INNOVATIONS IN MANAGEMENT OF OBESITY AND INACTIVITY IN PEDIATRIC PRIMARY CARE

NCT # 02724839
Date: 08-17-18

APPLICATION FOR STUDY
SUBMITTED FOR EXPEDITED REVIEW

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BACKGROUND

Obesity is an increasingly common condition of childhood (18% of all US 6-11 year olds, 24% of black children)[1] that has both acute and long-term adverse effects—depressed mood and academic achievement, diabetes, stroke, and premature death.[2-4] Obesity is particularly challenging to treat or prevent because it involves changing two essential health behaviors part of daily life: diet and exercise.[5] These behaviors lie squarely within the domain of pediatrics and preventive health; school-aged children visit their primary-care doctor annually. Thus public health experts in obesity have called for innovations in primary care to address them.[4,6-9] Yet effective means to prevent, identify, and treat obesity or inactivity within primary care are lacking;[4] and several research interventions have had only modest effects, even with one-on-one family-centered counseling methods.[10,11]

Within the context of a 20-minute well-child check, with competing patient-related medical and behavioral needs, it is exceedingly difficult to counsel effectively about a patient's diet or to effectively promote physical activity.[12] Yet this is the expectation and *standard of care* for overweight/obese patients. The Pediatric Primary Care Clinic (PPC), cares for 1100 overweight/obese children aged 6-11 years (37% of the PPC school-aged population of 3100) annually. The two options for PPC patients are to bring the patient back for a one-month follow-up visit to check progress on diet and exercise goals (no-show rate 60-70%), or to refer to an outside intensive weight-management program, Healthworks!. Only 14% of patients who are referred to Healthworks! make it to an initial appointment within 60 days, and only half of those continue in the program after the initial visit. *What primary care lacks is a system to activate patients to make healthy changes in diet and exercise and to support patients when they inevitably encounter barriers, particular low-income families that experience food insecurity and lack safe places to be active.*

Furthermore, there is no opportunity in the PPC to allow patients/peers from the same neighborhood and/or from similar financial and cultural circumstances to share "**practical tips**"—relevant and neighborhood-specific knowledge about good places to

purchase fresh fruits/vegetables and safe parks to visit, or tips about making meals for picky eaters on a tight budget as a single parent. In Europe, group-based counseling programs connected to primary care have been used to effectively curb overweight among school-aged children.[13,14] We hypothesize that peer-facilitated group sessions about nutrition behaviors, where patients from similar neighborhoods will connect socially and share barriers and successes, will similarly activate patients to make nutritional changes.

In addition to peer-led nutrition groups, we intend to use Fitbit Flex devices for this study. The Fitbit Flex device, when worn on the right wrist, was found to reasonably and reliably estimate step counts (compared to video observations on a treadmill) and energy expenditure (compared to indirect calorimetry) during walking and running among 10 adult males in a study accepted for publication in the International Journal of Cardiology (Diaz, KM et al., accepted March 2, 2015). Although there are no published studies in children, Fitbit devices are the most commonly used consumer-grade pedometers/accelerometers in adult and pediatric research studies, including a feasibility RCT (Clinicaltrials.gov # NCT02031185) among 14-18 year olds at Seattle Children's Hospital (Jason Mendoza, MD MPH). Fitbit devices can sync wirelessly via Bluetooth with all major mobile phone carriers with a free app, with laptop computers with the free app and Bluetooth capability, and with computers via a USB dongle that comes with the device. The devices can store activity data at epochs of one minute, hour, or by day; and for up to one week, two weeks, or one month, respectively, before needing to be synced. Through the free app, the devices also allow participants to share their activity levels with their friends and challenge each other. The Fitabase software allows researchers to track activity levels of all research participants, and can produce CSV data for excel spreadsheets for analysis, as well as heat maps, charts and displays. It also allows researchers to track participants' syncs, thus enabling the research team to remind the participant to sync if it has been a while. At CCHMC, Kimberlee Bernstein (CRC, Gastroenterology) is using currently using Fitbits and Fitabase for an ongoing study (R01, Stavra Xanthakos), and has been impressed with

its functionality. We hypothesize that giving parent and child dyads a Fitbit and the Fitbit app will activate parents and children to increase physical activities.

We propose in this application to deploy *evidence-based strategies that have already been tested in other settings*. Our *goal herein* is to adapt and tailor them to the PPC population—to design and pilot an intervention that involves group-based nutritional coaching and the Fitbit and to collect the necessary preliminary data and experience to test the intervention in a larger trial.

PURPOSE OF STUDY

Hypothesis: We hypothesize that giving parent and child dyads a Fitbit and the Fitbit app will activate parents and children to increase their physical activity. We hypothesize that peer-facilitated group sessions about nutrition behaviors, where patients from similar neighborhoods will connect socially and share barriers and successes, will similarly activate patients to make nutritional changes (Aim 1). Additionally, we expect an improvement pre-post in physical activity levels, self-efficacy and intentions for physical activity, self-reported consumption of fruits, vegetables, and child quality of life, and a decrease in consumption of sugar-sweetened beverages and fast and junk-food (Aim 3).

We will address this overarching hypothesis with the following Specific Aims:

Specific Aims:

1. Adapt existing proven interventions—group nutrition sessions and Fitbit-- with patient and community stakeholder input, to identify the most promising approaches (Phase 0).

2. Pilot the nutrition sessions and Fitbit intervention for feasibility and acceptability (Phase 1).

3. Evaluate the intervention for efficacy through the an interrupted time series using groups meeting bi-weekly (Phase 2) and groups meeting monthly (Phase 3).

Specific Aim 1

The *goal* of the design phase is to collect stakeholder input on evidence-based strategies for promoting nutrition and physical activity and design them to meet the real-world needs and circumstances of patients, families, and communities. We will primarily focus on designing the group-based nutrition support groups—to understand what content PPC families want and what format would work best, as the Fitbit device is already a popular consumer device and is used in many research studies to increase physical activity. This aim will be accomplished through four parts: (1) an environmental scan, (2) PI interviews with community stakeholders, (3) focus groups and interviews with PPC parents, and (4) design team meetings. We have already started steps 1 & 2, and begun assembling the design team during the development of this application.

The environmental scan will be of existent group-based programs in primary care and obesity clinics nationally. We will continue literature reviews[15-17] and draw on the substantial expertise of this proposal's team of researchers in obesity and community engagement and innovators in primary care redesign to identify and select candidate programs. We will also contact the authors of the European studies[13,14] for generalizable learnings. We will conduct Skype or phone interviews, and expect visits to one or two sites, with input and final selections made by the proposal team. The PI will also interview relevant community stakeholders (e.g., Gabriel's Place, the Nutrition Council, school health personnel, the YMCA, Cincinnati Parks, and the Cincinnati Recreation Commission) to assess potential partnerships for Aim 1 design work and/or participation in group sessions for delivery of nutritional or activity content for Aim 2 & 3.

DURATION

This project is planned to span 2 years. Phase 0 & 1 will be conducted during Year 1. Phase 2 & 3 will be conducted during Year 2.

POTENTIAL BENEFITS

There are no potential direct benefits for participants in Aim 1. Benefits to others for information gleaned from Aim 1 are contributions to designing a system that better meets patients' needs for activity promotion and dietary guidance. Participants in Aims 2 and 3 may benefit by receiving practical tips of how to improve their diet, where to shop for inexpensive fruits and vegetables, and where are safe and fun parks to play in.

POTENTIAL RISKS, DISCOMFORTS AND INCONVENIENCES

The potential risks of this study are minimal, primarily loss of confidentiality. We will use unique IDs to separate any identifying information from the data collected for this study. Participants will be able to opt out of any part of the study that makes them feel uncomfortable. As a pilot study, we will be cautious and attentive to any aspects of this study that make participants uncomfortable that we did not anticipate.

RISK/BENEFIT ANALYSIS

Given the minimal risks and potential benefits of identification and discussion of improved knowledge and guidance strategies, combined with the potential benefits of improved health, the benefits outweigh the risks.

INFORMED CONSENT AND ASSENT

All study staff having direct contact with study participants will be trained in the ethical conduct of research including the process for obtaining informed consent. We request a waiver of documentation of consent for focus group and interview participants in Aim 1 as the consent document would be the only piece of identifiable information collected.

Written informed consent will be obtained from all participants for Aims 2 and 3.
We will also collect a separate consent form giving permission for the study team to use photographs, audio recordings, and video recordings of participants to aid in the dissemination of the research methods. Participants who decline to give this secondary consent will not have photographs, audio recordings, or video recordings of them made. If such recordings are made accidentally they will be deleted as soon as the error is discovered. Participants would not be notified in such an instance.

COMPENSATION

Participants will be paid $10 for attending a nutrition group session, $10 for first upload of their child's data to the Fitbit website or app, $10 at the completion of the pilot phase of the study. Participants in the intervention phases will receive $15 or a t-shirt upon finishing the study. Additionally, the Fitbit devices used by participants will be theirs to keep.

METHODS

Study Design and Rationale

Specific Aim 1: 1. Adapt existing proven interventions—group nutrition sessions and Fitbit-- with patient and community stakeholder input, to identify the most promising approaches (Phase 0).

Qualitative feedback about what content and format patients desire for nutrition group sessions will be collected in Aim 1. Written or audio transcripts of focus groups and interviews will be reviewed by Drs. Brown, Copeland, and Mitchell only. Summary results from these transcripts will be shared with the larger design team, including Drs. Brown, Copeland, Mitchell, Siegel, members of the the PPC Obesity task force (social worker, dietician, medical assistants and staff physicians), community partners (e.g., Myrita Craig) and PPC patient champions There will be no identifiable data in this summative results reviewed by the design team.

Specific Aim 2: Pilot the nutrition sessions and Fitbit intervention for feasibility and acceptability (Phase 1).

The results of patient surveys regarding satisfaction with the Fitbit intervention and the group sessions in Aim 2 will be collected, de-identified, and shared with the design team. The Fitbit Flex device, when worn on the right wrist, was found to reasonably and reliably estimate step counts (compared to video observations on a treadmill) and energy expenditure (compared to indirect calorimetry) during walking and running among 10 adult males in a study accepted for publication in the International Journal of Cardiology (Diaz KM et al, accepted March 2, 2015). Participants can choose to share activity levels with friends and each other. Fitbit tracks physical activity and participants' syncs, and can provide CSV data for Excel spreadsheets for analysis, as well as, heat maps, charts and displays. We will also pilot a co-facilitation model utilizing a parent leader paired with a community professional with nutrition or health expertise to lead the group nutrition sessions. If successful, this model will be implemented in phases 2 and 3 as well. Additionally, we will collect surveys from the parents relating to their own depression, social support, and perceived stress pre- and post-intervention. These include the Parenting Stress Index - Fourth Edition-Short Form[18], the Perceived Stress Scale[19], the Patient Health Questionnaire[20], and the Multidimensional Scale of Perceived Social Support[21] These questionnaires will be piloted for feasibility of administration and possibly included in phases 2 and 3.

Specific Aim 3: 3. Evaluate the intervention for efficacy through the an interrupted time series using groups meeting bi-weekly (Phase 2) and groups meeting monthly (Phase 3).

In Aim 3, parents will report their child's activity levels and child's quality of life as measured by the PedsQL at baseline, midpoint, and at the end of the study; Children will report their self-efficacy and intentions for physical activity at baseline, and at the end of the study.. Parents will also report on 5 measures of their own and their child's diet and sedentary habits 12 times during the group sessions and at least four time points in the following 2 months after the groups sessions are complete: 1) number of sugar-sweetened beverages consumed by the child on previous day, 2) number of servings of

fruits and vegetables consumed by the child on that day, and 3) number of hours of TV/screen time 4) number of meals/snacks with fast food, 5) number of servings of snack food. To establish baseline control limits for each subject individually, and an average of the group collectively, we will also ask parents to report these same 3 outcomes on 10 randomly sampled and non-continuous days (7 times on a weekday and 3 times on a weekend day) during the month prior to the first session. We will query parents via email, phone calls and/or texts, per their preference. (While more baseline data points are desirable, we are concerned about the participant burden involved with collecting more data points. During the pilot phase, we will experiment with texting to collect outcome data from patients. If it appears feasible to collect data more frequently, we will consider collecting more than 7 baseline data points from some or all participants.). We will use Fitabase software to track the child's (and parent's) physical activity level over the course of the 3 month trial, and for up to 3 months after the trial ends. We plan to use the initial week of Fitbit use as the baseline of the participant's physical activity level, recognizing the limitations that giving patients a device to measure their physical activity may encourage them to increase it from its true baseline. We will also collect information about food allergies, dietary restrictions, and most frequently shopped grocery stores via questionnaire once at the beginning of the study.

All data will be seen and analyzed only by the study personnel. A trained research assistant will collect height and weight measurements for both the parent and the child in triplicate (measured to the neariest 1.0cm and 0.1kg) with portable stadiometers and high-precision scales at 0, 3 and 6 months Child participants will be assigned a unique ID. Any children's names that are used on forms for tracking purposes will be blacked out and replaced with the unique ID. As they are collected, paper forms will be kept in a file box that study staff will keep with them at all times. After collected, paper forms will be stored in a locked file cabinet at CCHMC. All data will be entered into password-protected CCHMC electronic database. Only study personnel will have access to the data and all will have completed HIPAA and research ethics participation. All data collection and storage procedures will be reviewed by the CCHMC IRB for their compliance with HIPAA regulations.

Another source of qualitative data will be "practical tips" that participants share at nutrition sessions. Nutrition group sessions cannot be blinded, and the intention of these sessions is to develop connection and emotional support among participants. No sensitive information will be asked or collected at these sessions; participants will share only what they feel comfortable sharing. Running concurrently with the adult group nutrition sessions, the children will have general nutrition and exercise content delivered through the childcare provider for each session. The purpose, format, and content of these group sessions will be thoroughly explained during the consent process for Aims 2 and 3.

Study Site

The Pediatric Primary Care Clinic (PPC) at Cincinnati Children's Hospital Medical Center (CCHMC). Additionally, Gabriel's House in Avondale will be utilized (see letter) as an alternate location.

Data Collection

Specific Aim 1:

Focus groups will be moderated by Dr. Mitchell or her designee and attended by the PI; the PI will conduct parent interviews. The goal of both is to understand *what* nutritional coaching PPC families want or need (e.g. meal planning, tips for purchasing inexpensive healthy foods, tips for increasing vegetable consumption); *how* they want it delivered (e.g., didactic vs. facilitated group discussion); *whom* they would like to deliver the content (e.g., health professional, community health worker, peer); and *where* they would want it delivered (e.g., at CCHMC vs. Gabriel's Place). We will present examples of group-based nutritional coaching and peer support programs and will ask families to react and suggest changes. Interviews and focus groups will focus on user-centered design, to understand what people think and feel (e.g., about a new proposed process or design), rather than traditional research focus groups that dissect what people say and do (e.g., to identify benefits and barriers to a health behavior).[22-24] We will also solicit PPC families' input on the Fitbit intervention to identify potential problems to mitigate them for the next phase, but we expect necessary adaptions to be minimal. A <u>*key outcome*</u> of Aim 1 will be the identification of 2-5 PPC "champions" We envision that

these “champions” will likely be PPC parents who are improving their own diets and exercise and have made changes in their household to improve her children’s diet and exercise opportunities. We plan to engage this pool of “champions” as candidates to lead group sessions in Aim 2 & 3, assist with recruitment for Aims 1-3, and participate on the design team of Aim 1.

Specific Aim 2:

We will conduct a small pilot of 4 group sessions and the Fitbit intervention for the parent-child dyads. The *rationale* for this pilot is to give peer-leaders a chance to practice leading group sessions and to work out any bugs in the interventions planned for Aim 3. (For instance, patients may bring other siblings to sessions thus we will need to practice offering child-care arrangements vs. involving these siblings in sessions.) Fitbit devices are the most commonly used consumer-grade pedometers/accelerometers in adult and pediatric research studies, including a feasibility RCT (Clinicaltrials.gov # NCT02031185) among 14-18 year olds at Seattle Children’s Hospital (Jason Mendoza, MD MPH). At CCHMC, Kimberlee Bernstein (CRC, Gastroenterology) is currently using Fitbits and Fitabase for an ongoing study (R01, Stavra Xanthakos), and has been impressed with its functionality. The device connects through USB port or Bluethooth technology to all mobile devices. Thus the purpose of the Fitbit pilot will primarily be to orient the CCHMC team to Fitabase capabilities, how to interact with patients about results, and interfacing with the Fitbit team to optimize its deployment for PPC patients. Through 4 group sessions we will have the opportunity trial sessions at CCHMC vs. Gabriel’s Place (see letter) and sessions that are parent-only vs. parent-and-child-combined, to see which participants prefer and which works best. We considered, and rejected, a factorial design to test these factors due to the need to recruit a large number (>80) of independent subjects. For this study, power analysis is not applicable since in an interrupted time series the participants are examined on an individual level not as a whole.

CONTENT/FORMAT OF SESSIONS- As per design principles, we will remain flexible in our preconception of the final intervention, but we expect group sessions to involve both

parents and children (split into smaller groups as necessary) and to consist of four parts: (1) a facilitated 20 minute discussion of barriers and successes[25] related to healthy eating ,(2) a brief, interactive teaching session about healthy eating, (3) a review of Fitbit results (at the group level) and a discussion of successes and problems with the program for PPC patients, and (4) a healthy meal. The facilitated discussion will operate similar to group therapy,[26] building relatedness and competence[27] among participants as they see peers facing similar barriers. We expect patient to find inherent value in the connection gained through discussion, which will aid in retention for subsequent sessions. We also expect to gain informal insights and practical tips from the successes that parents share, e.g., planting a window box garden and successfully inciting their child to taste new vegetables grown at home. The brief teaching session will focus on practical, implementable strategies (e.g., MyPlate strategies of filling half the plate with fruits and vegetables, how to deal with picky eaters) to be delivered in simple terms by community partners (see Myrita Craig letter) or residents/ nutrition students. *Outcomes* (1) attendance at group sessions, and (2) satisfaction with each the group session. We will work with the design team to make necessary refinements prior to the efficacy trial in Aim 3.

Specific Aim 3:

We plan an interrupted times series. To maximize participation in group sessions, we will split the nutrition arms into two groups. We anticipate a 67% show rate in each group.[28] Dividing the nutrition counseling sessions into two groups allows the respective groups to self-sort according to convenience factors such as neighborhood (e.g., Avondale, Price Hill, etc.) and preferred time (afternoon or evening).

We will track the following **outcomes for Aim 3** beginning at the first session (baseline), at each group nutrition session, and at least 2 time points afterwards: (1) attendance at session, (2) satisfaction with session; self-reported consumption on prior day of (3) fruits and vegetables, (4) sugar-sweetened beverages, (5) fast food and (6) snack-food; and (7) TV/screen time used. Additionally, we will track (1) child self-efficacy and intention to be physically active,[29] (2) child quality of life as measured by the PedsQL.[30] We will also track satisfaction with the group sessions. Although not a primary outcome that we

would expect to change given the modest intensity of this intervention, we will also track child BMI 0, 3 months, and 6 months. We will track participants' physical activity levels over one week as measured by the Fitbit device, which is highly accurate and reliable when compared to research-caliber accelerometers (Diaz, KM et al., accepted March 2, 2015). Finally, we will track lost-to-follow-up and no-shows, by making a strong effort to re-contact families to obtain information on reasons for not participating.

Training of Study Personnel

Dr. Mitchell and CCTST Engagement Core resources will train the PPC champions to be group facilitators for nutrition sessions (Feb 2016) and retrain as necessary (May, Aug 2016). Dr. Mitchell has experience in this area through directing Community Leadership Institute, which builds capacity of non-profit community agency professionals. *This "train the trainer" model builds capacity of community resources and will be more sustainable than a model that relies on CCHMC staff or personnel to facilitate sessions and/or deliver content*. Trained peer facilitators will receive $40 and a healthy meal for each session facilitated. Additionally, all study staff having direct contact with study participants will be trained in the ethical conduct of research including the process for obtaining informed consent.

Study Population (inclusion/exclusion criteria)

Aim 1: We will recruit approximately 100 parents of children aged 6-11 years whose medical home is the PPC (N=18,000 patients) and whose BMI is greater than the 85th percentile for age and sex (n=1100 patients) to participate in either focus groups or one-on-one interviews for Aim 1. Fliers will be placed prominently in clinic and subjects will be recruited at well-child checks or ill visits by attending physicians associated with this proposal and /or the research assistant who will staff the clinic and approach potentially eligible families during downtimes in their clinic visit. We will use PPC electronic medical record (EPIC) to identify PPC patients aged 6-11 years old who have been identified or measured as being overweight per clinic records. They already have a relationship with the PPC as the PPC is their primary medical home. We will use the most recent contact information in EPIC to recruit via telephone and mailed letters (see attached letters). We

believe we will have no difficulty recruiting 100 patients out of the 1100 potentially eligible patients, but will adjust recruitment strategies, including additional staffing hours of the research assistant, if necessary. There will be a study phone number that potentially interested subjects will call which will be staffed by the research assistant. We will also encourage participants to recruit their friends and peers who are also PPC patients to call the study phone number.

Subjects that participate in Aim 1 will be eligible to participate in the pilot for Aim 2 or the interrupted time series for Aim 3. At the conclusion of their interview/focus group, they will be asked if they wish to participate in future research related to the topic including a clinical trial, and if so 3 forms of contact will be recorded (e.g., cell phone, home phone, and email address). We will recruit up to 25-30 children aged 6-12 years whose BMI is greater than 85th percentile for age and sex, and their parents to participate in the pilot for Aim 2.

Additional inclusion criteria include: both parent and child interested in making nutritional and/or physical activity changes, and agree to participate in at least 4 group sessions and trialing the Fitbit intervention. Exclusion criteria for Aim 2 are as follows: participation in Healthworks! Weight management clinic in the past two years; child has a current prescription for an atypical anti-psychotic medication (because weight gain is a common side effect with these medications); parent does not have access to either a smartphone or a computer at home (as they would be unable to easily sync Fitbit data). The same criteria will be used to recruit up to 100 patients and parents dyads for Aim 3. To minimize contamination, subjects that participate in Aim 2 will not be eligible to participate in Aim 3. In addition to contacting interested participants from Aim 1, we will continue to recruit for Aims 2 and 3 through attending physicians, the research assistant, fliers, and the study phone line. We expect these recruitment strategies to be sufficient to recruit 100 patient-parent dyads over 9 months, but will adjust strategies if necessary. Retention for Aim 3 is one of the outcomes we will measure for this efficacy trial and pilot.

Inclusion of Women and Minorities

No racial, ethnic, or gender group will be excluded from participation in the study. Our patient population is approximately 60% African-American, 85% Medicaid, and 10% self-pay. We expect the parents that want to make diet and activity changes for themselves and their families for Aims 2 and 3 will primarily be women, but men will not be excluded.

Inclusion of Children

Children are the primary subjects of the proposed study. Children aged 6-12 years old and who are >85th percentile for BMI for age and sex will be eligible. This age range was chosen because obesity represents a significant problem for this age group and this age group is still dependent on parents for selecting and preparing foods and snacks served at home. Moreover, this age group covers the elementary grades Kindergarten through 6th grade in Cincinnati, thus this age group is used to doing things together at elementary schools. The investigative team has ample experience working with this age group and their parents. The sample size of 100 patients for the efficacy trial in Aim 3 was selected to provide a sufficient number of children to contribute a meaningful analysis of the intervention's effect on children's nutrition and physical activity habits.

Statistical Methods and Data Analysis

Data analytic plan:

Aim 1: Drs. Mitchell, Brown, and Copeland, who each have experience with ethnographic methods, will review transcripts of focus groups and interviews for themes and suggestions. Results will be reviewed by a larger design team, to include Drs. Brown, Siegel, Bolling, members of the PPC Obesity Task Force (staff physicians, dietician, social worker), community agency partner(s), and 1-2 patient "champions," identified from focus groups and interviews. Another *important outcome* is the bringing together of this cluster of accomplished researchers in different fields, clinicians, patients, and community members for design team work that builds capacity for future

grant applications. The design team will work collaboratively to plan the pilot group sessions for Aim 2 and make any necessary tweaks for Aim 3 efficacy trial.

Aim 3:

Individual- and group-level data for self-reported consumption outcomes (fruits and vegetables, sugar-sweetened beverages, fast food, snack-food, TV/screen time) and Fitbit-generated physical activity data will be plotted in time series on control charts. Statistical process control will be used to evaluate the impact of our interventions. A centerline (mean) and control limits will be established using pre-intervention data. The mean will be recalculated and the centerline adjusted when the following criteria are met: a "shift" of six or more consecutive points either above or below the mean or a "trend" of at least five consecutively increasing or decreasing data points. These are considered statistically significant changes, as there is < 5% chance of observing these patterns by chance.[31] In addition, individual data points falling outside the control limits are statistically unlikely to occur in the absence of a "special cause" and will be further examined for association with the intervention or other factors.[32]

Data and Safety Monitoring Plan

The data safety and monitoring plan for this low-risk study involves ongoing review of the research protocol, subject recruitment, data integrity and patient safety. The design team will meet monthly during Aims 2 and 3 to review recruitment, retention, and any adverse events. We will report any adverse events promptly to the IRB per CCHMC policies and procedures. We will also report study progress and any barriers to recruitment or retention to the PPC Obesity task force, which meets monthly. We proposed to enlist a Safety Officer from General and Community Pediatrics, who is not directly affiliated with this proposal, to whom we will submit reports on recruitment, retention, and performance information. A Safety Officer is proposed rather than a full Data Safety and Monitoring Board (DSMB) as this study carries low risk. A full DSMB will be developed should that be deemed necessary.

FUTURE USE

There is a gap in the literature of effective ways to prevent, identify, and treat obesity or inactivity within primary care, particularly for low-income families at greatest risk for obesity and inactivity. This study is intended to design a primary care-based intervention for obese/overweight children that is patient/family-centered, group-based, and embedded in the community.

PUBLICATION

The authors plan to present and publish the outcomes of this study.

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