Study Title: IMPACT: Increased Monitoring of Physical Activity and Calories with Technology

Principal Investigator, Co-investigator(s): Dr. Justin Moore and Dr. Joseph Skelton

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Background, Rationale and Context

Background: Since severe obesity in youth (BMI for age ≥120th percentile) has been steadily increasing, intensive clinical intervention is necessitated, which is often delivered in specialized pediatric obesity clinics. Since the home environment and parental behavioral modeling are two of the strongest predictors of child weight loss during behavioral weight loss interventions, a family-based treatment approach is warranted. This strategy has been moderately successful in our existing, evidence-based pediatric weight management program (Brenner FIT), but since programs such as Brenner FIT rely on face-to-face delivery of programmatic elements, the dose delivered is limited by the time constraints experienced by families enrolled in treatment. Therefore, the purpose of this study is to refine and pilot a tailored, mobile (mHealth) component to augment an existing, evidence-based pediatric weight management program (Brenner FIT) to determine acceptability from a patient and clinical staff perspective, feasibility, and economic costs relative to the established weight management protocol alone [i.e., Brenner FIT vs. Brenner FIT + mHealth (Brenner mFIT)].

Objectives

Primary Aim 1: Finalize an intervention for adolescent youth with obesity, consisting of podcasts/videos and electronic self-monitoring, to promote reduced caloric intake and increase physical activity.

Primary Aim 2: Pilot the intervention in dyads (n = 40) recruited from a pediatric weight loss clinic, to establish acceptability and feasibility of the intervention relative to standard care (n = 40).

Secondary Aim: To establish costs associated with development and implementation of mHealth components when delivered with the Brenner FIT program.

Methods and Measures

Design

For this project, we will randomize 80 youth with obesity (13 – 18yrs) and a caregiver (dyads) to the Brenner FIT condition or the Brenner mFIT condition. All participants will complete baseline measures prior to randomization, and at three and six months. All youth participants will receive a commercially available activity monitor. Caregivers will receive podcasts with a story about a caregiver supporting weight loss in a child by providing healthy foods/activities for his/her family, including healthy eating and physical activity information. Children will receive animated videos that contain healthy eating and physical activity messaging, with an engaging story of a child losing weight. All participants will have access to a website and mobile apps where they will track weight, diet, and physical activity for themselves (youth) or their child (parents). Based on their reports of weight, eating, and physical activity, the messaging received from clinical staff by the families will be individually tailored to promote healthy behaviors and overcome perceived barriers. The proposed research is innovative in that it explicitly incorporates theory into the intervention and evaluation components of the project and builds upon an existing literature on mHealth interventions that use mobile technology.

Setting

Brenner Children's Hospital is a 160-bed, 400,000 sq. ft. children's hospital, a part of Wake Forest Baptist Medical Center (WFBMC). This $132 million facility is the only children's hospital in northwest North Carolina and has more than 30,000 pediatric visits each year. Brenner Children's Hospital is one of only 51 Level I pediatric trauma centers in the country and one of only 3 in the state. Brenner is the only children's hospital in western North Carolina and treats children from all bordering states. Brenner Children's Hospital is staffed by over 140 full-time pediatric faculty, and over 4,500 children are admitted to Brenner each year. Over 21,000 pediatric subspecialty visits occur annually at outpatient clinics. Brenner Children's Hospital is also home to specialty programs such as Brenner Families in Training (Brenner FIT). Brenner FIT, an interdisciplinary, family-based pediatric weight management program led by Co-Investigator Joseph Skelton, MD, MS, is a premier program of Brenner Children's Hospital. [1,2,3,4] Brenner FIT is an evidence-based program that focuses on the treatment of obesity in children ages 2 to 18 who have a medical concern related to their weight. A physician referral is required, and treatment involves the entire family. The Brenner FIT team includes physicians, family counselors, dietitians, social workers, activity/play specialist and physical therapist. Brenner FIT is available for English and Spanish-speaking families. Brenner FIT also offers free nutrition and parenting classes to all members of the community.

Subjects selection criteria

Brenner FIT will serve as the base of the study and recruitment source and serves a diverse array of children: patients are majority female (58%) and self-identified as white/European American (45%), black/African American (40%), or another race (5%). Ethnically, eighteen percent are Hispanic/Latino. The average patient is clinically obese as indicated by BMI (35.9 +/- 8.6) and BMI z-score (2.6 +/- 0.5). Half of the patient population is in their teenage years (13-18yrs).

