Study Title: Feasibility of the Camp Power Up Program on Children's Body Weight and Quality of Life
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PENNINGTON BIOMEDICAL RESEARCH CENTER LSU

PBRC Institutional Review Board
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PBRC IRB # 2017-014 **Acronym:** Power Up

PROTOCOL TITLE: "Camp Power Up"

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Objectives

The objective of this study will be to evaluate the effects of a one week weight management summer camp on children's weight, self-reported health behaviors, quality of life, mood and feelings, self-esteem, weight management efficacy, enjoyment of physical activity, and body image. Children will also report acceptability and enjoyment of technology-supported physical activity options, specifically the HD Expresso stationary bicycles ("cybercycling").

Background

Obesity affects 17% of children and adolescents in the U.S.[1] Children are entrenched in an obesogenic environment, often with little support in the home, school, or medical environment to make healthy choices. Obesity is increasingly common in underserved communities that lack access and resources for physical activity and healthy eating. Louisiana is a prime example of the need for effective obesity treatment, ranking 1st nationally for adult obesity and 4th for adolescent obesity with the highest obesity prevalence among African American adolescents.[1] We urgently need evidence-based

programs to help children and families change lifestyle behaviors, achieve clinically significant weight loss, and thereby reduce the prevalence of pediatric obesity.

The U.S. Preventive Services Task Force identifies behavioral treatment including dietary, physical activity, and behavioral counseling components as a viable option for pediatric obesity treatment,[2] yet a key challenge is how to implement these programs to maximize access and participation. Summer (between school years) represents an opportunity for intensive intervention to change health behaviors and help children to lose weight. During the summer months, children gain weight at a more rapid pace[3,4] and spend more time engaged in sedentary behavior[5] compared to the school year. The American Diabetes Association launched Camp Power Up as a summer week-long day camp for youth who are obese and/or at high risk for developing type 2 diabetes. The camp will focus on wellness education, nutrition, physical activity, and obesity prevention. The purpose of the proposed study is to examine effects of Camp Power Up on children's weight status and their psychosocial health.

Inclusion and Exclusion Criteria

Children must meet the following eligibility criteria to participate in the study:

- Aged 6 to 14 years
- Enrolled in the ADA Camp Power Up

Number of Subjects

We plan to enroll up to 62 participants total. A total of 12 participants were enrolled in summer 2017 and an additional 50 are anticipated for summer 2018.

Recruitment Methods

All children selected to participate in the ADA summer camp program will be asked to participate in this study. The ADA anticipated enrollment of approximately 50 children for the one week session each summer (summer 2017, summer 2018). Recruiting efforts include, but are not limited to the institution's email listserv, social media posts, and flyer drops.

Study Timelines

The enrollment and participant's participation in the study will last approximately one week (five daytime sessions). The primary analyses will be completed by January 1, 2018 for the summer 2017 camp. The primary analyses for the summer 2018 camp will be completed by January 1, 2019.

Study Endpoints

AIM 1: Evaluate the effects of a one-week obesity prevention summer camp on children's weight, self-reported health behaviors, quality of life, mood and feelings, self-esteem, weight management efficacy, enjoyment of physical activity, and body image. Difference scores will be calculated between initial and final assessment, and effect sizes will be calculated using linear mixed models to determine clinical significance of weight-related and psychosocial changes throughout the program.

AIM 2: Examine the acceptance and feasibility of implementing the program at Pennington Biomedical Research Center's TReCC.

Acceptance and feasibility will be assessed by the number of participants enrolled and the number of camp sessions attended. Cybercycling acceptability and enjoyment will be assessed by a survey administered to the child after cybercycling for about 15 minutes.

Endpoints

The primary endpoint is the change in body weight. The secondary endpoints include self-reported changes in health behaviors, quality of life, mood and feelings, self-esteem, weight management efficacy, enjoyment of physical activity, and body image, as well as acceptability/enjoyment of cybercycling.

Procedures Involved

All participants will be explicitly told that their participation is voluntary and that they may terminate their participation at any time.

Consent and Assent Process. Informed consent for the child will be obtained from one of the participant's parents/legally authorized representatives prior to conducting any study procedures. The parent/legally authorized representative will be given an informed consent form to read and sign indicating their permission to allow their child to participate in the study. Parents will return this consent form to the study staff before the child's first visit. Because there is not a greater than minimal risk, informed consent will be obtained from one parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

Participants 12 years of age and older will be given a written assent form to read and sign before participating in any study procedures. Participants 6-11 years of age will be read an assent script and asked to verbally assent before participating in any study procedures. Participants 9-11 years of age with a high reading comprehension and maturity level may give written assent, rather than verbal assent, if deemed appropriate by the investigator or research staff member performing the assent. The study procedures will be explained using age appropriate terms, and children will be given the opportunity to ask questions about the study.

