Official Title: Effect of Time-based Energy Intake Goals on Weight Loss During Obesity Treatment NCT ID: NCT06455995

Document Date: 06/11/2024

Consent for Research Participation

Research study Title: Daily Eating Habits for Total Health (DEPTH)

Researcher(s): Hollie Raynor, PhD, RD, LDN, University of Tennessee

Samantha Ehrlich, PhD, University of Tennessee

Key Information for You to Consider

The information in this box is a short summary to help you decide if you want to be in this research study. More detailed information is listed later in this form. Please ask questions if there is anything you do not understand. Please take your time. You should not feel rushed or pressured to make a decision.

- **Voluntary Participation**. You should only be in the research study if you completely understand the research study and want to volunteer. You do not have to be in this research study.
- **Purpose**. This research study will determine the effect of time-based energy goals on weight loss in adults over 12-months.
- **Research Procedures and Activities.** If you decide to be in the research study, we will ask you to complete individual appointments to collect information at 0, 3, 6, and 12 months. Additionally, you will also be asked to complete 33 program meetings over 12 months. All meetings will occur face-to-face at the Healthy Eating and Activity Laboratory. You will receive goals for diet and physical activity.
- **Duration.** If you agree to be in the research study, your participation will last for about 13 months. The program will involve 60-minute program meetings once a week for months 1 to 6, twice a month for months 7 to 9, and once a month for months 10 to 12 (for a total of 33 sessions).
- **Benefits**. Possible benefits for you include weight loss, consuming a healthy diet, and being more physically active. Your participation will help us learn more about the effect of time-based energy goals in overweight and obesity treatment that will benefit others in the future.
- **Risks.** Some risks of this research study include you may not lose weight, eat healthier, be more active, or maintain weight loss.
- **Alternatives.** Instead of being in the research study, you could talk to your health care provider for possible alternatives for weight management. This could include diets with lower daily calorie recommendations, drug interventions, and surgery.

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Why am I being asked to be in this research study?

We are asking you to be in this research study because you are between the ages of 25 and 60 years old and you have overweight or obesity according to medical standards, and you have no medical conditions which would indicate that you should not participate.

What is this research study about?

The purpose of this research study is to determine the effect of time-based energy goals on weight loss in adults over 12 months.

Who is conducting this research study?

This research study is being conducted by Drs. Raynor and Ehrlich from the University of Tennessee. This research is receiving funding from the National Institutes of Health.

How long will I be in the research study?

If you agree to be in the research study, your participation will last for about 13 months and will involve 60-minute program meetings once a week for months 1 to 6, twice a month for months 7 to 9, once a month for months 10 to 12. There will also be individual appointments at 0, 3, 6, and 12 months to collect information. These meetings will occur face-to-face at the Healthy Eating and Activity Laboratory.

What will happen if I say "Yes, I want to be in this research study"?

For individual appointments at 0, 3, 6, and 12 months, you will attend two appointments at the Healthy Eating and Activity Laboratory. At these appointments, we will collect your height, weight, and waist circumference, as well as measures related to your dietary intake, sleep, physical activity, and appetite. At your first visit, you will be asked to wear a continuous glucose monitoring (CGM) system for 7 days. This system includes a small, wearable sensor and transmitter that records glucose numbers every 5 minutes. At your visit, a team member will apply the CGM sensor to the upper back portion of your nondominant arm. The sensor probe is a platinum/silver wire about the width of 2 human hairs that remains beneath the skin. Loose-fitting clothing, particularly around the arm/shoulder, will be recommended. You will also be asked to wear a small device around your wrist for 7 days to measure your physical activity and sleep. Additionally, you will be asked to take pictures of the food and drinks you eat using your phone. The pictures should be taken at the start and end (showing food and drink not eaten) of all eating occasions. If you do not have a phone that is compatible with the research study's website, we will provide one for you. We will then call you on three separate days during the week you are taking pictures and wearing the devices to ask you to describe the food and drinks you ate during the last 24 hours. These calls will take about 30 minutes each. You will also be asked to rate your feelings related to hunger, fullness, and appetite throughout the day for 7 days. For some of these ratings, you will receive a prompt via smartphone tone to complete the rating, while for other ratings you will be instructed to complete them at designated times. You will also be asked to complete some questionnaires that ask about demographics (e.g., age, education, employment status, sex assigned at birth, gender identity), health, weight loss history, sleep and wake habits on workdays and workfree days, and daily routines.