- **Inclusion Criteria**
  Youth with obesity, 13 – 18yrs, and a caregiver 30 – 60yrs. Caregivers must live in the home with their youth participants. Participants must also have access to a smartphone or tablet.
- **Exclusion Criteria**
  Adolescents under the age of 13 will be excluded. Caregivers, who are not between the ages of 30-60 years old will also be excluded. If participants do not have access to a smartphone or tablet, they will not be able to participate.
- **Sample Size**
  80 dyads which consist of youth and caregiver pairs.

Interventions and Interactions

Conditions	
Control condition: Brenner FIT (ie, standard	After referral, families attend an orientation, in

care)	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. Motivational interviewing, modified by Brenner FIT for use with families, 5 is the key to treatment; family counselors are trained in cognitive behavioral therapy, parenting support/mindfulness, and employ these approaches to assist families in developing healthy habits. 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 FIT is successful in enrolling families into research studies, including African Americans and Latinos.6,7,8,9 Brenner FIT sees ~200 new patients/families per year; ~66% of those enrolled successfully lose weight. The children who are successful display a decrease in BMI z-score of 0.07 to 0.1, with an average BMI z score decrease at 8 months of 0.11. A .1 - .15 decrease in BMI z-score is linked with healthy changes in cardiometabolic biomarkers.10,11
Intervention Brenner mFIT (Brenner FIT plus mHealth) will include all components of the standard Brenner FIT program and six mHealth components that are designed to target theoretically supported constructs	**Component 1:** A mobile-enabled 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 program interface (API) that integrates data from the two commercial apps (MealLogger and Fitbit™) with data entered by participants. Data integration is detailed in a later section. **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. Mobile apps have been shown to facilitate increased self-monitoring,[12] which supports tracking of progress on behavioral goals (a component of Brenner FIT) by youth and reporting to the caregiver and clinical team. Tracking app data will be integrated into the mobile-enabled website. **Component 3:** Caregiver podcasts will 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. Podcasts have been used successfully in two previous studies by the team,[13,14] and target several constructs from Self-determination Theory and Social Cognitive Theory including: 1) outcome expectations, 2) self-efficacy, 3) incentive motivation, and 4) autonomy support. Podcasts will be 5-10 minutes long each and downloadable via the mobile webpage. 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 journey, and the difficult social situations they find themselves engaged in. The stories and scenarios are informed by our formative work with adolescent patients and will contain elements of humor and drama, while targeting several constructs from Self-

	determination Theory and Social Cognitive Theory including: 1) observational learning, 2) outcome expectations, 3) autonomy, and 4) relatedness. Like the podcasts, the videos will be accessible from the mobile-enabled website and sharable via social media once released for viewing. **Component 5:** Participants will be encouraged to follow each other and a curated list of health professionals on MealLogger. These interactions will be encouraged during Brenner FIT group sessions. Our team has extensive experience with developing and evaluating social media messages for support during weight loss. In a previous weight loss intervention that used Facebook for social support, we found that messages that were framed as polls or requests for suggestions from the group garnered the most interaction.[18] **Component 6:** Tailored feedback will be provided by clinical staff based upon reports generated from self-monitoring data. Clinical staff will receive a weekly report for each adolescent patient that will be given 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 dyads 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.

Outcome Measure(s)

Type	Name	Time Frame	Brief Description
Primary	BMI z-score	Baseline, 3 & 6 months	Weight status of caregivers and youth will be quantified through calculation of BMI derived from measurement of height and weight at the intake and follow-up visits. Both height (plus/ minus 0.1 cm) and weight (plus/minus 0.5 kg) will be recorded twice and values will be averaged to produce the final value using a Tanita(registered trademark) digital scale and a Seca(registered trademark) Height Rod (respectively). BMI will be calculated as kg /m2. BMI z-score will be calculated using CDC growth charts.
Secondary	Physical activity	Baseline, 3 & 6 months	Physical activity data will be collected using ActiGraph (trademark) accelerometers worn continuously over 7 days except during bathing and sleeping.
Secondary	Diet	Baseline, 3 & 6 months	To assess diet in participating youth, we will use NCI's automated, self-administered 24-hour dietary recall, the Automated Self-Administered 24-hour (ASA24 (registered trademark) dietary assessment tool (version: ASA24-2016) on three, non-consecutive days (including one weekend day).
Secondary	Economic costs of the mHealth intervention costs	Baseline, 3 & 6 months	Clinical costs of the mHealth intervention will be compiled over the duration of the program. Examples include materials (eg, printing of materials for parents, youth, staff), equipment, training costs (eg, hourly wages for employees), and costs for ongoing interactive support (eg, time allocated to social media).