Parent survey. Parents will be asked to complete a questionnaire that will provide information on the child's sociodemographic characteristics, including sex, date of birth, and parents' marital status, highest level of education, family income, occupation, and employment status, as well as brief medical history. Parents will report their own height, weight, age, and sex.

Anthropometric measurements. Height and weight of each child will be measured in a private setting with the child dressed in light clothing. Height will be measured to the nearest 1.0 cm using a portable stadiometer. Weight will be measured to the nearest 0.1 kg using high-precision electronic scale. Percent body fat will be recorded from this scale. Body mass index (BMI) z-score will be calculated based on the child's age, sex, height, and weight, then compared to the 2000 Centers for Disease Control and Prevention (CDC) Growth Charts to calculate percentile and z-score.

Surveys. A pre-test and post-test psychosocial questionnaire will be completed by each participant at the beginning (session 1 or orientation) and end (session 5) of the program. The questionnaire will collect information about lifestyle, including diet and physical activity habits, media use, and sleep.

During summer 2017 camp only, children will be asked to complete a friendship nomination survey at the start and end of the 5-day ADA camp. On day 1, each child will be asked whether they know any other child participating in the camp. On day 5, another friendship nomination survey will be completed detailing the friends that the child met during the course of the camp. These friendship nomination data will be used to provide a longitudinal illustration of the ego-centric and overall social network developed during the span of the camp. This friendship nomination method has been used in the National Longitudinal Study of Adolescent Health, a nationally representative study in which one of the primary aims were to measure the association between adolescent social contexts and health and well-being.The survey questions will be from the following validated scales:

Impact of Weight on Quality of Life (IWQOL-Kids) (Summer 2017 only): The IWQOL-Kids is a 27-item measure of weight-related quality of life. Each item begins with the phrase, “Because of my weight,” and contains five response options, ranging from “always true” to “never true.” In addition to a total score, there are scores on four domains: Physical Comfort, Body Esteem, Social Life, and Family Relations. Scores range from 0–100, with higher scores representing better quality of life. The IWQOL-Kids has demonstrated good internal consistency, as well as sensitivity and responsiveness.[6,7] The IWQOL-Kids will be administered to participants aged 11 and older.

PedsQL (Summer 2017 and 2018): The PedsQL is a general health related quality of life self-report measure with complementary scales for children (ages 6–14).[8] The measure assesses physical, emotional, social, and school functioning, and provides a psychosocial summary score as well as a total score. Scores range from 0–100, with higher scores representing better quality of life. The PedsQL has been shown to be both reliable and valid in this age range.[8]

Weight Efficacy Lifestyle questionnaire (WEL; Summer 2017 and 2018): The WEL assesses self-reported eating habits and perceived self-efficacy in regards to eating and weight loss.[9] The WEL consists of 20 items designed to measure five hypothetical dimensions of efficacy for weight management: availability, negative emotions, physical discomfort, positive activities, and social pressure. The items were slightly reworded to make them easily understandable to a pre-adolescent population. Good reliability and validity have been reported for the WEL in adult populations[9,10] and adequate scale reliability in children (α=0.94).[11]

The **Physical Activity Enjoyment Scale (PACES; Summer 2017 and 2018):** The PACES is a 16-item measure of enjoyment during physical activity.[12]

The **Body Image Assessment of Preadolescents (BIA-P; Summer 2017 only):** The BIA-P is a reliable and valid measure of body image in children ages 6 to 14.[13,14]

During summer 2018 camp only, children will be allowed to use the HD Expresso cybercycling stationary bicycles in the TReCC for 15 minutes each. Afterwards, they will complete a brief survey on their enjoyment and acceptability of the cybercycling.

(Summer 2018) One month after the conclusion of the camp, an optional post-camp celebration will be hosted at a local community center for all parents and camp participants. Participants' height and weight will be measured. Participants will be asked to complete a brief survey.

The following is the train schedule for procedures:

	PRE-VISIT	V1 Day 1	V2 Day 5	1 month Post-Visit
Consent	x			
Parent Questionnaire	x			
Assent	x			
Height		x	x	x
Weight		x	x	x
Child Questionnaires		x	x	x

Power analysis.

Difference scores will be calculated between initial and final assessment, and effect sizes will be calculated using linear mixed models to determine clinical significance of weight-related and psychosocial changes throughout the program. Acceptance and feasibility will be assessed by the number of participants enrolled and the number of camp sessions attended.