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Following completion of these measures at baseline, you will come to 33 group program meetings. These meetings will occur weekly for months 1 to 6, twice a month for months 7 to 9, and monthly for months 10 to 12. At these meetings, there will be other adults who are participating in the program. The meetings will be led by a trained interventionist and topics will be related to healthy eating and activity and behavioral strategies for meeting your program goals.

Program meetings will be audiotaped for the purpose of the treatment standardization. Individuals will not be identified in any way and all information will be kept confidential. Tapes will be destroyed within 2 years of completion of the research study.

You will have dietary goals to consume 1200-1500 calories per day and less than 30% of your daily calories from fat. You will be asked to eat your first meal within 60 minutes of waking and to eat all your meals and snacks for the day within 12 hours. You will be encouraged to eat four times each day, including three meals and one snack. You will also have to engage in moderate to vigorous intensity physical activity for at least 40 minutes per day on at least 5 days per week. You will be asked to track your eating, physical activity, and weight throughout the program. To help you with your tracking, you will be provided a subscription to the diet tracking software CronometerPro, a Fitbit wristband for tracking physical activity, and a Bluetooth scale to monitor your weight at home.

You will be randomized, which is like a coin toss, to one of three groups within the program. The three groups are: 1) DEPTH-Morning group, for which participants are asked to eat 70% of their daily calories within the first 6 hours of their eating window and 30% in the last 6 hours of their eating window; 2) DEPTH-Evening group, for which participants are asked to eat 30% of their daily calories within the first 6 hours of their eating window and 70% in the last 6 hours of their eating window; or 3) DEPTH group, for which participants do not have goals to distribute their calories in any particular way during their eating window.

What happens if I say "No, I do not want to be in this research study"?

Being in this research study is up to you. You can say no now or leave the research study later. Either way, your decision won't affect your relationship with the researchers or the University of Tennessee.

Instead of participating in the research study, one option available to you is to consult your health care provider for possible alternatives for weight management. Alternative treatments that your health care provider may suggest include diets with lower daily calorie recommendations, drug interventions, and surgery.

What happens if I say "Yes" but change my mind later?

Even if you decide to be in the research study now, you can change your mind and stop at any time. If you decide to stop before the research study is completed, you may contact the Healthy Eating and Activity Lab at 865-974-0752 to let us know you would no longer like to participate. Any of your information already collected for the research study will be returned to you if you request it.

Are there any possible risks to me?

It is possible that someone could find out you were in this research study or see your research study information, but we believe this risk is small because of the procedures we use to protect your information. These procedures are described later in this form.

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The diet goals provide a balanced diet, with approximately only 500-1000 kcal per day decrease from usual intake, and so you should expect to feel hunger prior to meals. The physical activity goal is for moderate-intensity activities that are to be increased gradually over time in order to prevent injury. However, it is still possible that you may become injured when starting to be more physically active, but this is a risk for any new physical activity program. A potential risk is that you may not lose weight and maintain the weight loss while in the program. However, this is a potential risk in any overweight and obesity treatment program.

Risks associated with continuous glucose monitor (CGM) insertion:

- Failure or lack of sensitivity of the continuous glucose monitor sensor that requires replacement / insertion of new sensor
- Discomfort from insertion of sensor
- Bruising less than ½ inch
- Bleeding less than ¼ teaspoon
- Sensitivity to adhesives with use of continuous glucose monitor resulting in skin irritation, redness, blistering, scarring, systemic allergic reaction or secondary skin infection
- Swelling or redness at insertion site
- Breakage of the continuous glucose monitor sensor under the skin with possible symptoms of skin irritation and inflammation. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Please call the research study team or seek immediate medical assistance. Seek professional medical help if you have symptoms of infection or inflammation – redness, swelling or pain – at the insertion site.

