demonstration during each class. The classes will be audio recorded for quality assurance.

If you are randomly selected to participate with your support person, they will participate in all except the first class with you, and you both will learn about communication skills.

Virtual measurement visits at weeks 24, 48 and 72 (30 minutes to 1 hour)

These visits will occur via video call. At these visits, study staff will ask you to:

- Weigh yourself on the study-provided scale and share a picture of the displayed weight
- Complete surveys about:
  - Quality of life
  - Support from people in your life around eating and exercise
  - Strategies for changing your eating and exercise habits
  - The relationship with your support person

You may skip any question on the surveys you do not wish to answer.

Surveys at weeks 12, 36, and 60 weeks

You will be asked to complete surveys about:

- Support from people in your life around eating and exercise
- Strategies for changing your eating and exercise habits
- The relationship with your support person

You may skip any question on the surveys you do not wish to answer.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Attend the online group classes.
- Attend virtual measurement visits. If you miss a visit, please contact the study team.
- Tell the Lead Researcher or research staff if you believe you might be pregnant (if of childbearing potential), develop a serious health condition, or are planning to receive bariatric surgery.
- Complete the surveys as instructed.
- Ask questions as you think of them.

Following the 72-week visit, our study team may reach out to you to invite you to take part in a one-time interview about your experience in the study. You do not have to participate in this and we will provide additional consent information at that time.

You will receive a general report of the results from the study once the study has been completed.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

There is a risk that your personal 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 with sharing publicly. Participants will be asked to not share information about other participants outside of the group classes.

Sensitive questions about your personal life (e.g., quality of your relationship) asked in the surveys 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 classes. If the study staff notices that you experience notable emotional distress, they may discuss it with Dr. Voils (Lead Researcher) or Dr. Pabich (study physician). If you are experiencing emotional distress, you should contact your physician or other healthcare provider, such as a mental health professional.

Dietary changes and/or weight loss can result in low blood pressure or blood glucose (sugar) 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.

There are minimal risks of injury or heart problems due to increased participation in exercise. These risks will be minimized by screening for reasons why it might not be safe for you to do exercise. 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 exercise. You should not do the exercises if you do not want to, or you feel that you cannot for any reason (during classes or on your own). If you experience any symptoms while exercising, such as chest pain, difficulty breathing, or 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.

In addition to the risks described above, you may experience a previously unknown risk or discomfort.

Participant Name: _____ Date: _____

Title of Study: Collaborate2Lose: Collaborating with support persons to improve long-term weight loss

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: Corrine I. Voils, PhD

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There may be no direct or personal benefits to you from your taking part in this research study. However, the information we get from this study might help other Veterans make lifestyle changes. You may also learn skills that help you lose weight by changing how you eat and getting regular exercise. Lastly, you may experience a positive change in your relationship with your support person.

You will receive a general report of the results from the study once the study has been completed.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

Instead of being in this research study, you could enroll in the MOVE! weight loss program at the VA on your own, without the participation of another adult in your household.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- The research team will assign you a study ID to protect your identity and securely store the link between your study ID and private information.
- Your information will be stored securely. Any study data recorded on paper will be stored in a locked file cabinet within a locked office at the William S. Middleton Memorial Veterans Hospital. Electronic data will be stored on a secure password- and firewall-protected VA server.

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Current VA regulations require us to retain all research data and information per VA Records Control Schedule (RCS) 10-1 regulations for a period not to exceed 7 years after the close of the study.

Your identity will not be disclosed unless you give specific consent or if required by law. There are times when we may have to show your records to other people. For example, representatives from offices and agencies that oversee research may review your records, such as federal agencies that oversee research such as the Office for Human Subjects Protections, the VA Office of Research Oversight, or the VA Office of the Inspector General.

Your data will be shared with researchers at the Edward Hines VA Medical Center. Information will also be shared with researchers at the VA Puget Sound Healthcare system. These researchers are working on this study with us. By signing this consent and HIPAA authorization form, you are giving us permission to share your data with these researchers.

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).

Your identifiers may be removed from the identifiable private information and after such removal, the information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

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.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO), the VA Health Services Research and Development Service, VA Institutional Review Board, Hines VA and the local VA medical facility Human Research Protections Program, and local VA Finance office for study payment.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted, you will not have access your research-related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 07/03/2023
Per PI/SC Amendment 01

LSI Approval Date: N/A

LSI Verification Date: N/A

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Corrine Voils, PhD and their research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment, or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL I BE PAID FOR MY PARTICIPATION IN THE STUDY?

You can earn up to $135 over the course of your participation in the study. You will receive $15 for providing your weight during the virtual measurement visits at 24 and 48 weeks. You will also receive $15 for completion of the surveys at 24 and 48 weeks. You will receive $25 for providing your weight during the virtual measurement visit at 72 weeks, and $25 for completion of the surveys at 72 weeks. If you choose to participate in an interview following the 72-week assessment, you will receive $25. You will be paid by direct deposit. If you do not have a bank account, you will be paid through a Direct Express debit card that will be mailed to you. The study team will need your name, address, bank account, and social security number in order to pay you. You will receive payment through the [LOCAL VA]. This generates an Internal Revenue Service Form 1099 regardless of the amount. Study payments are treated as earnings by the IRS. Thus, you may need to report these on your taxes.