Analytical Plan

	Youth Only Measures
Physical Activity	Physical activity data will be collected using ActiGraph™ accelerometers (Shalimar, FL) currently owned by the team. The accelerometers will be set to collect data in "raw" format and analyzed by converting the data to 1-second epochs to account for the intermittent and sporadic nature of children's PA and to improve the ability to capture the transitory PA patterns of children. During each 7-day data collection period, these monitors will be affixed to a strap on the subject's non-dominant hand. This protocol is being employed in NHANES and has been used successfully in studies of PA.[19-21] We will distill the cut points in a manner consistent with emerging research[22] that allows for comparability with waist-based estimates.[23,24] Participants will be instructed to wear the monitor continuously over the next 7 days except during bathing and sleeping. Participants will also be given activity logs with the monitors[25] and small gifts to encourage compliance. Text messages will be sent on the first morning of monitoring and after the last day of monitoring to encourage compliance and timely monitor return. Once an accelerometer is received, data from the accelerometer will be downloaded using the manufacturer's software and USB computer interface. We will reduce, clean, and process the accelerometer using custom scripts in Stata as in our previous studies. We have used these strategies effectively in community-based data collection.[26,27,28,29,30,31] The accelerometers will be initialized and set to record beginning at 5:00am the day following their distribution. This will provide 7 days of data for analysis, from which we will extract four or more complete

	(>10 hour) days.
Diet	To assess diet in participating youth, we will use NCI's automated, self-administered 24-hour dietary recall, the Automated Self-Administered 24-hour (ASA24®) dietary assessment tool (version: ASA24-2016) on three, non-consecutive days (including one weekend day). The ASA24-2016 is available on both computers and mobile devices. All youth participants will complete one ASA24 at their baseline orientation, and at 3-month and 6-month follow-up office visits to encourage compliance while allowing youth and caregivers to ask questions and gain comfort with using the system. The project coordinator will contact participants within six days (on a randomly selected day) following the office visits to inform participants that they should complete the second/third dietary recall and will offer to conduct the recall over the phone if the youth need assistance (the ASA24 has been shown to perform equally well as a self-administered or interviewer administered questionnaire).[32,33] A series of follow-up reminder messages and/or phone calls will be made by the coordinator to encourage completion of the second/third of the two recalls if not completed within 24-hours following the first contact after the clinic visit.

	Caregiver and Youth Measures
Psychosocial Variables	We will assess family and individual (youth and caregiver) constructs to identify potential mediators or moderators of observed effects of the intervention; these will be incorporated into a future, larger trial. Brenner FIT uses Family Systems Theory as a guiding model to addressing child and parent behaviors within the context of their family,[34,35] and presently uses a number of scales to assess families participating in Brenner FIT. Specifically, Brenner FIT families complete the Family Assessment Device General Functioning subscale (capturing family function),[36,37] Olson's Family Communication Scale,[38] perceived stress,[39,40] self-efficacy for physical activity,[41,42] behavioral self-regulation,[43,44,45] and health behaviors of the family (captured by a measure designed and tested specifically for families participating in weight management).[46] In addition, we will administer scales to capture Social Cognitive Theory and Self-determination Theory constructs targeted by the intervention that are not captured as part of the intake process. These include outcome expectations, autonomy,[47] autonomy support,[48] and relatedness. All psychosocial data will be collected at baseline (prior to randomization), at 3 months, and 6 months. Details regarding the variables collected, their theoretical rationale, and measurement instrument are presented in Table 2 (**see Table 2 below this chart).**
Socio-demographic Variables and Weight Status	We will collect parental report of the caregiver and youth participant's age, sex, race, and ethnicity. Weight status of caregivers and youth will be quantified through calculation of BMI derived from measurement of height and weight at the intake and follow-up visits. Both height (±0.1 cm) and weight (±0.5 kg) will be recorded twice and values will be averaged to produce the final value using a Tanita® digital scale and a Seca® Height Rod (respectively). BMI will be calculated as kg /m2 . Height and weight will be measured without shoes in normal clothing. BMI z-score will be calculated using Centers for Disease Control and Prevention (CDC) growth charts.

