University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 2/20/23
IRB Study # 20-0765
Title of Study: Optimization of a mHealth Behavioral Weight Loss Intervention for Young Adults
Principal Investigator: Deborah Tate
Principal Investigator Department: Nutrition
Principal Investigator Phone number: (919) 966-7546
Principal Investigator Email Address: dtate@unc.edu
Funding Source and/or Sponsor: NIH National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK)

Study Contact Telephone Number: (919) 966-5853
Study Contact Email: KEERICKS@email.unc.edu

CONCISE SUMMARY

This is a research study to test a behavioral weight loss program to help young adults adopt healthier eating and activity habits and learn effective ways to manage their weight. The 6-month program is delivered using a smartphone app and digital health tools including a physical activity tracker and a smart scale.

Participants will be asked to complete online questionnaires at the beginning of the study, after 3 months, and again at the end of the study after 6 months. These questionnaires will take approximately 45-60 minutes. They will also be asked to take their weight measurement 3 times in a row at home on the provided scale at each of these time points. After the first weight measurement and set of questionnaires (baseline assessment), all participants will have an individual video chat session with a health coach to learn about getting started. All participants will receive a standard weight loss program through the study smartphone app, which will have weekly lessons, feedback on progress, as well as a combination of tools to help them keep track of their diet and physical activity, and meet goals for diet and physical activity. Participants will also receive up to 10 personalized messages per week in the smartphone app to help support their behavior changes.

You may benefit from this program by losing some weight now and learning effective ways to manage your weight in the future. The greatest risk of this study is the possibility of injury when increasing physical activity as part of the weight loss program.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed on the following screens. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given the opportunity to download an electronic copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this study is to discover which program components are most helpful for young adults in a smartphone-delivered weight loss program that encourages healthy eating, increased physical activity, and self-weighing. There have been very few effective weight loss programs (also called interventions) that meet the unique needs of young adults. Improvements in these interventions are needed in order to help more young adults successfully achieve healthy weight loss. One way to improve interventions may be to incorporate easy-to-follow recommendations for making diet and activity changes, using digital tools that collect information such as activity, weight, and food intake, and using information from the digital tools to provide personalized daily messages that encourage and support continued changes in healthy behaviors.

You are being asked to be in the study because you have indicated that you: 1) are a young adult, age 18-39, 2) have a BMI/body mass index between 25-45 kg/m^2, and 4) have a smartphone with a data and text messaging plan. Your participation will help researchers answer questions that will support the development of interventions to help young adults lose weight.

Are there any reasons you should not be in this study?

You should not be in this study if you:

- Have Type 1 diabetes or currently receiving medical treatment for Type 2 diabetes.
- Have other health problems which may influence the ability to walk for physical activity or be associated with unintentional weight change, including cancer treatment within the past 5 years or tuberculosis.
- Have reported a heart condition, chest pain during periods of activity or rest, or loss of consciousness on the screening questionnaire.
- Have lost 10 or more pounds (and kept it off) in the last 6 months.
- Have had weight loss surgery.

- Are currently taking medications or supplements that could affect your weight.
- Have reported a past diagnosis of or receiving treatment for an eating disorder (such as anorexia nervosa or bulimia nervosa).
- Are currently pregnant, have been pregnant within the past 6 months, or are planning to become pregnant within the next 6 months.
- Have been hospitalized for depression or other psychiatric disorder within the past 12 months.
- Have a history of psychotic disorder or bipolar disorder.
- Have another member of the household as a participant or staff member on this trial.
- Are currently participating in a weight loss, nutrition or physical activity study or program or other study that would interfere with this study.

How many people will take part in this study?
Approximately 608 people will take part in this study.

How long will your part in this study last?
This study involves a 6-month weight loss program. Your total time in the study will last approximately 7-8 months, which includes two to three weeks to complete study assessments and other activities before the weight loss program starts and one to two weeks after the program ends to complete assessments.

What will happen if you take part in the study?
If you decide to take part in the study, you will be sent a Bluetooth-enabled digital scale and a Fitbit activity tracker. When you receive your devices, we will ask you to download the Fitbit app and set up a Fitbit account if you do not already have one, download the study smartphone app using the login information we provide, and link the two accounts. Our staff will check that the study is able to receive your data.

