Official Title: Feasibility of a Coordinated Parent/Child Dyad Weight Loss Intervention

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Wake Forest®
School of Medicine

Department of Family Medicine

A COORDINATED PARENT/CHILD DYAD WEIGHT LOSS INTERVENTION: DYAD PLUS

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

SUMMARY

You are invited to participate in a research study. The purpose of this research is to develop a program that would help to facilitate self-monitoring, positive communication, joint problem solving, and social support to increase physical activity, healthy eating, and weight loss. You are invited to be in this study because your child is currently enrolled in Brenner FIT. Participants will be randomized to either,

A) Receive a youth only intervention (Brenner FIT Standard Care for your child),
B) A co-enrollment condition where both adolescents and adults will be enrolled in an age appropriate weight loss program. This means that the child will get Brenner FIT Standard Care and you, the adult, will be a part of the By Design Essentials weight loss program,
C) A co-enrollment condition where the child will get Brenner FIT Standard Care, you will be a part of the By Design Essentials weight loss program, PLUS six dyad group sessions.

All research studies involve some risks. There are limited risks involved with participating in this study. There are limited risks involved with participating in this study outside of the collection of relevant data. Trained project staff members will collect all measures, and these individuals will be trained to encourage you to not take part in any data collection that makes them uncomfortable. There is the possibility that your child may benefit from participation in this study by gaining knowledge around healthy eating and physical activity. Data will be collected at the Brenner FIT clinics and/or virtually via Webex or Zoom by study staff.

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/her contact information is: [redacted] or via email at [redacted].

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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 your child is currently enrolled in Brenner FIT and you are eligible for an adult weight loss program called By Design Essentials. Participation is voluntary. Please take your time in making your decision as to whether or not you and your child 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 create a coordinated approach to aid self-monitoring, positive communication, joint problem solving, and social support to increase physical activity, healthy eating, and weight loss in comparison to a non-coordinated approach or Brenner FIT alone.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

90 people at will be enrolled, which includes 45 parent/child dyads.

WHAT IS INVOLVED IN THE STUDY?

If you join the study, you will be randomized into either the Brenner FIT Standard group, the Brenner FIT (child) and By Design (adult), or the Dyad Plus group which includes the Brenner FIT (child) and By Design (adult) programs plus six additional classes. 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 each group, which are described below;

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Name	Description
Group A: 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 physical activity 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, physical activity, and parenting. Specialized visits with the physical activity specialist or dietician are scheduled as pertinent issues arise. Clinic visits include individualized goal setting (for behaviors family/clinician have agreed to address), healthy eating and physical activity education, and behavioral counseling to implement changes at home.
Group B: Co-enrollment in Brenner FIT Standard Care (child) and By Design Essentials (adult)	Your child will receive standard Brenner FIT standard care (please see group A for a description). For **By Design Essentials**, a dietitian provides each adult participant with a detailed program manual that describes the prescribed diet. The dietitian utilizes standard behavioral techniques to promote lifestyle behavior changes that enable participants to implement and maintain behaviors necessary to adhere to the dietary prescription. Participants also receive a standard exercise program designed to promote exercise energy expenditure. The exercise prescription includes consults and personal training sessions. Behaviorists meet with participants to provide counseling to learn the skills necessary to adopt the prescribed dietary pattern and exercise plans. Please see the document titled "By Design Program Summaries" for more information.

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Group C: Co-enrollment in Brenner FIT Standard Care (child) and By Design Essentials (adult), *PLUS* a coordinated component	This group includes having your child enrolled in Brenner FIT Standard care, the adult enrolled in By Design Essentials, plus six additional classes. These six additional classes are dyad group sessions, which will focus on one-on-one parent/child communication sessions, joint goal setting/tracking, and home environment assessment. This innovative approach will seek to employ components of motivation and communication theories to increase self-monitoring, positive communication, problem solving, and social support to increase healthy physical activity and eating behaviors to increase the effectiveness of the weight loss programs beyond gains observed in matched controls. The exact mixture of sessions will depend on the needs of the family, but it is expected that the dyads will participate in six, one-hour sessions in addition to those required by their weight loss program. Joint goal setting and tracking will be enabled by commercially available devices and apps, Each caregiver and child will receive an activity monitor, activity app, and a food app (digital food diary) that allows self-monitoring of consumption and "social accountability," which will allow caregivers and the Brenner FIT team to monitor and encourage. Furthermore, two home visits will be conducted to evaluation the home food and activity environments to inform tailored feedback to families.

*As a continued safety measure, participants that are assigned to Group C will conduct the 6 additional classes via WebEx instead of in-person. These will be conducted in either group or individual format, depending on the topic and preference of the participants.
*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 Fitbit™ with data entered by participants.

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Time Period*	Activities
Baseline Assessments	• Study staff will measure height and weight of parent and child • Both parent and child will complete psychosocial surveys • Both parent and child will complete a physical activity questionnaire • Both parent and child will complete a food frequency questionnaire • Physical activity data will be collected using Fitbit worn continuously over 7 days (youth) • Fasting serum biomarkers: glucose, insulin, hemoglobin A1c, AST, ALT, and total cholesterol (child; collected as part of standard care)
3 Months	• Study staff will measure height and weight of parent and child. • Study staff will review treatment goals and overall progress with parent and child
6 Months	• Study staff will measure height and weight of parent and child • Study staff will review treatment goals and overall progress with parent and child • Both parent and child will complete psychosocial surveys • Both parent and child will complete a physical activity questionnaire • Both parent and child will complete a food frequency questionnaire • Physical activity data will be collected using Fitbit worn continuously over 7 days (youth) • Fasting serum biomarkers: glucose, insulin, hemoglobin A1c, AST, ALT, and total cholesterol (for parent and child if collected as part of standard care)

Enrollment completion, following the signing up this form, will take place virtually in order to reduce patient/staff contact. Following full consent, you will be sent your participant ID's, login information for dietary recalls, and links to the surveys that will need to be completed. Participants will receive a private meeting link that will allow study staff to interact with them during the process of completing all intake surveys. Additionally, study follow-up will be completed distance via distance when it is suitable or preferred. These meetings would be completed using WebEx.

As a part of the study, reminders about study meeting will be conducted via phone and/or email. Please provide the phone number and/or email that you would like to use for reminders.

Phone Number:_____

Email:_____

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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?

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 individuals will be trained to encourage participants to not take part in any data collection that may make them uncomfortable. They will also be trained to conduct the anthropometric measures in a very sensitive and discrete manner.. 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. You and your 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 able to provide valuable information about enhanced weight management strategies to promote physical activity and healthy eating in weight loss clinics.

What Other Choices Are There?

You and your child do not have to be in this study to receive treatment associated with the Brenner FIT pediatric weight management program or the By Design adult weight management program. You should talk to your doctor about all the choices you have.

What Are the Costs?

Costs for your regular medical care, which are not related to this study, will be your own responsibility. This includes any associated copays that are due at the time of your visit.

A $750 stipend will be provided to the Adult Weight Management Center for **adult** participants that are randomly assigned to Group B or Group C. This will cover the following components:

- Personal training sessions
- Remote monitor kit, including body weight scale and Carium app
- Behaviorist visits
- Program materials

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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.

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 biospecimens 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 biospecimens 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?

You will receive $20 after attending your baseline (first meeting) and completing all assessments. You will receive an additional $20 for attending and completing all assessments during your 6-month follow-up meeting.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

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 Happens if You 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

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$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 treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Justin Moore at telephone number [redacted] or via email at [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any information we collect about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: participant age, sex, race, ethnicity, weight status, nutritional recall, physical activity behaviors.

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.

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.

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

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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."

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.

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Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least three 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 website 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.

Information that identifies you may be removed from the data and/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.

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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 [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 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

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