Official Title: Increased Monitoring of Physical Activity and Calories With Technology
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Wake Forest®
School of Medicine

Department of Family and Community Medicine

IMPACT: INCREASED MONITORING OF PHYSICAL ACTIVITY AND CALORIES WITH TECHNOLOGY

Informed Consent Form to Participate in Research
Justin B. Moore, PhD, MS, Principal Investigator

SUMMARY

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 take part in this study because you and your child are enrolled in Brenner FIT. Your participation is voluntary. 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. Your participation in this research will involve last about 6 months.

Participation in this study will involve randomization into 1 of 2 groups. One group will receive standard Brenner FIT care. The other will receive standard Brenner FIT care and additional mobile health (mHealth) components such as physical activity trackers, websites, podcasts, and animated videos. The aim is to maximize the benefits of the Brenner FIT pediatric weight management program with the use of innovative and tailored technology. Further explanation will be given in chart form in that pages following this summary.

All research studies involve some risks. There are limited risks involved with participating in this study. Exercise of any kind can result in minor discomfort (eg, muscle soreness) or serious injury (eg, torn muscles or ligaments). Participants will also wear accelerometers while participating in twice annual data collection. Minor discomfort from the strap that secures the monitor is a possibility. There is the possibility that you may benefit from participation in this study by learning new skills and techniques to manage diet and physical activity.

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. Justin Moore (Principal Investigator). If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: [redacted] or via email at [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 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 a child that is eligible for Brenner FIT. Your participation is voluntary. 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 determine if the use of innovative and tailored technology can maximize the impact of established strategies for a pediatric weight management program, such as Brenner FIT.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 160 people will participate in this study. This number consists of 80 parent/child pairs.

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in any group.

Conditions	Details
Brenner FIT Standard Care	After referral, families attend an orientation, in which they are then scheduled for an initial introductory 2-hour intake group session and cooking class; these occur within 2-4 weeks of the orientation. Monthly 1-hour long visits with the dietitian, counselor, and PA specialist are held for 6 months, in which the child and caregiver see the pediatrician. During the 6 months of treatment, they attend 4 group classes, choosing from topics such as meal planning, PA, and parenting. Specialized visits with the PA specialist or dietician are scheduled as pertinent issues arise. Clinic visits include individualized goal setting (for behaviors family/clinician have jointly agreed to address), healthy eating and physical

	activity education, and behavioral counseling to implement changes at home. Self-monitoring is part of the treatment, using hand-written, paper diet and PA logs, completed by parents and children and returned to clinicians
Brenner mFIT (Brenner FIT plus mHealth)	Brenner mFIT will include all components of the standard Brenner FIT program and six mHealth **components.** **Component 1**: A mobile-enabled website developed for the project and accessible via phone, tablet, or personal computer will serve as a central hub for the materials. Podcasts, animated videos, tracking summaries (for parent and child), goal setting, and clinical feedback will be delivered via the website utilizing an application that integrates data from the two commercial apps (MealLogger and Fitbit™) with data entered by participants. **Component 2:** Tracking apps chosen by the study team after consultation from caregivers and patients in or formative and prior work will be utilized for dietary and physical activity self-monitoring. Caregivers and adolescents will be instructed to download the MealLogger (https://www.meallogger.com/)(and Fitbit™ (https://www.fitbit.com/) apps to their mobile devices, and adolescents will be given a Fitbit™ Zip® activity tracker which syncs with the Fitbit app. **Component 3:** Caregiver podcasts provide recommendations that will assist them in navigating their pediatric weight management journey. These easily accessible podcasts will help caregivers deal with the emotions that come with raising an adolescent in treatment for a medical condition (ie, obesity), provide strategies and encouragement to caregivers to

	help their adolescent build autonomy for healthy behaviors, engage in age/ability appropriate physical activity with their child, cook healthy family meals, and provide healthy snacks. Podcasts will also focus on positive communication, interactions, and challenges often encountered in parenting. Caregivers will download and listen to one podcast each week in weeks 1-12. **Component 4:** A total of six videos will be developed based upon prior feedback from adolescents enrolled in the Brenner FIT program. Videos will be made available to the youth weekly for the first six weeks. These videos will depict various situations that participants may face as a part of a program like Brenner FIT. Each video will help them as they deal with the negative and positive emotions of their weight-loss. **Component 5:** Participants will be encouraged to follow each other and a curated list of health professionals on MealLogger. The aim is to encourage discussions around healthy meal planning. These interactions will be encouraged during Brenner FIT group sessions. **Component 6:** Tailored feedback will be provided by clinical staff based upon a weekly report for each adolescent patient that will give a quick summary of the level of self-monitoring, nutritional content of recorded meals, level of physical activity engaged in, and progress on behavioral/weight loss goals. Staff will then use this information to engage with participants via face-to-face meetings, direct texts, and emails to give feedback based upon behavioral progress, encouragement to engage in greater self-monitoring, and/or theoretically informed messages to promote self-efficacy, positive outcome expectations, and self-regulatory behaviors.

Time Period	Activities*
Baseline assessments	• Study staff will measure your height and weight • You will complete one survey
3 Months	• Study staff will measure your height and weight • Study staff will review treatment goals and overall progress
6 Months	• Study staff will measure your height and weight • Study staff will review treatment goals and overall progress • You will complete one survey

*As a continued safety measure, participants will be given the option to complete surveys and follow-up meetings virtually. For this process, after completion of this consent form, participants will be sent a link for both the parent and child to complete post-consent surveys and dietary recalls (adolescent). Study staff will be available via Webex to answer any questions that participants have while completing these assessments. 3 month and 6 month follow-up visits can also be conducted virtually. If participants already have in-person visits scheduled with a physician close to their 3 and 6 month follow-ups, study staff will attempt to couple these meetings to reduce contact.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 6 months.

