Official Title: Pilot Investigation of a Novel Therapeutic Intervention for Food Addiction: Food Addiction Clinical Treatment (FACT) Program
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Wake Forest®
School of Medicine

Department of General Surgery

INVESTIGATION OF A NOVEL TELEHEALTH INTERVENTION FOR FOOD ADDICTION: THE FOOD ADDICTION CLINICAL TREATMENT (FACT)

Informed Consent Form to Participate in Research
Shenelle Edwards-Hampton, PhD, Principal Investigator

SUMMARY

You are invited to participate in a telehealth (virtual) research study. The purpose of this research is to investigate a new telehealth program for food addiction. You are invited to be in this study because you have indicated that you are experiencing difficulty with food addiction and are interested in an intervention. Your participation in this research will involve 16 weekly, 90 minute visits. All appointments will take place via a video conference platform that is HIPAA compliant. Thus, in order to participate, you will need 1) to have access to internet on a weekly basis at the time of meetings, 2) an electronic device, such as a smartphone, computer, or tablet that has audio and a camera 3) the ability to download video conference software, and 4) access to a private, confidential space without others around during meetings. .

Participation in this study will involve weekly group therapy via a video conference platform, homework, and assessments that include answering questionnaires. During meetings you will be asked to participate via keeping your video camera on throughout the entire meeting. All research studies involve some risks. It is possible that you may experience emotional discomfort from participating in therapy or that you may be exposed to sensitive personal information disclosed by other group members. It is possible you may benefit from participation in the study in that the program has specifically been developed to assist individuals with the management and reduction of food addiction behaviors. You may learn new techniques and skills that will reduce your food addiction symptoms or behaviors which may lead to improvement in emotional well-being and quality of life.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to and are free to discontinue participation at any time. There may be other choices for programs available to you, such as participation in individual or other group therapy with a qualified professional. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Shenelle Edwards-Hampton, PhD. If you have questions, suggestions, or concerns regarding this study, or you want to withdraw from the study, Dr. Edwards-Hampton's contact information is: [redacted].

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a telehealth research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have indicated that you are experiencing difficulty with food addiction. There is no current standard of care for food addiction. People with food addiction do not receive specialized interventions and often end up in a wide range of programs such as 12-step programs, weight loss surgery, standard weight loss programs, or Cognitive Behavioral Therapy (CBT; a treatment intervention that attempts to change thoughts and behaviors) for binge eating disorder. The purpose of the current study is to develop a telehealth intervention specific to food addiction. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to test a new telehealth program for food addiction to see whether it is helpful in reducing problematic food-related emotions and behaviors.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to twenty-five people will take part in this telehealth study through the Atrium Health Wake Forest Baptist Weight Management Center. In order to identify the 25 participants needed, we may need to screen as many as 60 people, because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

Should you choose to participate in this study you will be asked complete a number of assessments estimated to take 90 minutes; these will be sent to you for you to complete electronically and the secure link will be sent to you via email and data will be maintained in a HIPPA compliant, secure electronic storage system. The assessments will include self-report questionnaires related to your mood, eating behaviors, cognitive functioning, vital signs (such as weight and height), and general history.

Following the initial assessments, and when other participants have been successfully recruited to participate in the telehealth program, you will be contacted and asked to participate in your first group telehealth session which will continue weekly for 16 weeks. As part of your telehealth sessions, you will be asked to keep your device camera on at all times, complete brief homework assignments, participate in discussions and activities in breakout sessions during telehealth sessions, and complete a brief questionnaire at the end of every session related to the content

covered in each session. After the program is complete, you will complete the same group of assessments from your initial visit prior to participating in the group telehealth sessions.

Once you have consented to participate in the study, study personnel may contact you via MyWakeHealth, phone/text messages, or emails.

How Long Will I Be in the Study?

You will be in the study for approximately 18 weeks. You can stop participating in the study at any time without penalty.

What Are the Risks of the Study?