Before starting the program, you will complete assessment measures. For your first assessment, you will be asked to weigh yourself 3 times in a row on the scale that we send you. You will be asked to complete a set of **online questionnaires** that will take you approximately 30-45 minutes. These questionnaires will include demographics and questions related to your diet and physical activity. You will also complete an online **food questionnaire** about your food intake on one weekday and one weekend day during the week that you do your online questionnaires. Each food questionnaire will take approximately 15 minutes. We will ask you to use your Fitbit and scale for one to 2 weeks before starting the weight loss program so that we may collect information about your usual behavior.

After this assessment period you will start the program. You will have an individual Kickoff Session in a video chat with a health coach to provide information on how to use the study app, and review guidelines on daily self-weighing, dietary tracking, and exercise safety.

Everyone in the study will receive the same standard program in the study app that will include weekly lessons and weekly feedback based on your progress measured by your diet tracking, Fitbit activity data, and scale data. What makes the program different for each participant is that each participant will be randomly assigned to different components of the program, which

include how you will track your diet, how your activity goals are set, and how your daily messages are personalized. Being randomized is like flipping a coin, so you will not get to choose which components you get in your app. We are testing how these different components are associated with using the study app and reaching behavior and weight goals.

After your Kickoff Session and for the entire 6-month program, you will be asked to weigh yourself on the provided Bluetooth scale each day, wear your Fitbit, and track your foods and beverages. For the purpose of the research study, it is important that you are the only person in your household who uses the scale and the Fitbit during the study. The data from your app, Fitbit, and scale will be transmitted to the study. It is anticipated that you will spend approximately 15 minutes per day tracking your foods and using the study app. You will receive notifications in the app up 12 times per week, which will alert you to new messages in your app (up to 10 per week), new weekly lesson content, and weekly feedback. For this reason, it is important that you keep your notifications ON for the study app on throughout the program.

Follow-up Assessments: After 3 months, you will be asked to repeat **online questionnaires** that will take you approximately 30 minutes. After 6 months, you will be asked to complete the **online questionnaires** that will take approximately 30-45 minutes and the **food questionnaire** about your food intake on one weekday and one weekend day during the week that you do your online questionnaires. Each food questionnaire will take approximately 15 minutes. At each follow up assessment at 3 and 6 months, we will ask you to step on your scale 3 times in a row for a weight measurement.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You may also benefit by participating in this study by receiving accurate and important information about weight loss and health. Your participation may help you lose weight, and you could experience improvements in physical health associated with weight loss and making healthier choices. However, there is no guarantee that any or all of these changes will occur as a result of you participating in this study.

What are the possible risks or discomforts involved from being in this study?

There are no major risks associated with the assessment visits or participating in the study.

Risks of Increasing Physical Activity.

There may risks associated with increasing physical activity, including, but not limited to, injuries to the muscles or joints of the body. Other risks include abnormal blood pressure, fainting, dizziness, disorders of heart rhythm, exacerbation of exercise-induced asthma symptoms, and very rare instances of heart attack, stroke, or even death. To help ensure your safety, the study will follow guidelines and safety recommendations for physical activity set forth by the American College of Sports Medicine. The study will provide you with information and recommendations for safely starting an exercise program and increasing your physical activity and will make modifications to your program if you experience any of the above problems. The safest way to start becoming more physically active is to begin slowly and build up gradually. During this study, you will receive information on exercise safety. These are not intended to be a substitute for consultation with your personal physician and/or health care

provider. You may want to talk with your doctor by phone or in person before you start becoming much more physically active. You should report any problems to the researchers.

Risks associated with Questionnaires

As part of the study, you will be asked about personal factors related to your eating, physical activity, and weight. You may feel uncomfortable while completing the surveys, because of the personal nature some of the questions. You can elect not to share this private information. You should contact researchers if you feel that you have experienced any emotional distress as a result of study participation.

Risk of Breach in Confidentiality

This would mean that a person or persons outside the study team will find out that you are participating in this study and/or access the information you share with the study. This is a very rare possibility. Though the likelihood is very rare, it is possible that your data could be accessed by others should you lose your mobile device or lend the device to other people. In addition, there is a possibility that others may see your smartphone communications, including notifications or messages when the application is open, or see an open webpage while you are completing online questionnaires. If you would like, you may set up a passcode on your mobile phone to help prevent unauthorized access to your device, text messages, and research data. Additional information on how your study records will be kept private is written below.

