Implementation of Education on Calorie Tracking Application to Improve Adherence to a Calorie Restricted Weight Management Program

NCT06428695

IRB Approval Date: 05JUN2024

PRINCIPAL INVESTIGATOR: Melanie Smith, DO
STUDY TITLE: Implementation of Education on Calorie Tracking Application to Improve Adherence to a Calorie Restricted Weight Management Program
STUDY SITE: Outpatient Weight Management Center

Cohort: Volunteers aged 18 years or older with a BMI greater than 25kg/m2

WHO DO YOU CONTACT ABOUT THIS STUDY?

Ben Ramirez, [redacted].

KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.
You are being asked to take part in a research study at Aurora Sinai Outpatient Weight Management Center.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research interventions in which they would want to participate. Take the time you need to ask any questions and discuss this study with the primary investigator and with your family, friends, and personal health care providers. For the remainder of this document, the term "you" refers to you as the decision-maker and the individual being asked to participate in this research.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. If you choose to leave the study, please inform your study team to ensure a safe withdrawal from the research. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

WHY IS THIS STUDY BEING DONE?

The research proposes to enhance knowledge and self-management skills among participants with a BMI greater than 25kg/m2. The purpose of this research study is to assess the impact of a one-hour dietary self-monitoring tool education session for participants in a calorie-restricted weight management program on their knowledge of the use of the tool to help them adhere to a calorie-restricted weight management program.

WHAT WILL HAPPEN DURING THE STUDY?

If you decide to take part in this study, you will be asked to:

- *Actively listen to a one-hour education session on the use of a dietary self-monitoring tool.*
- *Answer a written pre-test prior to the education session.*
- *Answer a written post-test following the completion of 8-week calorie-restricted weight management program.*

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this study, your involvement is expected to last for 1 hour for an education session, and then and 8-week participation in a calorie-restricted weight management program.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

Approximately 30 will be participating in this study.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

The expectation of participation in this study is that there should be no physical or emotional risks or discomfort over and above usual participation in the calorie-restricted weight management program alone. The data provided in the pre and post-test will be confidential. The information will only be available to the researcher.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

Education on the use a calorie counting app offers several potential benefits, including heightened awareness of dietary intake by providing a clear understanding of nutritional content. The app contributes to effective weight management, accommodating goals such as weight loss, maintenance, or muscle gain, while also facilitating nutritional balance through monitoring macronutrient distribution. Additionally, the participant can set and monitor personalized health goals, gain education on food choices, and practice portion control.

Are there any potential benefits to others that might result from the study?

This study has the potential to help any individual entering a weight management program with the needed education to manage the chronic disease of obesity. Through accountability for caloric eating, this application has the potential to help with weight loss, which in turn can have positive effects on other comorbidities.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

If you decide not to participate in this study, there are other options available. These include weight management at an affiliated clinic in Milwaukee, Wisconsin, or an online health management program.

DISCUSSION OF FINDINGS

Participants will not receive any return of research results.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR DATA

As a participant in this study, information will be obtained from you. Information will only be utilized for this study that has been described in the consent form. Your data will not be shared for future research. Data obtained by this study may be stored by the researcher for no more than one year.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We are committed to safeguarding the confidentiality of your personal information within your medical record. The researcher overseeing this study adheres to relevant laws and policies to maintain the privacy of your identifying information to the best of their ability. Nevertheless, there is a potential risk that, despite our utmost efforts, your identity or details about your involvement in this research could unintentionally be disclosed or accessed by unauthorized individuals.

INVESTIGATIONAL REVIEW BOARD

This research has received approval from the Investigational Review Board at Delta State University, Cleveland, Mississippi. In addition, this research has received approval has been received from Advocate Health-Wake Forest University School of Medicine.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, about your rights as a research participant, or about any research-related injury, contact the Co-investigator, Ben Ramirez, [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact 1[redacted]

CONSENT DOCUMENT

Please keep a copy of this document for your own reference.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date & Time AM/PM
Signature of Person Obtaining Consent	Print Name of Person Obtaining Consent	Date & Time AM/PM
Signature of Investigator	Print Name of Investigator	Date & Time AM/PM