Participant Name: _____ Date: _____

Title of Study: Collaborate2Lose: Collaborating with support persons to improve long-term weight loss

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: Corrine I. Voils, PhD

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution. You do not give up any legal rights or release the VA from any liability by signing the form.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:
DURING THE DAY OR AFTER HOURS:
Samantha Pabich, MD at 608-262-2122 x7320

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary. You may refuse or discontinue taking part in this study at any time without any penalty or loss of benefits. You may withdraw and still receive the same standard of care that you would otherwise have received. If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress.

If you decide to withdraw from the study, the research team may continue to review your data already collected prior to your withdrawal, but cannot collect further information from you, except from public records, such as survival data.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The Lead Researcher may terminate your participation in the study for safety reasons, such as if you become pregnant (if of childbearing potential), or if you develop a condition (such as cancer) where it is no longer safe for you to participate. Should this happen, the research team will let you know.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions or concerns about this research, please contact the VA Lead Researcher, [insert name and phone number].

You may also contact the study coordinator, [insert name and phone number].

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

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Principal Investigator: _____ VA Facility: _____

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WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

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.

PERMISSION TO COMMUNICATE ABOUT THE STUDY BY EMAIL

We are requesting your email address so we can send you study-related forms and materials. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the study coordinator, [insert name and phone number]. If the study team does not answer, please leave a message.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

A member of the study team has explained the research study to you. You have been told of the procedures, possible risks or discomforts, and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive an electronic copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 07/03/2023
Per PI/SC Amendment 01

LSI Approval Date: N/A

LSI Verification Date: N/A

Participant Name: _____ Date: _____

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KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the VA Health Services Research and Development Service. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this research study is to compare weight loss between Veterans who participate in a weight management program with or without a support person (an adult they are living with). If you choose to participate, you will be in this study for up to 80 weeks (up to 8 weeks for screening and a 72-week program).

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

- You are comfortable talking in small groups about weight management and effective communication.
- You may learn skills to help the Veteran you support lose weight.
- You are comfortable being a support person for your study partner in the weight loss program.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

- You don't want to talk about weight management or communication strategies in small groups with people you don't know.
- You are uncomfortable being a support person for your study partner in the weight loss program.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer or change your mind later.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is [insert name] at the [insert site]. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, their contact information is: [insert name and phone number].

Participant Name: _____ Date: _____

Title of Study: Collaborate2Lose: Collaborating with support persons to improve long-term weight loss

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: Corrine I. Voils, PhD

DETAILED INFORMATION ABOUT THE STUDY

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 4 years. Your individual participation in the study will take 80 weeks (up to 8 weeks for screening and a 72-week weight management program). A total of 300 participants will participate in the study.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Consent (30 minutes)

At this visit via video call, study staff will review the consent with you. If you decide to participate, an electronic version of the consent will be emailed to you for your electronic signature.

Initial Surveys (30 minutes)

You will be emailed a link to complete surveys online. These surveys are about:

- Demographic information, including age, gender, sex, race, ethnicity, education, employment status, travel distance to VA, weight-related diseases, previous weight loss attempts, and pregnancy status (if of childbearing potential)
- Support from people in your life around eating and exercise
- Strategies for changing eating and exercise habits

You may skip any question on the surveys you do not wish to answer.

These measurements will help our study team to better understand how being a support person and attending classes may change health behaviors, weight, and the relationship with their study partner.

First Group Class

Within 8 weeks of consenting to be in the study, your study partner will attend the first online class by themselves. At this class, they will find out if you will participate in the classes with them or not. Your assignment will be random, like flipping a coin.

Weight management program

If you are assigned to the group to participate in the classes with your study partner, you will attend 21 online group classes via a video call led by a member of the research team. The classes will be every other week until week 30, then every 4 weeks (at weeks 34, 38, and 42), and then every 8 weeks (at weeks 50, 58, and 66). Each class will take up to 2 hours. At these classes, you will learn about nutrition, exercise, goal setting and communication skills. You will be invited to participate in an optional 10-15 minute exercise demonstration during each class. The classes will be audio recorded for quality assurance.

Participant Name: _____ Date: _____

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Study visits at weeks 24, 48 and 72 (30 minutes to 1 hour)

At these visits, study staff will ask you to:

- Complete surveys about:
  - Support from people in your life around eating and exercise
  - Strategies for changing eating and exercise habits
  - The relationship with your study partner

We will also ask you to provide your current weight.

You may skip any question on the surveys you do not wish to answer.

Surveys at weeks 12, 36, and 60 weeks

You will be asked to complete surveys about:

- Support from people in your life around eating and exercise
- Strategies for changing your eating and exercise habits
- The relationship with your study partner

You may skip any question on the surveys you do not wish to answer.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- If assigned to the group to participate in the classes with your study partner, attend the online group classes.
- Complete the surveys as instructed.
- Ask questions as you think of them.