Being in this study involves some risk to you. We welcome you to discuss the risk of being in this study with the study staff. Potential risks and side effects related to the study include: 1) emotional discomfort from telehealth interventions intended to reduce food addiction behaviors, such as participating in food logging, limiting types of food intake, limiting portion sizes, etc 2) exposure to sensitive personal information of others, 3) physical or emotional discomfort from fasting to complete the resting metabolic rate and completing fitness testing, 4) changes or conflicts in social relationships due to modifying your habits or behaviors, or, 5) emotional discomfort from changing eating behaviors that have been enjoyable and/or rewarding for you. Should you experience emotional symptoms, such as depression, anxiety, or suicidal ideation while participating in this study, please notify staff members and you will be provided with local referrals for the treatment of these symptoms.

In addition, there is a risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other consequences that we cannot predict. You should tell the research staff about anything you may be concerned about to help limit your risk of experiencing negative consequences.

It is important to note that the treatment will occur in a group telehealth setting, with other participants. Thus, confidentiality will be limited, in so far as other group participants will be able to see you and interact with you around group content during sessions. Group members will be asked to participate in private, confidential location and to keep their device cameras on during the entire meeting.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

As part of this study, you will be asked questions about depression symptoms and substance use. If we learn that you or someone else is in danger of harm to self or others, the study team is required to report that information to the proper authorities to ensure your safety and you will be

provided with referrals for the treatment of these symptoms.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. However, we hope the information learned from this study will be of benefit to you and to other people in the future who struggle with food addiction. The benefits of participating in this study may be: improvement in symptoms of food addiction including problematic eating behaviors.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive help for your food addiction. You should talk to your doctor about the various program choices available to you. Instead of being in this study, you may choose to seek a program with a therapist trained in eating disorders and related conditions in the community or at another facility.

WHAT ARE THE COSTS?

All study costs, including procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. Findings from assessment measures, including substance use, will be held confidential and steps will be taken to minimize to the fullest extent possible the ability to directly identify any given participant and their self-report. To help ensure participant privacy and confidentiality, only a unique study identifier will appear on the data collection form. However, there is always some risk that even de-identified information might be re-identified.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid a total of $50 via a reloadable debit card for completing all scheduled study visits. You will be mailed a $20 debit card at your initial study assessment visit and $30 debit card at your final assessment visit after 16 weeks of the program.

The findings from this research may result in the future development of products that may be of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is internally funded by Atrium Health Wake Forest Baptist Weight Management Center.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** demographic information (eg age, race/ethnicity, height, weight), psychological characteristics and behaviors, and medical conditions and information.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a system called RIPPLE. Any identifying information (participant name, address, social security number, email, phone number) will be stored separately from de-identified data in Ripple™. Participant personal information will also be kept in Ripple™, a secure web application designed for the storing and management of personally identifying information of research participants. Ripple™ was initially developed at the University of Michigan to provide a user-friendly, web-based secure interface where research teams can centralize the storage and management of research participants' personal information, including name, participant ID, demographics, and study workflow (e.g., appointments). Participant information managed with Ripple is private and secure. This information is kept in fully encrypted format inside dedicated databases that are segregated from other Ripple accounts and thus only authorized study staff will have access to the study data. As this study is being completed in conjunction with research investigators/staff from the University of Michigan and Stonehill College, study investigators/staff that are approved by the WFBMC IRB may have access to your PHI.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, and to provide required reports. Some of the people, agencies and businesses that may receive and use your health information include: the research sponsor, investigators at other sites who are assisting with the research; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; University of Michigan and Stonehill research colleagues assisting this study, representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This

information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable. If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information will either be destroyed or it will be de-identified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center.

You can tell Dr. Shenelle Edwards-Hampton that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Shenelle Edwards-Hampton, PhD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to participate in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

Medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any negative

consequences of withdrawing from the program. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

What Happens if I Experience an Injury or Illness as a Result of Participating in this Study?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical programs for research related injuries or to report a study related illness, adverse event, or injury you should call Shenelle Edwards-Hampton, PhD at [redacted]. If it is after normal business hours, please contact her via the 24-hour line, [redacted]

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Shenelle Edwards-Hampton, PhD at [redacted]. If you are experiencing overwhelming acute mood symptoms or having thoughts or harming yourself or someone else. Please call the National Suicide Prevention Lifeline, a 24-hr hotline, at 1-800-273-8255.

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 the Chairman of the IRB at [redacted] or the

Research Subject Advocate at [redacted]

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm