Evaluation of an Adaptive Intervention for Weight Loss Maintenance

NCT04116853

9/20/2021

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study (this "Research Study")?

Support and Tracking to Achieve Results (Project STAR)

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Kathryn M. Ross, M.P.H., Ph.D., 352-273-5235
Research Coordinator: Meena Shankar, M.S., R.D., 352-273-7665

4. Who is paying for this Research Study?

The sponsor of this study is internal funding from the University of Florida and the National Institute of Diabetes and Digestive and Kidney Diseases.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

The purpose of this research study is to find the best timing and frequency to provide follow-up counseling to participants who have completed weight-loss treatment sessions. This testing will help the study team find out when and how often to provide counseling after weight-loss treatment sessions end to decrease or avoid weight regain.

You are being asked to be in this research study because your weight and height fall in the high body mass index/obese category. Obesity increases the risk of health problems such as high blood pressure, diabetes, and heart disease.

You will be involved in the study for approximately 2 years.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

b) What is involved with your participation, and what are the procedures to be followed in the research?

- Measurements of height and weight
- Measurement of physical activity
- Questionnaires and 24-hour diet recalls
- Weight-Loss Sessions: Group sessions held weekly for 16 weeks, reduced calorie diet, and physical activity/walking.
- Weight-Loss Maintenance Program: Follow-up sessions scheduled based on group assignment for 20 months.
- Self-monitoring of weight, diet, and physical activity using a third-party scale and smartphone application.
- Self-report questions: Brief, weekly questions related to factors that might influence eating, activity, and weight changes.

c) What are the likely risks or discomforts to you?

EXERCISE

The recommended exercise for this study will be walking. Walking has a very low injury rate.

RISK OF DIETING

The research on lifestyle interventions for weight loss shows that there are very few risks associated with this type of intervention, if the daily energy intake is more than 1,000 calories per day.

PRIVACY

Since the program takes place in a group setting, your confidentiality cannot be guaranteed. We will ask other group members to keep the discussions confidential, but we cannot guarantee that everyone will do so.

You will be asked to use a third-party smartphone application to track your weight, eating, and activity habits and a study-developed smartphone application to submit responses to brief questionnaires. Accounts may be set up in this third-party application to limit provision of any personally-identifiable information, and you will be given the option to set this account up using a personal email that you provide or by using a study-created, secure email account. Any information that you provide to the third-party smartphone application may be stored by the app developer or its third parties. Information shared in the app is your decision and may identify you individually. This app is open and subject to "user" changes and modifications to who could possibly see your information.

You will be given a study scale to track your weight. In the event of University closures, emergencies, or while social distancing procedures are in effect, the scale will be shipped by BodyTrace, Inc. to your home. For shipping purposes, your name and address will be provided to BodyTrace, Inc.

QUESTIONNAIRES

You may feel some discomfort when completing questionnaires. You may choose not to answer these questions if you do not feel comfortable in responding.

d) What are the likely benefits to you or to others from the research?

Possible benefits to you include weight loss and increased physical activity.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

Participation in this study is voluntary. You may refuse study participation. Your decision will not affect the health care you receive at the University of Florida Health Science Center now or in the future.

Other options for weight management include joining a different weight-management program.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

You are encouraged to continue receiving medical care as needed from your primary care provider or community health center. No part of this study is part of your normal clinical care.

7. What will be done only because you are in this Research Study?

- Measurement of height: Month 0 (self-reported height will be recorded if social distancing procedures are in effect).
  Measurement of weight: Month 0, Month 4, Month 12, and Month 24.
- Measurement of physical activity: Month 0, Month 4, Month 12, and Month 24: You will be given a hip-worn physical activity monitor. The monitor will measure your physical activity over a 7-day period after each of the four assessment visits.
- Questionnaires and 24-hour dietary recalls: Month 0, Month 4, Month 12, and Month 24
- The baseline (Month 0) assessment visit will take place before the weight-loss sessions begin. The baseline study measures must be complete before you are able to proceed to the weight-loss sessions.
- Weight-Loss Sessions: Group sessions will be held weekly for 16 weeks including guidelines for a reduced calorie diet and physical activity/walking. All sessions will be audio recorded so that the study team can determine if the sessions were delivered as planned and to document specific problems and solutions. In the event of University closures, emergencies, or if social distancing procedures are in effect, group sessions will be held by Zoom UFLPHI.
- Weight-Loss Maintenance Program: Follow-up sessions are scheduled based on group assignment. If you lose 5% of your initial weight after the 16-week program, you will be eligible to continue in the weight-loss maintenance program. You will be randomly assigned to one of two groups. Random assignment is like flipping a coin to decide the group assignment. The two groups are described below:

Group A: Monthly follow-up telephone calls with a trained staff member for 20 months. These calls will be individual phone calls that will include discussions of progress and will focus on strategies to help you maintain lost weight.

Group B: The schedule for follow-up telephone calls over the 20-month period will be determined based on information related to your monitoring of weight and food intake and responses to weekly questionnaires. Calls can also be scheduled at your request. These calls will be individual phone calls that will include discussions of progress and will focus on strategies to help you maintain lost weight.

If you are in Group A or B, your phone call sessions will be audio recorded so that the study team can determine if the sessions were delivered as planned and to document problems and solutions.

- Daily self-monitoring of weight via a study-provided “smart” scale and diet and physical activity via a third-party smartphone application.
- Weekly self-report questions: Brief questions related to factors that might influence eating, activity, and weight changes.

If you have type 2 diabetes, high blood pressure, or coronary heart disease, the study team will request that you obtain written approval from your primary care provider for participation in this study.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information collected and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

We will contact you with reminder messages regarding study visits or other brief study-related information. If you choose, the study team can send reminders or study-related information via text message. If you choose to receive text messages, your calling plan's text messaging charges will apply. Please select an option for study visit reminders and other study-related information:

Yes, please send me study visit reminders and other study-related information via text message.
No, please do not contact me via text message for study visit reminders and other study-related information.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect background information, measurements of height and weights, medical history, nutrition/physical activity information, and questionnaires related to weight control strategies/ability to reach goals. Your weight information will be tracked on the study scale and sent through the cellular network to a server from which the team will download data. No identifiable information will be transmitted or stored on the server. The nutrition and physical activity information that you enter on your smartphone app will also be sent through the cellular network with no identifiable information being transmitted or stored. To minimize risk of breach, data collected from the third-party application by the researchers will be encrypted during transfer and storage. Data will be linked across the smart scale, third-party smartphone application, our study-designed smartphone application, and research servers using a numeric ID assigned to the participant.

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- The study sponsor (listed in Question 4 of this form);
- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;
- Government agencies which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

Approximately 2 years.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

Up to 1,230 adults may take part in this study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

EXERCISE

The recommended exercise for this study will be walking. Walking has a very low injury rate. The risk of having a heart problem due to walking for exercise is extremely rare in healthy people. The most common risks of exercise are injuries to the muscles and joints. Muscle strain and soreness may follow exercise, but it usually only lasts a short time and generally does not get in the way of normal activity.

You will receive instruction in proper exercise methods. The instructions will include methods for warm-up, stretching prior to exercise, and “cool-down” after exercise. Walking will be recommended to begin at a low level (such as 10 min/day, 4 days/week) and will be gradually increased up to the target goal (such as 30 min/day, 6 days/week). The increases will be decided based on your progress. If an exercise-related injury or illness does occur, it may be appropriate to change your exercise goals or to suggest a different type of exercise (for example, use of a stationary bike rather than walking). If the injury or symptoms do not resolve after an appropriate period, you will be referred to your primary care provider for further care. You will be encouraged to follow the primary care provider’s instructions regarding exercise.

RISK OF DIETING

The research on lifestyle interventions for weight loss shows that there are very few risks associated with this type of intervention, if the daily energy intake is more than 1,000 calories per day. In this study, the targeted daily caloric intake will be higher than this minimum amount. Participants are instructed to eat a well-balanced diet, so that they avoid the risks associated with very-low-calorie diets.

PRIVACY

Since the program takes place in a group setting, your confidentiality cannot be guaranteed. We will ask other group members to keep the discussions confidential, but we cannot guarantee that everyone will do so. Please keep this in mind when deciding what to share in the group meetings. Study staff members follow professional, legal, and ethical guidelines of confidentiality. You may contact one of the study staff members privately if you have a health-related or personal concern.

During the first session, group members will be asked to commit to following the guidelines for appropriate group participation. The guidelines include respect for privacy. If you do not follow these procedures, you may be disqualified from the study. Group members will be encouraged to share nutrition and physical activity information without sharing personal medical or family information. If you wish to discuss this section further, you may ask questions now or call the Research Coordinator listed on the front page of this form.

You will be asked to use a study-provided smart scale and third-party smartphone application to track your weight, eating, and activity habits and a study-developed smartphone application to submit responses to brief questionnaires.

You will be asked to provide information that will be necessary to create an account on the third-party smartphone application, including gender, height, weight, and date of birth. We will ask if you would like to set up this account using a personal email account that you identify; if you do not wish to use a personal email address, this account may be set up using a study-generated email address. Researchers will have access to the data that you provide through this smartphone application linked with an identification number with no connection to your name or any other information that could be used to identify you.

Any information that you provide to the third-party smartphone application may be stored by the app developer or its third parties. Information shared in the app is your decision and may identify you individually. This app is open and subject to “user” changes and modifications to who could possibly see your information.

To protect confidentiality, data collected using the study smart scale, the third-party smartphone application, and the study-developed smartphone application will be linked using only an identification number that does not include references to your name, address, or phone number. We will also encrypt your data during both transfer and storage.

Both in-person group weight loss sessions and individual follow-up counseling sessions that are completed over the telephone will be audio recorded. These audio recordings will be created in order to monitor whether the weight loss sessions and phone counseling sessions are being delivered as intended. Individuals will be identified by first name only and all information will be kept confidential. Audio files will be stored on secure UF server space, and devices used to create audio recordings will be stored in locked drawer in a locked room. Audio files will be typed into written form without any information that could identify you (i.e., no names or any other identifiable information will be recorded in this written form). The written form will be used to document common nutrition and activity problems and the solutions that were discussed. Audio files will be destroyed when the study is closed.

Zoom UFLPHI is a HIPAA-compliant method of video conferencing that will be used in the event of UF closures, emergencies, or while social distancing procedures are in effect. Zoom UFLPHI meeting access will be password protected. Your password will be sent to you separately from the meeting link. The audio and video data are protected and encrypted.

QUESTIONNAIRES

You may feel some discomfort when completing questionnaires that inquire about healthy lifestyle behaviors, your emotions and feelings, or your social interactions with friends and family. You may choose not to answer these questions if you do not feel comfortable in responding.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University

policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. 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 Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

13a. What are the potential benefits to you for taking part in this Research Study?

Possible benefits to you include weight loss and increased physical activity. If you are eligible to participate in the maintenance program, at the end of this program (2 years from your study start), you will be provided with a summary of your weight and data collected over the course of the maintenance program.

13b. How could others possibly benefit from this Research Study?

The information gained from this study may help improve the future treatment of adults with obesity.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

14. What other choices do you have if you do not want to be in this study?

Other options for weight management include joining a weight-management program such as Weight Watchers, TOPS (Take Off Pounds Sensibly), or Overeaters Anonymous. You may also discuss options for weight management with your primary care provider.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- You do not qualify to be in the study because you do not meet the study requirements. Ask the Principal Investigator if you would like more information.
- You need a medical treatment not allowed in this study (e.g., bariatric surgery, organ transplantation, or use of weight loss medication).
- The investigator decides that continuing in the study would be harmful to you.

- Study treatments have a bad effect on you.
- You are unable to keep appointments as directed.
- The study is cancelled by the National Institutes of Health (NIH), and/or for other administrative reasons.
- You become pregnant and the study treatment could be harmful to the baby.

If you are nursing, pregnant or planning to become pregnant during the next year, you will not be allowed to participate in this study. You will be asked to confirm to the best of your knowledge that you are not pregnant. If you become pregnant during the course of this study, you agree to notify the Research Coordinator or your Group Leader immediately.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

No. There will be no extra cost to you for participating in this Research Study.

A scale for daily use will be provided at no cost to you while you are participating in the study. A third-party smartphone application and study-developed smartphone application will be provided to you at no cost while you are participating in the study.

17. Will you be paid for taking part in this Research Study?

You will receive $50 for completing the Month 4 visit, $50 for completing the Month 12 visit, and $50 for completing the Month 24 visit. You will also receive a scale for daily use, a third-party smartphone application, and study-developed smartphone application at no cost.

University employees are no longer paid through the University payroll system. Instead, UF employees will be paid in a manner consistent with other participants in this research study.

If you are a Foreign National with J-1, F-1, H1B, E3, O1 or TN status, you are urged not to participate in this research study. Participating and receiving compensation could put your immigration status in jeopardy. If you have F1 or J1 status and have questions, please contact the UF International Center. If you have H1B, E3, O1 or TN status, contact UF Immigration and Compliance Services.

Your payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (RPP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study coordinator.

18. What if you are injured while in this Research Study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the Research Team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this Research Study.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date

Consent to be Photographed, Video and/or Audio Recorded

With your permission, you will have the following done during this research (check all that apply):

☐ photographed ☐ video recorded ☒ audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study, Dr. Kathryn Ross, or her successor, will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under her direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions Dr. Ross has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☒ The following will be **destroyed once the study is closed** (initial next to all that apply):

____ photograph(s) _____ video recording(s) __✓__ audio recording(s)

☐ As described in the Informed Consent Form, and for the purposes of **education at the University of Florida Health Science Center**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) ____ audio recording(s)

☐ As described in the Informed Consent Form; for the purposes of **education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) ____ audio recording(s)

_____ _____

Signature Date