Following the 72-week visit, our study team may reach out to you to invite you to take part in a one-time interview about your experience in the study. You do not have to participate in this and we will provide additional consent information at that time.

You will receive a general report of the results from the study once the study has been completed.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

There is a risk that your personal 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 with sharing publicly. Participants will be asked to not share information about other participants outside of the group classes.

Sensitive questions about your personal life (e.g., quality of your relationship) asked in the surveys 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 classes. If the study staff notices that you experience notable emotional distress, they may discuss it with Dr. Voils (Lead Researcher) or Dr. Pabich (study physician). If you are experiencing emotional distress, you should contact your physician or other healthcare provider, such as a mental health professional.

In addition to the risks described above, you may experience a previously unknown risk or discomfort.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There may be no direct or personal benefits to you from your taking part in this research study. However, the information we get from this study might help other Veterans make lifestyle changes. You may also learn skills to help the Veteran you support make lifestyle changes. Lastly, you may experience a positive change in your relationship with the Veteran you support.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

Instead of being in this research study, you can support your study partner in other ways.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- The research team will assign you a study ID to protect your identity, and will securely store the link between your study ID and private information.
- Your information will be stored securely. Any study data recorded on paper will be stored in a locked file cabinet within a locked office at the William S. Middleton Memorial Veterans Hospital. Electronic data will be stored on a secure password- and firewall-protected VA server.

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Current VA regulations require us to retain all research data and information per VA Records Control Schedule (RCS) 10-1 regulations for a period not to exceed 7 years after the close of the study.

Participant Name: _____ Date:_____

Title of Study: Collaborate2Lose: Collaborating with support persons to improve long-term weight loss

Principal Investigator:_____ VA Facility: _____

Principal Investigator for Multisite Study: Corrine I. Voils, PhD

Your identity will not be disclosed unless you give specific consent or if required by law. There are times when we may have to show your records to other people. For example, representatives from offices and agencies that oversee research may review your records, such as federal agencies that oversee research such as the Office for Human Subjects Protections, the VA Office of Research Oversight, or the VA Office of the Inspector General.

Your data will be shared with researchers at the Edward Hines VA Medical Center. Information will also be shared with researchers at the VA Puget Sound Healthcare system. These researchers are working on this study with us. By signing this consent and HIPAA authorization form, you are giving us permission to share your data with these researchers.

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).

Your identifiers may be removed from your identifiable private information and after such removal, the information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

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.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO), the VA Health Services Research and Development Service, VA Institutional Review Board, Edward Hines VA Medical Center and the local VA medical facility Human Research Protections Program, and local VA Finance office for study payment.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 07/03/2023
Per PI/SC Amendment 01
LSI Approval Date: N/A

LSI Verification Date: N/A

Participant Name: _____ Date: _____

Title of Study: Collaborate2Lose: Collaborating with support persons to improve long-term weight loss

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: Corrine I. Voils, PhD

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted, you will not have access your research-related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care, and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility, or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study. It will also not affect your study partner's rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Corrine Voils, PhD and their research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL I BE PAID FOR MY PARTICIPATION IN THE STUDY?

You can earn up to $135 over the course of the study for completing the study visits ($30 at 24 weeks, $30 at 48 weeks, and $50 at 72 weeks) and for participating in a qualitative interview following the 72-week study visit ($25). You will be paid by direct deposit. The study team will need your name, address, bank account, and social security number in order to pay you. You will receive payment through the [LOCAL VA]. This generates an Internal Revenue Service Form 1099 regardless of the amount. Study payments are treated as earnings by the IRS. Thus, you may need to report these on your taxes.

Participant Name: _____ Date: _____

Title of Study: Collaborate2Lose: Collaborating with support persons to improve long-term weight loss

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: Corrine I. Voils, PhD

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution. You do not give up any legal rights or release the VA from any liability by signing the form.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:
DURING THE DAY OR AFTER HOURS:
Samantha Pabich, MD at 608-262-2122 x7320

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary. You may refuse or discontinue taking part in this study at any time without any penalty or loss of benefits. You may withdraw and still receive the same standard of care that you would otherwise have received. If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress.

If you decide to withdraw from the study, the research team may continue to review your data already collected prior to your withdrawal, but cannot collect further information from you, except from public records, such as survival data.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The Lead Researcher may terminate your participation in the study if your partner who you are supporting withdraws from the study, or for safety reasons. Should this happen, the research team will let you know.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions or concerns about this research, please contact the VA Lead Researcher, [insert name and phone number].

You may also contact the study coordinator, [insert name and phone number].

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

Participant Name: _____ Date: _____

Title of Study: Collaborate2Lose: Collaborating with support persons to improve long-term weight loss

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: Corrine I. Voils, PhD

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

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.

PERMISSION TO COMMUNICATE ABOUT THE STUDY BY EMAIL

We are requesting your email address so we can send you study-related forms and materials. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the study coordinator, [insert name and phone number]. If the study team does not answer, please leave a message.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

A member of the study team has explained the research study to you. You have been told of the procedures, possible risks or discomforts, and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive an electronic copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 07/03/2023
Per PI/SC Amendment 01
LSI Approval Date: N/A

LSI Verification Date: N/A