Fitbit and Scale: You will also receive a Fitbit activity tracker and a Bluetooth-enabled scale. These devices require use of the companion Fitbit website and smartphone app. This is protected by a unique user login and password. Though you will need to enter your Fitbit username and password as part of the setup process for the study, we will not store your Fitbit usernames or passwords on our servers. All website information on your activity and weight data that are accessed by study staff will be kept confidential. The risk of breach of confidentiality over the Fitbit website will be partly subject to your comfort with sharing information on your individual profile. Fitbit will have access to the data that you choose to track within the Fitbit app/website and the information you choose to include on your individual Fitbit profile, but they will not have access to any other information about you that is collected as part of the research study.

Smartphone location: The app will store your home addresses on your iPhone and will use a geofencing technique to determine when you are out of town. Your addresses and location data will not be stored on study servers.

Risk of Wearing Fitbit Activity Tracker

There is also the possibility of minor skin irritation associated with wearable devices. We recommend taking it off occasionally, not wearing it too tightly, and keeping it clean and dry. You should regularly clean your wearable device—especially after working out or sweating. Rinse the wearable device with water or wipe it with a small amount of rubbing alcohol. Do NOT use hand soap, body soap, dish soap, or household cleaners which could get trapped beneath the band and irritate skin. Always dry the wearable device well before putting it back on. If you start to experience skin irritation on your wrist, we suggest you remove the device and contact a member of the study team to discuss the issue and determine whether you would like to continue participating in the study.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
The study team will store any personal information you provide, and your weight, dietary, and activity tracker data, in secure databases that comply with the University of North Carolina's policies on sensitive information storing and transmission. This means that there are very strong protections in place to keep your information from being accessed by individuals not authorized to access it. Information you share through online questionnaires uses a secure server that complies with the University security policies. You will be asked to voluntarily allow the study team to access your Fitbit data through the Fitbit website by entering your Fitbit username and password. Your usernames and passwords will not be stored by the study in any manner.

Participants will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What is a Certificate of Confidentiality?
This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research

subjects or for any purpose you have consented to in this informed consent document.

You should understand 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.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do. By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?

You will receive $50 for completing the baseline assessment, $25 for completing the 3-month assessment, and $75 for completing the 6-month assessment. This is meant to offset the time associated with completing these assessments. If you complete the 6-month assessment, you will also be able to keep the Fitbit activity tracker and scale (valued at $120 for both) that you will use during the study. If you live in the Chapel Hill, NC area, you may be asked to come into the study center to have your weight measured at each of the assessment timepoints. You will be given an additional $10 for each in-person measurement. If you decide to withdraw from the study or do not complete all of the study assessments, we will ask you to return the scale and Fitbit activity tracker to the UNC Weight Research Program.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

Who is sponsoring this study?

This research is funded by the National Institutes of Health. This means that the research team is

being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.
A description of this clinical trial will be available on 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 you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Consent for Unencrypted Communication

The following information is regarding un-encrypted communication (e,g., texting or email) by study staff and should be read as an addition to the consent information you have already been provided. All information previously provided is still true and remains in effect. Your participation continues to be voluntary. You may refuse to participate or may withdraw your consent to participate at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with your study team.
The study team would like to message you by email and text messaging however you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.
If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this addendum to the consent. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

- _____ Yes, I consent to the study team utilizing the following cell phone number and email address to send communication:
  - Email: __(auto-fill from REDCap)_____
  - Cell Phone Number __(auto-fill from REDCap)_____
- _____ No, I do not consent to receive un-protected communication from the study team.

Thank you for reviewing the Informed Consent document. Please choose one of the following:

- I have read the information and voluntarily agree to participate in this research study.
- I do not wish to participate in this research study.

You have indicated that you *will* participate in this research study. Please confirm by entering your initials here: _____

Type your name here: _____

Congratulations on enrolling in this research study.

Please download a copy of the consent form below for your records. If you have questions or concerns about the study, please contact the UNC Weight Research Program by phone at 919-966-5852 or email agilestudy@unc.edu".

If the individual selects "I do not wish to participate…":
Thank you for your time. You have chosen *not* to participate in this research study. If you have any questions, please contact the UNC Weight Research Program by phone at 919-966-5852 or email agilestudy@unc.edu.