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Wake Forest University
School of Medicine

Department of Pediatrics

THE STAY IN TREATMENT (SIT) STUDY 2

Informed Consent Form to Participate in Research
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SUMMARY

You are invited to participate in a research study. The purpose of this research is to learn more about the reasons that families who take part in weight-management programs like Brenner FIT stop attending appointments or drop out, and if we can use a statistical program on a computer to prevent it. You are invited to be in this study because you and your family are taking part in Brenner FIT. Your participation in this research will involve two visits and last about 6 months- the same amount of time you are in the Brenner FIT program. You may be in a part of the study where we send extra reminders by email, phone call, or text message to help keep your family involved in Brenner FIT.

Your participation in this research will involve two visits. At each of these visits, you will answer questions about your health and behaviors. This information will be used to determine if your family might be at high risk for dropping out before you complete 6 months of treatment. All research studies involve some risks. A risk to this study that you should be aware of is that the questions you are asked may make you feel uncomfortable. There is not the possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. 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 Dr. Joseph Skelton. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, you can reach him by telephone at [redacted] or by email at jskelton@wakehealth.edu.

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 Wake Forest University Health Sciences Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to be in this study because you and your family are taking part in the Brenner FIT program. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the 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 learn more about the reasons that families who take part in weight-management programs like Brenner FIT stop attending appointments or drop out, and if we can use a statistical program on a computer to prevent it.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 140 children/teens and their parents at 2 research sites will take part in this study, including approximately 70 families at this research site.

WHAT IS INVOLVED IN THE STUDY?

If you chose to participate in this study, you will be asked to complete two study visits- one at the beginning of your families' participation in Brenner FIT and one at the end of the program. Each of these visits should last approximately one hour. At your first visit, we will ask you to answer some questions about your health and weight, your family and health habits, your thoughts and feelings, emotions, physical function, satisfaction with the Brenner FIT program, and relationships with other teens. The information gathered at these visits will be analyzed by computer software and then used to determine if your family might be at high risk for dropping out of Brenner FIT before you complete 6 months of treatment.

The study is divided into 2 parts; depending on when your family begins the study, your family may receive extra telephone calls, emails or text messages to remind them of upcoming visits. The staff of Brenner FIT may receive information on your risk of dropping out as well.

At your second visit, you may be asked to talk with us for about 15 minutes about your experience in receiving the extra telephone calls, emails, or text messages. We would like to record this interview with an audio recorder. This is being done so that we can write down your comments and save an electronic copy to help us better plan programs like Brenner FIT in the future. You understand that you may request the filming or recording be stopped at any time during the interview. You can also withdraw your consent to use and disclose the audiotape before it is used. You should also understand that you will not be able to inspect, review, or approve the audiotapes (including articles containing such) before they are used in this study.

Please choose one of the following regarding the use and disclosure of the audiotape used in this research study:

_____ I would like the audiotapes of me to be destroyed once their use in this study is finished.

____ The audiotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

How Long Will I Be in the Study?

You will be in the study for about 6 months or until you have completed the Brenner FIT program.

You can stop participating at any time. 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 potential health or safety consequences.

What Are the Risks of the Study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff. There is a risk that some of the questions you are asked in this study may make you feel uncomfortable. You can refuse to answer any of the questions at any time. The additional telephone calls, emails, or text messages may also be an annoyance.

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.

Are There Benefits to Taking Part in the Study?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

What Other Choices Are There?

This is not a treatment study. Your alternative is to not participate in this study.

What Are the Costs?

All study costs, including any study products or 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 or permitted by law, or necessary to protect the safety of yourself or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

Audio recordings collected as a part of this study will be stored on microcassette in a locked file cabinet within a secure file room. These recordings will be kept as a part of the research study records for at least six years after the study is finished.

By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive a $25 gift card for each completed study visit.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the National Institute of Nursing Research, part of the National

Institutes of Health. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and the information we get from your medical records about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes questionnaires on family function and structure, emotions, family health behaviors, quality of life, and program satisfaction; body weight; and details of your participation in the Brenner FIT program including appointment attendance.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

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, to provide required reports and to get approval for new products.

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 Atrium Health Facilities; 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, videotapes, audiotapes or other recorded media which identify you unless we receive you're written authorization. Identifiers might be removed from the identifiable private information and

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.

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 not already in your medical record 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 will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Joseph Skelton 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:

Joseph A. Skelton, MD, MS
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be 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.

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 potential health or safety consequences. 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, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

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

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, Dr. Joseph Skelton, at [redacted] or [redacted] (after hours).

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