The CGM may identify that your blood glucose is high. If that happens, you will be referred to your primary care physician, and your research study participation may need to end.

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Are there any benefits to being in this research study?

There is a possibility that you may benefit from being in the research study, but there is no guarantee. Possible benefits for you include weight loss, consuming a healthy diet, and being more physically active. Even if you don't benefit from being in the research study, your participation will help us learn more about the effect of time-based energy goals in overweight and obesity treatment that will benefit others in the future.

Who can see or use the information collected for this research study?

We will protect the confidentiality of your information by removing any identifying information that would connect you to your data and responses. If information from this research study is published or presented at scientific meetings, your name and other personal information will not be used.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information or what information came from you. Although it is unlikely, there are times when others may need to see the information, we collect about you. These include:

- The Institutional Review Board at the University of Tennessee, Knoxville who oversee research to make sure it is conducted properly.
- Government agencies (such as the Office for Human Research Protections in the U.S. Department of Health and Human Services), and others responsible for watching over the safety, effectiveness, and conduct of the research.
- If a law or court requires us to share the information, we would have to follow that law or final court ruling.
- The National Institute of Diabetes and Digestive and Kidney Diseases, who is the research study sponsor paying for this research.
- A description of this research study will be posted on a public website, http://ClinicalTrials.gov, and summary results of this research study will be posted on this website at the conclusion of the research. No information that can identify you will be posted.

What will happen to my information after this research study is over?

We will keep your information to use for future research. Your name and other information that can directly identify you will be kept secure and stored separately from your research data collected as part of the research study.

We may share your research data with other researchers without asking for your consent again, but it will not contain information that could directly identify you.

Will I be paid for being in this research study?

All participants will receive a $50, $100, and $150 gift card to Target at 3, 6, and 12- month for completing assessments. These will be provided in person or by mail. Participant name and address will be collected in the instances that the gift cards are mailed.

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Will it cost me anything to be in this research study?

The only cost to you for this research study is money spent on mobile phone costs when submitting digital pictures of food before and after eating occasions and travel to the Healthy Eating and Activity Laboratory.

What else do I need to know?

We may need to stop your participation in the research study without your consent if you no longer meet the research study's eligibility requirements or if the research study is stopped for any reason. Additionally, it is possible that the funding agency, National Institutes of Health, may choose to end the research study. Should this happen, you will receive all benefits earned up to the point of the termination of the research study.

If we learn about any new information that may change your mind about being in the research study, we will tell you. If that happens, you may be asked to sign a new consent form. If this research study results in clinically-significant results, these results will not be automatically disclosed to participants. The University of Tennessee does not automatically pay for medical claims or give other compensation for injuries or other problems.

As part of the research study, you will be asked to track your eating, activity, and weight over the 12 months of the program. We will suggest specific apps and devices for you to use. The use of internet-based, third-party applications may decrease barriers to tracking and allows researchers to access your tracking data remotely. These applications may use or share your personal information and data for their own purposes not related to the research study (functionality, marketing, etc.). In most instances, you can limit the use of your personal information and data for these purposes by adjusting your privacy settings. The personal information and data you share with third-party applications is hosted on servers that are not maintained by the University of Tennessee, and it is possible that a data breach may occur that is outside the control of the researchers. You do not have to use digital applications to track your eating, activity, or weight. Tracking may be done using traditional pen and paper methods, if desired. The research team will still ask that you share your tracking records with them. You may also decide to use alternative tracking applications with which you are more comfortable.

As part of your individual appointments, you will be asked to take pictures of the food and drinks you eat using your phone and you will also be asked to rate your feelings related to hunger, fullness, and appetite. To complete some of these ratings, you will receive a prompt via smartphone tone to complete the rating, while for other ratings you will be instructed to complete them at designated times. To upload your pictures of your food and drinks you eat, you will go to https://healdepth.com/login. For the other ratings that you will be prompted to complete, you will receive a text message to your phone. The message will be sent to your phone using a service called Twilio. Within the message, you will receive a link that will have you answer questions. The information you provide (photos or ratings), will be stored for researchers to extract.

