Published in final edited form as:

Contemp Clin Trials. 2013 November ; 36(2): . doi:10.1016/j.cct.2013.09.001.

Family, Community and Clinic Collaboration to Treat Overweight and Obese Children: Stanford GOALS -- a Randomized Controlled Trial of a Three-Year, Multi-Component, Multi-Level, Multi-Setting Intervention

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Abstract

Objective—To test the effects of a three-year, community-based, multi-component, multi-level, multi-setting (MMM) approach for treating overweight and obese children.

Design—Two-arm, parallel group, randomized controlled trial with measures at baseline, 12, 24, and 36 months after randomization.

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Participants—Seven through eleven year old, overweight and obese children (BMI 85th percentile) and their parents/caregivers recruited from community locations in low-income, primarily Latino neighborhoods in Northern California.

Interventions—Families are randomized to the MMM intervention versus a community health education active-placebo comparison intervention. Interventions last for three years for each participant. The MMM intervention includes a community-based after school team sports program designed specifically for overweight and obese children, a home-based family intervention to reduce screen time, alter the home food/eating environment, and promote self-regulatory skills for eating and activity behavior change, and a primary care behavioral counseling intervention linked to the community and home interventions. The active-placebo comparison intervention includes semi-annual health education home visits, monthly health education newsletters for children and for parents/guardians, and a series of community-based health education events for families.

Main Outcome Measure—Body mass index trajectory over the three-year study. Secondary outcome measures include waist circumference, triceps skinfold thickness, accelerometer-measured physical activity, 24-hour dietary recalls, screen time and other sedentary behaviors, blood pressure, fasting lipids, glucose, insulin, hemoglobin A1c, C-reactive protein, alanine aminotransferase, and psychosocial measures.

Conclusions—The Stanford GOALS trial is testing the efficacy of a novel community-based multi-component, multi-level, multi-setting treatment for childhood overweight and obesity in low-income, Latino families.

Keywords

children; overweight; obesity; treatment; community; family

INTRODUCTION

The United States has experienced dramatic increases in obesity among both children and adults. National surveys from 1963 to 2010 demonstrate that the prevalences of child and adolescent obesity have more than tripled, with the majority of those increases occurring since 1980.[1–3] In the 2009–2010 NHANES, 29.0% and 15.2% of 6–19 year old non-Hispanic white children, 41.4% and 23.1% of 6–19 year old Mexican-American children, and 41.8% and 25.7% of 6–19 year old non-Hispanic black children had body mass index (BMI) 85th and 95th percentiles, respectively, on the 2000 Centers for Disease Control and Prevention (CDC) growth references.[3] Obesity in children and adolescents has been associated with hypertension, dyslipidemias, early atherosclerotic lesions, hyperinsulinemia, insulin resistance and type 2 diabetes mellitus, and many other medical, psychological, and social complications.[4]

Existing clinical childhood obesity treatment programs are expensive and time-consuming to implement, able to serve only limited numbers of children, not available in all communities, often inconvenient for children and families to attend, and generally produce modest outcomes.[4, 5] As the prevalence of childhood overweight and obesity has grown, innovative feasible, accessible, acceptable, affordable, and effective weight control programs are greatly needed. Thus, Stanford GOALS was proposed to develop and evaluate a new community-focused model for treating overweight and obese children. To overcome the shortcomings of existing approaches, Stanford GOALS links care provided in traditional medical settings to community resources, to deliver the bulk of treatment in settings where children and families live and play. The intervention simultaneously targets multiple influences on eating, physical activity and sedentary behaviors at multiple levels and in multiple settings. This novel, multi-component, multi-level, multi-setting (MMM) treatment

model was designed based on the existing research knowledge base, extensive experience performing childhood obesity prevention and treatment research and delivering pediatric care to overweight and obese children, and through input from a process of community based participatory research in the targeted local communities.

Stanford GOALS is part of the Childhood Obesity Prevention and Treatment Research consortium (COPTR), sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), to develop and test novel approaches to address childhood obesity. Phase 1 was an 18-month development and pilot study phase, completed in 2012. Phase 2 involves full-scale clinical trials at four field centers, Stanford University, Case Western Reserve University, University of Minnesota and Vanderbilt University, a research coordinating unit (RCU) at the University of North Carolina, Chapel Hill, and the project offices of the NHLBI and NICHD. Each field center is testing its own distinct interventions with its own unique, high-risk population and eligibility criteria, but informed by the collaborative planning, experience and results from all centers in Phase 1 and sharing a core set of common measures and protocols. This paper describes the design of the Stanford GOALS trial.

