Official Title: A Coordinated Parent/Child Dyad Weight Loss Intervention: Dyad Plus (Feasibility)
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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 coordinated program (Dyad Plus) 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 and you are eligible for an adult weight loss program called By Design.

If you participate in the study, you will be asked to enroll in By Design Essentials. Group sessions will be delivered consecutively over 6 months (20 total; 1.5 hours each). A dietitian provides each 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 of approximately 600 kilocalories/week. The exercise prescription includes resistance training for 2 days per week and aerobic training for 3 days per week, to meet a 600 kilocalories/week expenditure goal. Behaviorists meet with participants to provide individual and group-based counseling to learn the skills necessary to adopt the prescribed dietary pattern and exercise plans. Group sessions will be delivered consecutively over 6 months (20 total; 1.5 hours each).

Additionally, as a part of a coordinated approach, study staff will facilitate six sessions that will last approximately 1 hour each. These sessions are designed to help you and your child engage in self-monitoring, positive communication, problem solving, and social support to increase healthy physical activity and eating behaviors. Joint goal setting and tracking of healthy eating and physical activity will be enabled by commercially available device (i.e., a Fitbit) and a custom, mobile-enabled website. Fitbit trackers will be loaned to participants for the purpose of data collection. All applications are freely available and can be downloaded on any smart device. Any devices or applications used will not have access to any study data outside of physical activity and dietary information entered by study participants. These devices and applications support self-monitoring of foods that are eaten and include a social support component.

Furthermore, two home visits will be conducted to provide tailored feedback to you and your child on nutrition and physical activity in their environment. These will be completed by pairs of

individuals from the study staff. These will be conducted during the 1st month of the study and again during the 3rd month of the study.

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. 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. Each data collection team will include at least one female staff member, and female staff will collect all anthropometric data from all youth. Data will be collected at the Brenner FIT or By Design clinics. There is 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. 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 jusmoore@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 Research Subject Advocate at Wake Forest at [redacted].



WFU School of Medicine
Institutional Review Board
IRB Number: IRB00055004
Meeting Date Approved 5/4/2020
Version Valid Until: 3/15/2021

## 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?

20 people at will be enrolled, which includes 10 parent/child dyads.

## WHAT IS INVOLVED IN THE STUDY?

If you join the study, you will be enrolled in the Dyad Plus program, which is described below;

| Name | Description |
|---|---|
| **Dyad Plus (combination of Brenner FIT and By Design)** | This will include all components of the standard Brenner FIT program and By Design Essentials. Please see descriptions of Brenner FIT and By Design Essentials in the two following sections of this chart.<br><br>In addition, group sessions, one-on-one parent/child communication sessions, joint goal setting/tracking, and home environment assessment. Dyads will attend 6 meetings that will last approximately 1 hour each.<br><br>During sessions, information surrounding motivation and communication will be given |



WFU School of Medicine
Institutional Review Board
IRB Number: IRB00055004
Meeting Date Approved 5/4/2020
Version Valid Until: 3/15/2021

| | |
|---|---|
| | in order to help overcome obstacles that children or parents may face during their weight loss journey. The aim is to increase self-monitoring, positive communication, problem solving, and social support in order to increase healthy physical activity and eating behaviors to increase the effectiveness of the weight loss programs. Participants will learn how to set dietary and nutritional goals with their families. The home environment assessment will be used to provide feedback on ways that families can change physical activity and healthy eating behavior in their own particular settings. |
| **Brenner FIT** | 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. |
| | |

| | |
|---|---|
| **By Design Essentials** | A dietitian provides each 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 of approximately 600 kilocalories*/week. The exercise prescription includes resistance training for 2 days per week and aerobic training for 3 days per week, to meet a 600 kilocalories*/week expenditure goal. Behaviorists meet with participants to provide individual and group-based counseling to learn the skills necessary to adopt the prescribed dietary pattern and exercise plans. Group sessions will be delivered consecutively over 6 months (20 total; 1.5 hours each).<br><br>*A kilocalorie is the heat energy involved in warming up one kilogram of water by just one degree Celsius. In terms of nutrition, it is a unit of food energy. |

| Time Period | Activities |
|---|---|
| **Baseline Assessments** | • Study staff will measure your height and weight<br>• You will complete a self-administered 24-hour dietary recall, the Automated Self-Administered 24-hour (ASA24)<br>• Physical activity data will be collected using worn continuously over 7 days except during bathing and sleeping<br>• Physical activity data will be collected using accelerometers worn continuously over 7 days except during bathing and sleeping<br>• You will complete a questionnaire assess psychological attributes related to weight loss behaviors |
| **3 Months** | • Study staff will measure your weight<br>• Study staff will review treatment goals and overall progress |
| **6 Months** | • Study staff will measure your height and weight<br>• You will complete a self-administered 24-hour dietary recall, the Automated Self-Administered 24-hour (ASA24)<br>• Physical activity data will be collected using worn continuously over 7 days except during bathing and sleeping<br>• Physical activity data will be collected using accelerometers worn continuously over 7 days except during bathing and sleeping<br>• You will complete a questionnaire assess psychological attributes related to weight loss behaviors |

- Height and weight measurements will be completed by Brenner FIT clinic staff in a private room.
- Completion of the ASA24 will take approximately 30 minutes. For this we will provide a link where diet information from the past 24 hours will be entered.
- We will assess physical activity using accelerometers. It is a small device that can either

be worn around the waist or on the wrist. Participants will be required to wear it for 7 days at the beginning of the study so that staff can obtain a baseline measurement of physical activity. Participants will do this again during the 6-month mark. The accelerometers should remain on at all times except for when the participant is sleeping, bathing, or engaging in activity that requires high contact since this can damage the device and the information it is collecting.

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

## 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.

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. 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 anthropometric 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 anthropometric data from all youth. Data will be collected at the Brenner FIT or By Design clinics. 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 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 do not have to be in this study to receive treatment associated with the Brenner FIT pediatric weight management program. You should talk to your doctor about all the choices you have.

## WHAT ARE THE COSTS?

For the By Design Essentials program, this study will cover the out of pocket program fee. The out of pocket program fee covers components of the program that insurance does not usual cover. This includes things like personal training, exercise physiology consultation, and behaviorist visits. Your insurance will be billed for medical visits, dietitian visits, and the initial testing/assessments that are part of the evaluation used to develop your treatment plan. This means that you may have co-pays for office visits based on your insurance coverage.

## 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 Wake Forest Clinical and Translational Science Institute. 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?

Participating child/caregiver dyad will receive $20 for participating in data collection which includes the 3-month and 6-month assessments, for a total of $40 per participating dyad.

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 Wake Forest Clinical and Translational Science Institute. 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



WFU School of Medicine
Institutional Review Board
IRB Number: IRB00055004
Meeting Date Approved 5/4/2020
Version Valid Until: 3/15/2021

## 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 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 jusmoore@wakehealth.edu.

## 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. Additionally, fasting serum biomarkers will also be collected. This includes glucose, insulin, hemoglobin A1c, AST, ALT, and total cholesterol.

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.

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 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.



WFU School of Medicine
Institutional Review Board
IRB Number: IRB00055004
Meeting Date Approved 5/4/2020
Version Valid Until: 3/15/2021

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.

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.

## 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].



WFU School of Medicine
Institutional Review Board
IRB Number: IRB00055004
Meeting Date Approved 5/4/2020
Version Valid Until: 3/15/2021

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



WFU School of Medicine
Institutional Review Board
IRB Number: IRB00055004
Meeting Date Approved 5/4/2020
Version Valid Until: 3/15/2021