Data and Specimen Management

The Pediatric Obesity and Health Behavior Laboratory, supervised by Dr. Staiano, will have primary responsibility for data collection, data management, manual data entry, and data analysis. All electronic data will be stored in the secure Pennington database, with access given to only necessary, HIPAA-certified staff. All hard copies of data will be stored in a secure, locked cabinet at Pennington Biomedical Research Center. Access to data files can be made only with permission of the Academic Principal Investigator. Data will be stored for 5 years following study completion.

Provisions to Monitor the Data to Ensure the Safety of Subjects

This study does not involve more than minimal risk to participants. All data will be collected through non-invasive observations or surveys.

Withdrawal of Subjects

Participation is voluntary, so participants may withdraw from the program at any time. During the program, participants may be withdrawn from the program due to the unwillingness of the child/adolescent or the parent/legally authorized representative to cooperate with the study staff. Data that have already been collected during the course of the study from a withdrawn participant will be used, unless a specific request is otherwise received.

Risks to Subjects

The study contains no foreseeable risks, discomforts, or hazards to participants or family members.

Potential Benefits to Subjects

There is no direct benefit for the participant.

Vulnerable Populations

The ADA Power Up program will involve children as participants (6-14 years of age). As such, their parents and/or legally authorized representative will provide written informed consent allowing their child to participate in the study. In addition, participating children will provide verbal or written assent (depending on age and maturity level).

All participants will be explicitly told that their participation is voluntary and that they may terminate their participation at any time. If a participant indicates that they wish to stop participating, all study procedures they are undertaking at that time will be stopped to protect their rights and welfare.

Sharing of Results with Subjects

Individual participant results will be provided if the participant or parent requests them. Results from the study will be submitted for manuscripts in scholarly journals and presentations. All study reports for publication will present only aggregated data to minimize the risks that a participant can be identified from their participation in the study.

Setting

Program sessions will take place primarily at the TReCC or in the Conference Center. Anthropometry will be measured in the TReCC anthropometry room or in the Conference Center in private classrooms. The outpatient clinic and anthropometry room will be used as a back-up location if required.

Resources Available

Pennington Biomedical is a model for clinical research, since it houses basic, clinical and population research programs in one facility. TReCC is well-equipped to administer and support this study. Program-related assessments will be completed in TReCC, which has all the necessary equipment needed to perform the procedures described herein. The program personnel are highly qualified with extensive diabetes and obesity-related backgrounds and experience conducting research involving human participants, both here at Pennington Biomedical, and at other institutions.

Compensation

Subjects will not be compensated for participation in the study.

Confidentiality

All data collected in this project will be subject to the same confidentiality requirements that are in place for our other studies at the Pennington Biomedical. Study files will be kept in locked cabinets and access restricted to program staff. Personal identifiers are not included in computer files. No individual's data will be released without their specific written consent. Research staff, members of the Institutional Review Board, and personnel in charge of maintaining data security from the Pennington Biomedical Research may inspect and/or copy the medical records related to the study. Results of the study may be published; however, names and other identifying information will be kept private. Other than as set forth above, the participant's identity will remain confidential unless disclosure is required by law.

Provisions to Protect the Privacy Interests of Subjects

Privacy in the context of this study includes confidentiality of data and personal information. During interviews, measurements, and program sessions, the program staff will ensure full privacy of participants and will ensure that the data are stored in a secured area. Participant weight measurements will be conducted individually in private to protect the privacy interest of the subject.

Compensation for Research-Related Injury

No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) will be available for this research study. In the event of injury or medical illness resulting from the research procedures, participants will be referred to a treatment facility.

Economic Burden to Subjects

Participants and participating families will be required to bear the cost of transportation to and from all camp and study sessions.

Consent Process

Informed consent and assent will be obtained prior to conducting any program procedures. Because there is not a greater than minimal risk, informed consent will be obtained from one parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. The study procedures will be explained to parent(s) and prospective participants (6-14 years of age). The parent/legally authorized representative and prospective participant will be asked if they have any questions about the study. The parent/legally authorized representative and prospective participant will be offered a waiting period between informing the prospective participant and obtaining the consent. When the parent/legally authorized representative and prospective participant are both ready, the informed consent process will then proceed as follows.

For participants 12-14 years of age:

- Parent/legally authorized representative will be given an informed consent form to read and sign indicating their permission to allow their child to participate in the study.

- Following the obtainment of written parental consent, participants 12 years of age will be given a written assent form to read and sign before participating in any study procedures.

For participants between 6-11 years of age:

- Parent/legally authorized representative will be given an informed consent form to read and sign indicating their permission to allow their child to participate in the study.
- Following the obtainment of written parental consent, participants 6-11 years of age will be read an assent script and asked to verbally assent before participating in any study procedures. Participants 9-11 years of age with a high reading comprehension and maturity level may give written assent, rather than verbal assent, if deemed appropriate by the investigator or the research staff conducting the assent.

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