MATERIALS AND METHODS

Trial Design

Stanford GOALS is a two-arm, parallel group, randomized controlled trial to test the efficacy of a multi-component, multi-level, multi-setting (MMM) approach to treating overweight and obese children. The MMM intervention includes three major components: a community-based after school team sports program designed specifically for overweight & obese children, a home-based family intervention to alter the home food/eating environment, reduce screen time, and promote self-regulatory skills for eating and activity behavior change, and a primary care provider behavioral counseling intervention linked to the community and home interventions. Participants are randomized to either the MMM intervention or a community-based health education intervention for three years. Participants are assessed at baseline and annually. The primary outcome measure is change in BMI during the 36-month study. The primary hypothesis is: compared to health education controls, children randomized to the MMM intervention will have a significantly attenuated BMI trajectory.

Recruitment, Screening and Informed Consent and Assent

Two hundred and forty 7–11 year old overweight and obese participants are recruited through primary care providers and clinics, schools, community centers, churches, and other community locations in low-income, primarily Latino neighborhoods in East Palo Alto, Menlo Park and Redwood City, California, USA, near Stanford University. In our Pilot study of 40 families in just two neighborhoods, our sample was 94% Latino/Hispanic (mostly Mexican-American), 4% Black/African-American and 2% multi-racial. Prospective participants volunteer to be contacted by the research team. Participants who are potentially eligible by phone screening are scheduled for a visit to be formally assessed for eligibility. Signed consent/assent and HIPAA authorization are required from parents/guardians and children prior to participation. All study procedures have been approved by the Stanford University Administrative Panel on Human Subjects in Medical Research (Internal Review Board, IRB). Recruitment and enrollment is scheduled to be complete within 18 months, starting July 2012.

Eligibility Criteria and Exclusions

Children must be 7, 8, 9, 10 or 11 years of age on the date of randomization with a BMI 85th percentile for age and sex on the 2000 CDC BMI reference at the time of baseline measurement. To enhance internal validity, children are not eligible if they have been diagnosed with a medical condition or taking a medication that affects growth; have a condition limiting their participation in the interventions or assessments; they or their parent/guardian are unable to read, understand or complete informed consent in English or Spanish; plan to move away from the San Francisco Bay Area within the next 36 months; or are deemed to have another characteristic that makes them unsuitable for the study.

Randomization

Children are randomized to treatment or control conditions after completing all baseline measures. All eligible children within a household are assessed for inclusion in the study. For households that contribute multiple eligible children, one child is randomly selected for randomization and inclusion in the analysis. Only the statistician is aware of which child in a multi-child household is in the analysis sample. Efron's biased coin randomization^[6] is used to promote a balanced randomization within strata defined by BMI percentile at baseline (85th and < 95th percentile, 95th percentile). The investigators and all assessment staff will remain blinded to experimental assignment until after the final follow-up assessments are completed.

Methods to Limit Attrition

It is anticipated to be challenging to retain families for the full three years of the study. To limit threats to internal validity by differential attrition, we include many intervention strategies to enhance trust and identification with our study as a whole, and a number of strategies specifically designed to limit attrition: enrolling and randomizing participants only after they complete all baseline assessments are completed; compensating families for participating in each assessment visit; conducting follow-up visits in homes if families are unable to complete their measures in the clinic or community locations; frequently collecting contact information from non-household members who will know how to reach the participating families; and providing non-monetary incentives such as t-shirts, backpacks, lunch sacks, caps, and field trips to reinforce participation.

Treatment Interventions

The interventions are delivered over the entire three years of participation for each family. Interventions are based on Bandura's social cognitive model. In social cognitive theory, behavior develops and is altered and maintained through triadic reciprocity, the interplay of personal (cognitive), behavioral and environmental factors [7, 8] With respect to this intervention, *personal factors* include child and parent/guardian value systems which determine the nature of incentives that influence eating and activity patterns, expectations derived from observations and experiences about the consequences of different behaviors (outcome expectancies) and expectations about personal abilities to perform behaviors which will secure desired outcomes (efficacy expectancies). *Behavioral factors* include the skills available in the behavioral repertoire of the child or parent/guardian, and the degree of competence attained in using these skills. *Environmental factors* include peers, family members, teachers, coaches and even media figures who model attitudes and behaviors regarding eating, physical activity, parenting behaviors, etc., and are in a position, through their own actions, judgments or social positions, to influence the development of the participant's value system and standards of conduct regarding those attitudes and behaviors. Environmental factors include physical or structural influences such as televisions in kitchens and bedrooms, safe playgrounds and the availability of after-school and weekend

activities, as well as the environmental influences on eating that we are manipulating in this trial: glass, plate, bowl and serving utensil sizes, availability, visibility and convenience of food and beverages, and screen viewing while eating. Furthermore, Bandura's social cognitive model is particularly helpful in planning interventions by identifying four key processes that are important in learning and adopting new behaviors: attention, retention, production, and motivation.[7] These four processes guide the macro and micro development and implementation of all components of the overall program.

