Protocol Title: Healthy Kids Pilot

Co-PIs: Amanda Staiano, PhD, Corby Martin, PhD

Co-Investigators: John Apolzan, PhD

Medical Investigator: Daniel Hsia, MD

Sponsor: Internal funds

Protocol Version Date: 8/15/2017

Objectives

Specific Aims

The current pilot study, entitled Healthy Kids Pilot, is a pilot & feasibility study to demonstrate the feasibility and acceptability of using an mHealth approach (i.e. intervention delivered over smartphone, iPad/Tablet, or desktop/laptop) to promote healthy behaviors and healthy weight among children and their parents.

We will recruit up to 30 parent-child dyads into the intervention, where the designated child is between the ages of 6 and 10 years old, has a BMI percentile ≥ 85, free of diseases that affect metabolism, body weight, and food intake, including diabetes, HIV/AIDS, and cancer, and where the designated parent has a smartphone and is willing to use it for the intervention, including accessing the HealthTracker.

The primary outcome variable is acceptability/feasibility of the mHealth approach which will be evaluated by surveys of program acceptability and treatment satisfaction. Secondary outcomes will be change in BMIz in children and change in body mass of the participating parent. The primary aim of the study is:

Aim 1: to determine if an mHealth approach to promote healthy behaviors and healthy weight among children and their parents will be utilized by parents of 6-10 year old overweight/obese children.

Number of Subjects and Subject Timeline

We plan to enroll up to 30 parent/child dyads over 1 year. Each parent/child dyad will participate in this study for approximately 3-4 months.

Study Timeline

This project will occur from August 28, 2017, to August 1, 2018.

Setting

All evaluations and study procedures involving children and parents will be conducted off-site including at a local YMCA or other community locations or in the participant's home. The intervention will be conducted via remote counseling sessions delivered over the parents' Internet-connected device.

Scientific Rationale

The prevalence of childhood overweight and obesity has increased markedly over the past few decades, with obese children at increased risk of obesity-related medical conditions. The most effective approaches to attenuate weight gain in children, and their parents, include family-based behavioral treatments that concurrently target children and parents to promote healthy eating and exercise using behavioral management techniques to make sustained behavioral changes. However, in-person counseling is difficult to disseminate on the scale necessary to impact childhood obesity at the population level, and many families face barriers related to scheduling conflicts and transportation. Mobile health (mHealth) approaches promise to overcome barriers to the translation and dissemination of effective interventions and offer the ability to remotely monitor patients' progress and deliver treatment. Indeed, our multidisciplinary team of behaviorists, dietitians, and physical activity experts at Pennington Biomedical Research Center has shown that it is feasible to deliver mobile phone based interventions to parents that target their child's behavior and that when these programs are based on behavioral theory, they can be effective.

This protocol is a pilot & feasibility study that will provide data on acceptability, feasibility, and estimates of effect size for an R01 submission. The R01 submission will test the efficacy of a family-based weight management intervention (FWM) to reduce obesity in 198 children aged 6 to 10 years and their obese parents using two delivery modalities: in-person (n=84) vs. mHealth (n=84), compared to a health education control (n=30) group, over two years. The mHealth intervention will include remote behavioral counseling and include remote tracking of body weight, physical activity, and food intake. The overall goal is to leverage mHealth to reduce childhood obesity in a way that is both effective and acceptable for wide dissemination.

Sample Size Justification

This protocol is a pilot & feasibility study that will provide data on acceptability, feasibility, and estimates of effect size for an R01 submission. A sample size of up to 30 dyads will provide sufficient data for feasibility and acceptability.

Planned Statistical Analyses

To determine if this mHealth approach to promote healthy behaviors and healthy weight among children and their parents will be utilized by parents of 6-10 year old overweight/obese children, descriptive statistics will be used to examine adherence and scores on the treatment acceptability and treatment satisfaction surveys.

To obtain preliminary estimates of effect sizes, we will use mixed model analyses using an intent-to-treat approach. Model selection criteria using Akaike information criterion (AIC) will be employed to determine the best set of covariates, including, but not limited to, baseline demographic (e.g., sex, race) and anthropometric variables. T-tests based on the least squared means derived from the model are used to test the treatment effects. Responses such as change in body mass (kg and percent for the parents; BMIz for the children), physical activity, energy intake and diet quality, and treatment satisfaction and burden, will all be used in the mixed effect model and we will specifically include race and sex in the model to test if biological variables, such as sex, are associated with the outcomes.

Methods

Study Participants.

To be eligible for the study, the child must:

- Be 6-10 years of age
- Have at least one participating parent.
- Have a BMI percentile $\geq$ 85
- Be physically capable of exercise
- Be free of diseases that affect metabolism, body weight, and food intake, including type 1 or type 2 diabetes, HIV/AIDS, and cancer

To be eligible for the study, the parent must:

- Have a smart phone
- Be willing to use the smartphone for the mHealth intervention, including accessing the HealthTracker

Exclusion criteria for the child include:

- Significant cardiovascular disease or disorders via self-report from parent
- Other significant medical problems that would prevent them from engaging in regular physical activity.

Visits/Procedures

Below are the procedures that will be completed during study participation:

Procedure	Screening/ Baseline	Intervention	End of Study Follow-up
Assessment of or by the Parent			
Orientation Presentation	x		
Consent	x		
Height/Weight	x		x
Questionnaire (Medical History Survey)	x		
Acceptability Survey	x		
Pedometer (daily)		x	
RFPM (monthly)		x	
Treatment Satisfaction Survey			x
Assessment of Child			
Orientation Presentation	x		
Assent	x		
Height/Weight	x		x
Questionnaire (Lifestyle Survey, Treatment Satisfaction Survey)	x		x
Pedometer (daily)		x	
RFPM (monthly)		x	

Visits

Recruitment

Using a study flyer we will advertise through the public library system, seek support of community leaders, issue personal appeals through social organizations, and place advertisements in places of congregation. Participants will also be recruited using traditional advertisement mediums if necessary, including newspaper, radio, television, and social media. We will actively recruit new potential participants from the Pre-PLACE and other pediatric studies, and we will submit a privacy board request to recruit participants who were recently deemed ineligible from the Pre-PLACE study and other recent pediatric studies.

Telephone Screen

We will perform an initial telephone screen to determine if the potential participant appears to meet eligibility criteria. Individuals deemed eligible from the telephone screen will then be scheduled for a screening visit and will receive the consent/assent form by email.

Screening/Baseline Visit

The screening visit will occur at a local YMCA or other community locations or in the participant's home. Participants will be formally oriented to the study by receiving detailed information on the purposes, goals, procedures, participant flow, and timeline. A parent will sign an informed consent. Participants ages 9-10 will sign a written assent form. Participants ages 6-8 will provide a verbal assent for participation. Parents will complete a program acceptability survey and complete a medical history questionnaire for their child. Children will complete the Lifestyle Survey. Height and weight measurements will be taken for both the child and parent. If they meet initial inclusion criteria based on the information collected, the parent/child dyad will meet with an interventionist to conduct or schedule an initial face-to-face counseling session.

Follow-up Assessment Visit

Parent-child dyads will return to a local YMCA or other community locations or in the participant's home for a follow-up visit at 14-16 weeks following the commencement of the intervention. Participants will have their height and weight measured and complete surveys.

Procedures

Program Acceptability/Treatment Satisfaction Surveys

Parents will complete a survey assessing program acceptability at screening and a survey assessing treatment satisfaction at the final assessment visit.

Medical History

Parents will completea medical history questionnaire for their child.

Lifestyle Survey

Children will complete a lifestyle survey assessing sleep, dietary and physical activity habits, and media use.

Anthropometry

Height and weight will be measured using a portable stadiometer and a scale. Measurements will be taken without shoes and recorded to the nearest 0.1 cm and 0.1 kg.

Intervention

Parent/child dyads will attend remote counseling sessions (each approximately 30 minutes) delivered over their Internet-connected device (e.g. smartphone, iPad/tablet, laptop, or desktop computer). A Pennington Biomedical counselor will deliver the lesson, review progress based on the objectively measured data available on the HealthTracker; more detail below), and provide individualized advice and problem-solving strategies for the parent and the child. Counselors will attempt to meet face-to-face with parents for the initial intervention session. Eight lessons will be delivered electronically via smartphone, iPad/tablet, laptop, or desktop computer. Over the course of the 14-16 week study, families will also receive weekly contact via smartphone (most interactions will be via FaceTime, Skype, or phone, but email and text communication will also occur). Each lesson will include an interactive component for the parent and child related to healthy eating and active play, as well as an interactive parenting training component. The lessons are based on the family treatment methods that effectively promote child and parent weight loss that is sustained for 10 years (Epstein et al., 1990; Epstein et al., 1981).

The parent lessons are framed around these guiding principles: 1) weight and activity monitoring; 2) behavioral contracting with a goal of modeling appropriate strategies; 3) review of progress and problem-solving to address poor adherence to behavioral goals; and 4) food monitoring and goal setting for nutrient intake. Specific lessons will focus on how to motivate the child and how to manage non-compliance including praise and reward, positive reinforcement, selective ignoring, contracting, pre-planning for meals and physical activity, shaping behaviors, modeling, changes to the home environment, and facilitating social support for behavior change (Newton et al., 2011; Staiano et al., 2017). The dietary approach will employ food monitoring and goal setting for nutrient intake following the Traffic Light Diet, an effective approach for children and their parents within a clinically supervised, multi-component weight management program (Epstein et al., 1990). Foods are categorized as green, yellow, or red based on caloric density, and children and parents are given a goal to stay within a prescribed daily calorie range and to eat no more than four red foods each week. We will work with the parent to make systemic changes to what is served and how it is prepared in the home, focusing on preparation methods that decrease energy density and dietary fat, such as baking rather than frying foods. The physical activity approach will introduce free or inexpensive activity options and address barriers to physical activity. Counselors will work with parents to increase opportunities for play and activities that they and their children enjoy. We successfully used these lessons in prior and ongoing pediatric trials (Staiano et al., 2017; Williamson et al., 2005; Williamson et al., 2006) and have updated them over time. Specific targeted psychosocial constructs include increasing quality of life through active play and improving eating attitudes through modeling and introduction of healthy foods.

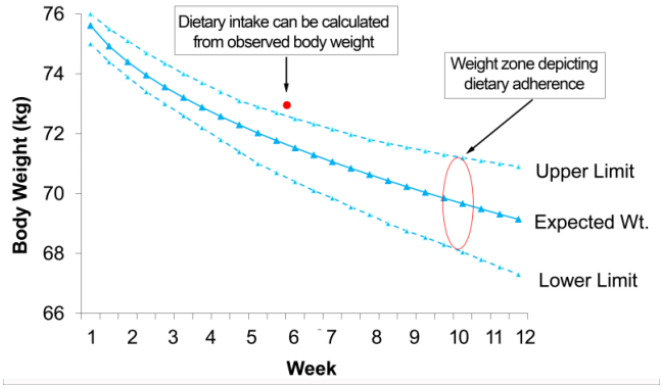
The HealthTracker is Internet-based software that allows us to deploy the intervention as an EMI (Ecological Momentary Intervention) and Just in Time Adaptive Intervention (JITAI). The HealthTracker serves as the “hub” of intervention delivery for the counselors and participants, and it promotes treatment fidelity, ongoing communication and progress reviews between the remote counseling sessions, and structures intervention delivery for the counselors. Further, the HealthTracker remotely collects objective data, namely body weight, in near real-time and these data are used to facilitate behavior change during the mHealth intervention, consistent with learning theory. The intervention is

based on the theory of planned behavior and the theory of reasoned actions (Ajzen, 1991) by fostering an environment conducive to behavior change where participants' behavioral goals are clearly defined, self-efficacy is promoted, and behavior is regulated through objective data. The intervention also incorporates aspects of social cognitive theory (Bandura, 1988) by reinforcing behavior change and fostering personal agency, clear outcome expectations, and goal setting. Though the counselor and participant's relationship is remote and relies on communication technology, counselors are able to deploy motivational interviewing techniques to address decreases in motivation, which are inevitable in longer-term interventions (Patrick & Williams, 2012).

Component	Frequency	**mHealth** (HealthTracker with Virtual Counseling)
Lesson & Material Delivery	Weekly (Wk 1-4) Biweekly (Wk 6-14)	• Counselor delivers 8 lessons to the child and parent during remote counseling sessions over video chat or phone call.
Body Weight	Daily (parent) Weekly (child)	• Sent automatically from the Body Trace Scale in the home to the HealthTracker. • Within minutes, the **Weight Graph** for the parent with individualized target weight zones are available for the parent and counselor on HealthTracker. • Children will be asked to weigh weekly, therefore the child weight graph will be sent remotely to the parent once per week.
Physical Activity (steps/day)	Weekly	• The **Steps Graph** for the parent, including individualized steps/day target, are available for the parent and counselor on HealthTracker. • The step graph for the children will be sent remotely to the parent once per week
Food Intake (kcal/day)	Monthly, with ~1 week of data per month	• Weight graphs will be continually used a proxy for adherence to energy intake targets. For nutrient information, parent captures own and child's food images using Remote Food Photography. Images are automatically transmitted via the SmartIntake app.[50,51]

The intervention largely is based on our previous successes with an mHealth weight management intervention for adults called "**SmartLoss**" (Martin et al., 2015; Martin et al., 2016). SmartLoss is an EMI and JITAI that promotes behavior change via the real-time capture of objective body weight and activity (step) data from participants' home environment. These data are wirelessly transferred to the Internet where they are graphed in relation to the individual participant's weight and step goals by our software and sent back to participants via their smartphone (these graphs are also available for the counselor, see Figure).

Weight Graph Zone of Adherence (Parent).

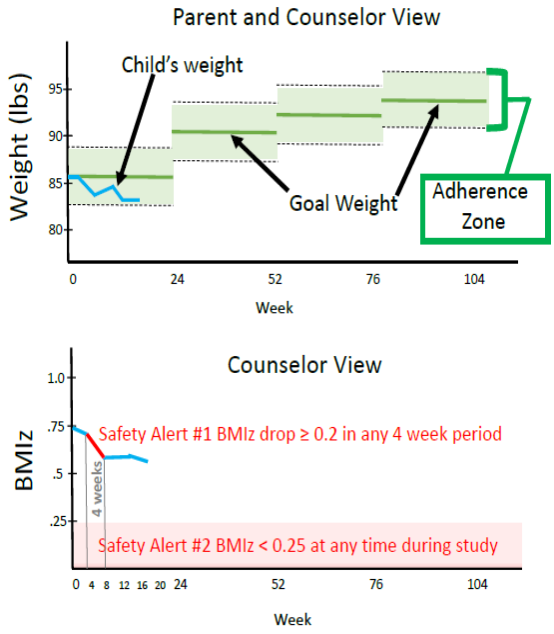


One cornerstone of SmartLoss is the ability to objectively quantify adherence to energy intake goals based on observed body weight. To achieve this aim, we developed and validated differential energy balance equations (Thomas et al., 2010) that predict weight change over time for an individual based on a prescribed energy intake target. Our software generates individual **weight graphs** that display the expected amount of weight loss over time, and the model

also generates upper and lower bounds around predicted weight loss. As shown in Figure 3, this creates a "zone of adherence" and a participant's body weight is plotted over time in relation to this zone. The participant is considered adherent to the diet if their weight falls within the zone; hence, change in weight serves as a proxy for energy intake/dietary adherence. This graphical feedback is used by counselors and participants to deploy different treatment strategies to modify energy intake to improve adherence.

Customization of the HealthTracker and the Intervention. The HealthTracker will be accessible 24 hours per day by counselors and parents anywhere that has Internet access (including mobile devices), and the data in the HealthTracker are available in near real-time. Parents will interact with the HealthTracker to review their step and weight graphs.

Figure 4. Weight Graph Zone of Adherence (Child).



Weight Graphs

Children and parents assigned to the mHealth intervention will each receive a **Body Trace scale** that wirelessly and automatically transmits their data to a website. Parents will be asked to weigh daily and weigh their child weekly, unless contraindicated due to anxiety, etc. The HealthTracker will plot the parent's weight on a graph (Figure 3). The child's weight graph is delivered remotely each week and will be plotted two ways, with the counselor seeing both plots and the parent only being able to see one plot (access to HealthTracker is password restricted).

As illustrated in the upper panel of Figure 4, the parent will see their child's weight in pounds plotted on a graph that has a zone of adherence that is flat over time and consistent with our recommendations to attenuate weight gain and reduce BMIz compared to the control group. The initial zone for the child will be set at their current weight ±3 pounds (we recognize this is an arbitrary zone, though we used a similar guideline in the DRIVEE study successfully). As noted earlier and illustrated in the lower panel of Figure 4, **two safety criteria** are evaluated by the study team in real-time via the HealthTracker to identify children who might decrease body mass too much and/or too quickly. Specifically, children will be identified who: 1) lose > 0.20 BMIz in any four-week period, or 2) obtain a BMIz < 0.25 which corresponds to the 60th BMI percentile. The weight graphs are available in real-time to the parents (and their children), and parents will receive copies of their and their child's most recent graphs every time they are contacted by their counselor.

Physical Activity

The child's daily activity (steps/day) will be tracked with a pedometer. The parent will be asked to document their child steps daily. The counselor plots the child's daily step data in relation to their individual goals. These step graphs are then used to help promote adherence to participants' activity goals. The pedometer has low participant burden and is worn on the waist. The parent and child's step

graph will be available weekly during the interventions sessions and will be delivered to the parents on the same schedule as the weight graph.

Food Intake

The weight graphs serve as a proxy measure of energy intake. Hence, recommendations to change energy intake will be guided by participants' body weight in relation to their individual zone. The Remote Food Photography Method (RFPM) and SmartIntake smartphone app, however, will also be used by the parents to provide the intervention team with information that they can use to help the parents modify their food preparation methods, portion sizes, shopping lists, and food choices to maximize the likelihood that the parents can adhere to their and their child's energy intake goals. Food image data from family meals (e.g., breakfast, dinner, afternoon and evening snacks) are extremely helpful in helping people to modify their food intake, particularly since these data are captured and transmitted to the study team in real-time.

RFPM data are collected with the SmartIntake app by parents who will use the app to capture images of food selection (and plate waste after meals). The app has barcode scanning capabilities and a Price Look-up (PLU) number entry system to easily identify foods in the images. The app also has text and voice message capability, allowing participants to easily record food descriptors that are automatically tagged to the food image. The SmartIntake app sends participants' food images to a Pennington Biomedical server where the images can be viewed on an Internet-based platform by the intervention team in real-time (and/or analyzed to calculate energy and nutrient intake). The RFPM includes Ecological Momentary Assessment (EMA) methodology to promote data quality and completeness by sending text messages or reminders to participants to capture images of the foods and beverages that they consume at their personalized meal times.

Data Safety Monitoring Plan

The proposed research risks are no greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e. minimal risk). Therefore, the protocol does not warrant the establishment of an independent Data and Safety Monitoring Board (DSMB). This Data and Safety Monitoring plan describes the safety monitoring procedures for the proposed study, including a description of how often and to whom serious and unexpected adverse events will be reported. The plan will help ensure the safety of all participants. The PIs will communicate via electronic submission to the IRB all unanticipated problems as defined by the IRB and all serious adverse events (SAEs) to the medical investigator within 24 hours. All less serious adverse events will be reported to the medical investigator within 3 days of occurrence.

1) Measurement and reporting of subject accrual, adherence to inclusion/exclusion criteria, protocol adherence, and rates of study completion – Review of subject accrual, adherence to inclusion/exclusion criteria and study procedures as listed in the protocol, and rates of study completion will occur every two months. These data will be reviewed by the study PIs.

2) Stopping rules – Data on subject accrual and completion rates will be synthesized and evaluated yearly to determine if the study should be terminated. One of the most likely reasons for early termination is the failure to recruit or retain participants; therefore, these data will be evaluated yearly to determine if failure to recruit or attrition is jeopardizing the ability to empirically test the study aims.

3) SAEs will be monitored quarterly by the study PIs and Medical Investigator, to ensure proper SAE reporting and to regulate procedures to protect participant safety.

Data Management and Confidentiality

The Ingestive Behavior Laboratory and Pediatric Obesity and Health Behavior Laboratory 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. Data collected at the sites will be securely transported to PBRC. Access to data files can be made only with permission of the Principal Investigators. Data will be stored for 5 years following study completion.

Withdrawal of Subjects

Participation is voluntary, so participants may withdraw from the study at any time. Data that have already been collected during the course of study participation from a withdrawn participant will be used, unless a specific request is otherwise received. Participants may be withdrawn from the study at the discretion of the study PIs.

Risks/Benefits to Subjects

The proposed research risks are no greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e. minimal risk). The risks for physical, psychological, social, or legal harm are minimal for the testing procedures planned for this study. Our research staff members have performed all testing procedures in many studies with no serious adverse events. There may be risks associated with changing dietary intake, but these will be mitigated by the interventionists who will counsel participants during the mHealth sessions and will perform periodic dietary assessments during the intervention. Children and parents will be asked to gradually increase their physical activity during the intervention. Risks to individuals who increase physical activity are rare, but could include: temporary shortness of breath similar to moderate exercise, muscle soreness the following day, dizziness, fainting, blood pressure elevation, irregular heartbeat or heart attack, mild irritation of the skin from the wearable step measuring devices used to measure physical activity. In addition to the risks listed above, participants may experience a previously unknown risk or side effect. Risks associated with study procedures will be continually assessed and monitored throughout the study by the investigators.

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.

Compensation

The total compensation for the study is $125 to be paid by check. The child can earn up to $50 and the parent can earn up to $75 for completion of the study. Both the child and the parent will each receive $25 for completing the Screening/Baseline assessment. The child will receive $25 and the parent will receive $50 for completing the end of study follow-up assessment.

References

Ajzen I. The theory of planned behavior. *Organ Behav Hum Decis Process.* 1991;50:179-211.

Bandura A. Organizational application of social cognitive theory. *Aust J Manag.* 1988;13:275-302.

Barlow SE, Expert C. Expert committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity: summary report. *Pediatrics.* 2007;120 Suppl 4:S164-192.

Centers for Disease Control and Prevention. How much physical activity do adults need? 2014. Available at https://www.cdc.gov/physicalactivity/basics/adults/. Accessed February 10, 2017.

Colley RC, Janssen I, Tremblay MS. Daily step target to measure adherence to physical activity guidelines in children. *Med Sci Sports Exerc.* 2012;44(5):977-982.

Department of Health and Human Services. *2008 Physical Activity Guidelines for Americans.* 2008.

Epstein LH, Valoski A, Wing RR, McCurley J. Ten-year follow-up of behavioral, family-based treatment for obese children. *JAMA.* 1990;264(19):2519-2523.

Epstein LH, Wing RR, Koeske R, Andrasik F, Ossip DJ. Child and parent weight loss in family-based behavior modification programs. *J Consult Clin Psychol.* 1981;49(5):674.

Hall KD, Butte NF, Swinburn BA, Chow CC. Dynamics of childhood growth and obesity: Development and validation of a quantitative mathmatical model. *Lancet Diabetes Endocrinol.* 2013;1(2):97-105.

Henes ST, Cummings DM, Hickner RC, Houmard JA, Lolasa, KM, Lazorick S, Collier DN. Comparison of predictive equations and measured resting energy expenditure among obese youth attending a pediatric healthy weight clinic: One size does not fit all. *Nutr Clin Pract.* 2013;28(5):617-624.

Martin CK, Gilmore LA, Apolzan JW, Myers CA, Thomas DM, Redman LM. Smartloss: A personalized mobile health intervention for weight management and health promotion. *JMIR mHealth and uHealth.* 2016;4(1):e18.

Martin CK, Miller AC, Thomas DM, Champagne CM, Han H, Church T. Efficacy of SmartLoss, a smartphone-based weight loss intervention: Results from a randomized controlled trial. *Obesity.* 2015;23:935-942.

Martin CK, Correa JB, Han H, Allen HR, Rood JC, Champagne CM, Gunturk BK, Bray GA. Validity of the Remote Food Photography Method (RFPM) for estimating energy and nutrient intake in near real-time. *Obesity.* 2012;20(4):891-899.

Newton RL, Martin CK, Williamson DA, Sothern M, Han H, Webber LS. Accelerometry measured ethnic differences in activity in rural adolescents. *J Phys Act Health*. 2011;8(2):287-295.

Patrick H, Williams GC. Self-determination theory its application to health behavior and complementarity with motivational interviewing. *Int J Behav Nutr Phys Act.* 2012;9(18).

Physical Activity Advisory Committee. Physical Activity Advisory Committee Report. 2008.

Staiano AE, Beyl RA, Hsia DS, Katzmarzyk PT, Mantzor S, Newton RL, Jarrell A, Tyson P. Step tracking with goals increases children's weight loss in a behavioral intervention. *Childhood Obesity* 2017. ePub ahead of print.

Thomas DM, Das SK, Levine JA, Martin CK, Mayer L, McDougall A, Strauss BJ, Heymsfield SB. New fat free mass - fat mass model for use in physiological energy balance equations. *Nutr Metab.* 2010;7(39).

Tudor-Locke C. Steps to better cardiovascular health: How many steps does it take to achieve good health and how confident are we in this number? *Curr Cardiovasc Risk Rep.* 2010;4(4):271-276.

Williamson DA, Martin PD, White MA, Newton R, Walden H, York-Crowe E, Alfonso A, Gordon S, Ryan D. Efficacy of an internet-based behavioral weight loss program for overweight adolescent African-American girls. *Eat Weight Disord.* 2005;10(3):193-203.

Williamson DA, Walden HM, White MA, York-Crowe E, Newton RL Jr, Alfonso A, Gordon S, Ryan D. Two-year internet-based randomized controlled trial for weight loss in African-American girls. *Obesity.* 2006;14(7):1231-1243.