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Who can answer my questions about this research study?

If you have questions or concerns about this research study, or have experienced a research related problem or injury, contact the researcher, Dr. Hollie Raynor at (865) 974-9126, ext. 1 or hraynor@utk.edu.

For questions or concerns about your rights or to speak with someone other than the research team about the research study, please contact:

Institutional Review Board
The University of Tennessee, Knoxville 2240
Sutherland Ave., Suite 2,
Knoxville, TN 37919-2333
Phone: 865-974-7697
Email: **utkirb@utk.edu**

Authorization to Collect Height and Weight

If you choose to no longer participate and attend program meetings and/or assessments as part of this research study, it would still be useful to us to know how you does over the next 12 months. We'd appreciate it if you'd give your authorization for the principal investigator to continue to obtain your most current weight from your primary care provider.

____ If I choose to no longer attend program meetings and/or assessments as part of this research study, you have my permission to collect my most current weight from my primary care provider.

____If I choose to no longer attend program meetings and/or assessments as part of this research study, you do not have my permission to collect my most current weight from my primary care provider.

A law, called the Health Information Portability and Accountability Act (HIPAA), protects your health information. When choosing to take part in this research study, and providing your permission above, you are giving us permission to obtain and use your health information. This health information includes information in your medical records and information that can identify you (like your name, or phone number), so generally this information cannot be used in research without your written permission.

If you give your permission, your health information that will be shared with us and used in the research study includes your weight

Your health information above will be shared with us by your health care provider (as stated on the document that you complete for the research study).

We may need to share your health information (weight) with other people or organizations. Below is a list of those people and organizations and the reasons why they may see or get your health information.

- Members of the research team and other authorized staff at the University of Tennessee, Knoxville who make sure it is safe for you to be in this research study, conduct the research

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study and analyze the research data.

- People at the University of Tennessee, Knoxville who oversee and evaluate research. This includes the ethics board and quality improvement program that work to ensure research is conducted properly.
- People from and agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- Business offices at the University of Tennessee, Knoxville may be given your name, address, payment amount and related information.
- National Institute of Diabetes and Digestive and Kidney Diseases who is the research study sponsor paying for this research.
- Groups monitoring the safety of this research study.

Some of these people or organizations that may see or get your health information may not have to follow the same privacy laws and protect your information in the same way that we will. Your health information will not be shared with anyone else without your permission unless all information that can identify you is removed.

Your permission to use and share your health information for this research study will continue until the research study ends and will not expire, unless you cancel it sooner. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Can I change my mind about the use of my health information?

At any time you may change your mind and withdraw your permission for your health care provider(s) to share or use your health information for the research; however you cannot get back information that was already shared.

To takeback your permission, you must write the researcher and tell him or her of your decision. You should also send a copy of this written notification to your health care providers. In the letter, state that you changed your mind and do not want any more of your health information shared or collected.

Dr. Hollie Raynor, 336 Claxton, Knoxville TN, 37996-1920; hraynor@utk.edu

Once you take away your permission, no new health information will be shared with us. However, health information that has already been collected or shared with us may still be used as necessary to maintain the integrity of the research and as required by law. Also, if you take away your permission, you may not be able to stay in the research study. You do not have to allow use of your health information, but if you do not sign this form to allow its use, you cannot take part in the research study. If you do not allow use of your health information, it will not affect your relationship with the researchers, the University of Tennessee, your health care provider(s) or any of the services and benefits you and your family receive from them in any way.

You have the right to see and copy your health information that is shared or used in this study. However, in order to complete the research, your access to this information may be restricted during the conduct of the study to maintain the integrity of the research. When the study is completed, you will be able to access to this information.

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STATEMENT OF CONSENT

I have read this form and the research study has been explained to me. I have been given the chance to ask questions and my questions have been answered. If I have more questions, I have been told who to contact. By signing this document, I am agreeing to be in this research study. I will receive a copy of this document after I sign it.

Name of Participant	Signature of Participant	Date

Researcher Signature (to be completed at time of informed consent)

I have explained the research study to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to be in the research study.

Name of Research Team Member	Signature of Research Team Member	Date

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