Table 2. Intervention targeted constructs to be measured, participant providing data, theory, and instrument/method used.

Construct	*C/Y	Theory	Instrument/method
Weight status	C/Y	–	Measured height and weight: used to calculate Body Mass Index (weight in kg / height in m^2) and calculate BMI z-score
Physical activity	Y	–	Accelerometry (7 days of monitoring): used to estimate minutes of moderate-to-vigorous physical activity per day
Dietary intake	Y	–	Automated Self-Administered 24-hour (ASA24-2016) dietary assessment tool: used to estimate average daily caloric intake
Autonomy	Y	SDT	Relative Autonomy Index; produces a continuous score
Autonomy support	C	SDT	Motivators' Orientations Questionnaire; produces a continuous score
Behavioral self-regulation	Y	SCT	Effortful control, problem solving, soothability, delay of gratification, and self-reinforcement measured by scales previously validated in adolescents; produces continuous scores for all subscales
Outcome expectations	Y	SCT	Expectations about outcomes of weight loss; produces a continuous score
Relatedness	C/Y	SDT	The relatedness and dependency subscales of the Depressive Experiences Questionnaire: produces a continuous score
Self-efficacy for PA	Y	SCT	Self-Efficacy for Exercise Behaviors; produces a continuous score
Self-efficacy to HE	Y	SCT	Self-efficacy to make healthy food choices; produces a continuous score

*Caregiver/Youth; **SCT**: Social Cognitive Theory[18,153]; **SDT**: Self-determination Theory[19,64]; **HE**: healthy eating; **PA**: physical activity

Results will be analyzed initially using descriptive statistics. Comparison between groups will be done using chi square tests for proportions, and t-tests or ANOVA procedures for continuous variables. Regression analysis will be performed to identify independent outcome predictors. Other inferential statistical analysis will be conducted as appropriate.

Human Subjects Protection

Subject Recruitment Methods

Children will be identified and recruited from the Brenner FIT pediatric obesity clinic. We will also work with primary care physicians in Pediatrics and Family Medicine clinics to refer new patients to Brenner FIT, and thus increase our pool of potential recruits. In addition, we will review medical records of current and newly referred patients for eligibility via EPIC. This includes looking at age, weight status, and language preference at a minimum for incoming patients on the schedules of Dr. Joseph Skelton, Dr. Gail Cohen, and the Brenner FIT team. Those deemed initially eligible will be informed of the study following their intake visit by Brenner FIT clinical staff. Those who express interest will get an in-person "warm handoff" to a research team member who will confirm eligibility, re-assess interest, and schedule an intake visit. At that visit, recruits will receive more information about the study and provide consent (adult) and assent (child).

- Before recruitment for participation: There is limited ability to mask the conditions from the clinical staff or their assignment from the participants represents However, the independence of our research staff from the clinical staff should protect against any expectancy effects biasing our data and protect patience identity.

- After recruitment for participation: To ensure confidentiality, 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.

- Any Protected Health Information collected from your child in this study that is maintained in the research records will be kept for at least six years after the study is finished.

Informed Consent

Signed informed consent will be obtained from each subject by study staff at the Brenner FIT clinic or virtually, prior to completion of any assessments.

Participant Interaction

- In light of the COVID-19 pandemic, we are also attempting to reduce the amount of face-to-face contact with program participants. We also propose giving participants the ability to complete post-consent assessments and follow-up outside of the clinic setting. The following steps will be taken for participants who opt to complete assessments at home: Participants will receive copies of the consent/assent forms to read before their visit with the physician
- Following their meeting with the physician, they will be provided with physical copies to read and sign in the presence of study staff
- Participants will be provided an accelerometer and receive baseline incentives for study staff. A WebEx appointment to complete the psychosocial assessments for the project will be sent to participants. Assessments must be completed within 24-hours after enrollment
- Once we receive the accelerometer, participants will be randomized to 1 of 2 groups. Participants will then be sent the respective information regarding their group assignment and additional action items depending on their group randomization
- For 3 and 6 month follow-up appointments, participants will receive a link to a WebEx invitation to meet with study staff virtually