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?

There are limited risks involved with participating in this study. Participants will wear accelerometers while participating. Minor discomfort from the belt that secures the monitor is a possibility. 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.

Trained project staff members will collect all measures, and these persons will be trained to encourage participants not to take part in any data collection that make them uncomfortable. They will also be trained to conduct the measures in a very sensitive and discrete manner. Each

data collection team will include at least one female staff member, and female staff will collect all measurement data from all students. Data will be collected at the Brenner FIT clinic.

Although there is a small risk in all studies that involve human subjects that data will be accessed by an unauthorized person, rigorous safeguards will be put in place to ensure the safety and integrity of the data. Each child will be assigned a numeric identifier, and this identifier (not a name) will be associated with each participant's data. Data will be kept in secure computer files and file cabinets, and access will be limited to the PI, Co-Is, and project coordinator.

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. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be improved weight outcomes for the enrolled participants. In addition, the research will help provide information as to whether using technology can maximize outcomes of a program such as Brenner FIT.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have.

WHAT ARE THE COSTS?

All study costs, including any materials used to collect information, will be paid for by the study.

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. There is always some risk that even de-identified information might be re-identified.

Participant 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or bio-specimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or bio-specimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

WILL YOU BE PAID FOR PARTICIPATING?

Both parent and child will receive a $15 Walmart gift card at the initial visit, 3-month visit, and 6-month visits with the study staff. This means that the parent and child will separately receive a total of $45.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by 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 about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** height, weight, dietary information, and physical activity behaviors.

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 Medical Center operations.

We will make every effort 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 North Carolina Baptist Hospital; 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.

We will be the mobile applications Fitbit and MealLogger. This will require you to download these applications to your smartphone and create an account.

The following privacy information is taken directly from MealLogger's privacy policy:

"We collect information from you in various ways when you use our Web sites and services. We may also supplement this information with information from other companies. We collect two general types of information, namely personal information and aggregate data. As used in this Policy, the term "personal information" means information that specifically identifies an individual and demographic and other information when directly linked to information that can identify an individual. Personal information includes your name and email address; your title, company and other profile information you provide; demographic information, etc. Our definition of personal information does not include "aggregate" data or information uploaded by you (including photos) that is not personally identifiable."

"Your account information and access to our service is accessible only through the use of an individual user ID and password. To protect the confidentiality of personal information, you must keep your password confidential and not disclose it to any other person. Please advise us immediately if you believe your password has been misused. In addition, always logout and close your browser when you finish your session. Please note that we will never ask you to disclose your password in an unsolicited phone call or email."

Additional information about MealLogger's privacy policy can be found at https://www.meallogger.com/privacy.

The following privacy information is taken directly from Fitbit's privacy rules for adults and children:

"Some information is required to create an account on our Services, such as your name, email address, password, date of birth, gender, height, weight, and in some cases your mobile telephone number. This is the only information you have to provide to create an account with us. You may also choose to provide other types of information, such as a profile photo, biography, country information, and community username."

"Your device collects data to estimate a variety of metrics like the number of steps you take, your distance traveled, calories burned, weight, heart rate, sleep stages, active minutes, and location. The data collected varies depending on which device you use. Learn more about the features of our various devices and how you can use MobileTrack. When your device syncs with our applications or software, data recorded on your device is transferred from your device to our servers."

"The Services include features that use precise location data, including GPS signals, device sensors, Wi-Fi access points, and cell tower IDs. We collect this type of data if you grant us access to your location. You can always remove our access using your Fitbit device or mobile device settings. We may also derive your approximate location from your IP address."

"When you access or use our Services, we receive certain usage data. This includes information about your interaction with the Services, for example, when you view or search content, install applications or software, create or log into your account, pair your device to your account, or open or interact with an application on your Fitbit device."

"Fitbit allows parents to set up accounts for their children to use with select Fitbit devices ("Children's Account"). Children's Accounts are subject to a separate Privacy Policy for Children's Accounts which explains what information we collect to set up these accounts, what information we collect from a child's use of our Services, and how we use and share that information. Parents or guardians must consent to the use of their child's data in accordance with the Privacy Policy for Children's Accounts in order to create such an account."

"Persons under the age of 13, or any higher minimum age in the jurisdiction where that person resides, are not permitted to create accounts unless their parent has consented in accordance with applicable law. If we learn that we have collected the personal information of a child under the relevant minimum age without parental consent, we will take steps to delete the information as soon as possible. Parents who believe that their child has submitted personal information to us and would like to have it deleted may contact us at privacy@fitbit.com."

We will also be using Actigraph physical activity monitors. No personal data will be stored or shared with this company. Actigraph software will only be used for the analyses of physical activity data. For data subjects (also known as "patients" or "participants"), each subject record is only required to have the following attributes:

1. Subject Identifier (a unique identifier provided by the data controller; typically providing a reference to another system)
2. Wear time of the activity monitor including

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.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

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. 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. Justin Moore 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:

Dr. Justin Moore
[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.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://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 Web site at any time.

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 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. Justin Moore at [redacted] or via email at jusmoore@wakehealth.edu.

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