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed three years after closure of the study via shredding and deletion of any electronic data consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

Our Data and Safety Monitoring Plan consists of several layers including ongoing monitoring by: the Principal Investigators, all study investigators and staff who have contact with the participant, and the Institutional Review Board of WFU Health Sciences, and an appointed medical safety officer. Prior to enrollment of participants, guidelines will be established for identifying adverse events and serious adverse events. The data received from participants will be kept confidential and will be identified with a unique code known only to the project coordinator and the PI. Paper records will be kept in locked file cabinets and any electronic data will be kept in secure computer files on the Wake Forest Baptist Medical Center server. The Data and Safety Monitoring Plan will be submitted to the IRB for approval prior to data collection.

First, we will hold bi-weekly meetings of all members of the study intervention team where we will review participants' status. This meeting will be directed by Dr. Skelton (co-I). Second, Dr. Skelton will be providing medical oversight of the intervention. He will individually review each participant's progress and medical history monthly. If a participant is observed to be in threatening health (regardless of whether it is related to the study or not) or describes an adverse event, his or her primary care provider will be notified. Dr. Skelton will also collaborate with Dr. Moore who will be providing oversight for the data management team to identify any concerns in the surveillance for adverse events. Third, all unanticipated problems and serious adverse events will be reported to the Institutional Review Board at WFU Health Sciences per institutional policy. A plan for regular ascertainment of adverse events will include monthly symptoms forms collected throughout the study at planned group and individual visits.

Since the proposed project does not involve a multisite clinical trial involving an intervention that entails potential risk to the participants, a Data and Safety Monitoring Board (DSMB) is not required. However, to ensure participant safety, the PI will invite individuals not directly involved with the project to join a scientific review board (SRB) to review aspects of the project including; the research protocol, plans for data and safety monitoring, evaluating recruitment progress, participant risk versus benefit, and other factors that can affect the study outcome and risks to the participants. They will also make recommendations to the investigators and the WFSM Institutional Review Board concerning continuation or conclusion of the trial. In the past, such advisors have included the department chair, biomedical ethics experts, community members, and public school/childcare officials. A caregiver of a child previously treated at Brenner FIT, but whose child is not currently enrolled in the study or the clinic will be identified and recruited fort the SRB if at all possible. Ongoing quality control will include regular data verification and protocol compliance checks to be performed by the project directors and research assistants. Research staff members will undergo CITI training at the Wake Forest Baptist Medical Center, as well as being trained on each task for which they are responsible. They will also perform quality control for others similarly engaged. The study team will meet weekly to discuss progress and problems of the project.

While a DSMB is not required, for the purposed of this study, there will be a medical safety monitor at the suggestion of the National Institute of Diabetes and Digestive and Kidney Diseases. For this study, Gail Michelle Cohen, MD, MS will serve as the medical safety monitor. Dr. Cohen is an Associate Professor in Pediatrics at Wake Forest School of Medicine. As a process of the continuous monitoring, the medical safety office will receive a report every six months that will include the study objective, a narrative of progress to date, recruitment and retention, visit completion, intervention adherence, data form completion, and adverse events (including serious ones). An example of this report is included at the end of this protocol document.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB sponsor, appropriate government agency if appropriate, or medical safety officer.

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Appendix

Data and Safety Monitoring Report
TITLE/Grant Number
PI
Reporting Period Dates

Checklist for **safety officer** to complete after reviewing the report:

1. Is participant recruitment and enrollment acceptable?

2. Is the retention rate acceptable?

3. Is the intervention visit completion /intervention adherence acceptable? (Any concerns with intervention adherence?)

4. Is the data collection completion rate acceptable? (Any concerns with missing data?)

5. Is the overall adverse event rate acceptable? (Any concerns with serious adverse events?)

6. Are there any situations that have occurred in the trial since the last safety report that warrant a study investigator conference (If yes, please explain in the space below this checklist)

7. Is there any need to communicate with XXXXXX IRBs and/or the NIDDK regarding data monitoring or safety of participants? (If yes, please explain in the space below this checklist)

Explanations/Comments (if applicable):

Recommendation of the Safety Monitor:

Safety Monitor Signature Date