We have chosen to highlight culture in our intervention design, specifically making Latino cultural values a central element of the intervention. There is growing consensus that prevention interventions should become more culturally appropriate by taking into consideration ethnic group differences in social, psychological, environmental, and cultural aspects of health.[9–12] The young children in our study are exposed to mainstream values and content in the popular media and, to a lesser extent in school, but these exposures are interpreted within the context of their own family, community and culture.[12, 13] To adequately incorporate the complexity of culture into our interventions, we address both changes in surface structure (culturally matched models, music, language) and deep structure (values, social and historical influences).[14] We address surface structure through culturally-matched providers (e.g., bilingual, Latino measurement and intervention staff), emphasis on Latino/Mexican-American foods, popular sports among Mexican-Americans, and holiday celebrations. To address deep structure we integrate cultural values, norms, attitudes, and expectancies into the goals and strategies of the interventions.[11] We explicitly design our interventions around elements associated with Latino culture, such as collectivism, familism, present orientation, religiosity, sense of ethnic prejudice, and use of social support as a coping mechanism.[15–19] For example we emphasize cultural awareness, traditional and immigrant foods and food preparation practices, and reactions to media representations of Latinos (in contrast to a mainstream “white” medical/health orientation which often focuses on “exercise,” “dieting,” and disease risks) and our focus on building a community atmosphere and social support among the children and families who attend intervention activities and events.

Within the social cognitive theory framework, we are also drawing from recent research in cognitive and social psychology to frame intervention components to promote greater magnitude and more sustained effects. We are incorporating strategies that have produced durable effects on educational performance among disadvantaged/minority children. We are applying these methods because of apparent similarities in both social- and self-stereotypes of failure and alienation experienced by disadvantaged minority students in educational settings and overweight and obese children relative to their experiences with weight control. This includes framing messages and activities to promote intrinsic motivation[20] and growth mindset implicit theories,[21, 22] and to affirm values[23, 24] and social belonging.[25] We also design intervention activities to maximize motivation for participation in the process of behavior change through use of stealth intervention principles.[26, 27]

Community-based after school team sports (Team GOALS)—One component of the MMM treatment model is a community-based after school team sports program designed specifically for overweight and obese children. Organized after school team sports can provide opportunities for regular and sustained moderate-to-vigorous physical activity and may also address neighborhood safety concerns that could keep children indoors with increased screen time and snacking. This program offers safe, supervised physical activity on a regular basis. The opportunity to be part of a team, play sports, wear uniforms and team colors, receive mentoring, modeling, and friendship from young adult coaches and opportunities to demonstrate skills in front of friends and family, may be fun for children and thus highly motivating.[26, 28] When provided in a supportive environment including

only other overweight children, these characteristics make team sports a highly attractive physical activity opportunity.

The team sports intervention for overweight and obese children is based on our prior research demonstrating significant effects on objectively measured physical activity and BMI.[29] After school team sports programs are offered at several community center sites in the targeted communities. The team sports program is conceptualized as an environmental intervention, available throughout the entire length of the study. Based on past study experiences, including the Phase 1 pilot study, team sports are offered five days per week year around, excluding most school holidays. Children are able to participate in as many or few of the days as they wish and may attend any one or more after school sites. The curriculum was designed in collaboration with community partners and youth sports groups to be appropriate for both boys and girls playing together. Team sports activity sessions approximate about 1–1.5 hours but, by partnering with the existing after school programs, most children attend for about 2–3 hours, including homework and tutoring periods. Based on the results of formative and pilot studies, sports are offered seasonally throughout the year. Sports are selected to allow involvement of children with limited prior sports experience and to be able to teach to children with varying skill and experience levels. An emphasis is placed on time spent in movement and game-play to promote higher intensity physical activity, and smaller groups favoring more participation and one-on-one attention. Trained lead coaches at each site are supported by trained undergraduate interns at practices. We put particular emphasis on motivational processes[7] and ability for growth in skills. [21, 22] Our results to date strongly support this approach.[29]

Home-Based Environmental and Behavioral Interventions (GOAL@Shome)—

The GOALS@home intervention includes 5 modules spread over the entire three years of the intervention: first, a module to promote environmental changes to reduce portion size, followed by three modules to promote behavioral and environmental changes in eating, physical activity and screen time behavior (delivered in an order chosen by the family) and a final maintenance and problem solving module. Each module includes multiple levels that each must be mastered before moving forward. Modules are delivered to families in participants' homes by trained, bilingual (Spanish and English) research assistants. Each module includes a variable number of levels and families must master the skills of each level before moving to the next.

Home-Based Environmental Intervention to Reduce Portion Size—Evidence is mounting that small changes in the environment may alter food choices and reduce consumption of food, without conscious cognitive awareness or control. [30] Two strategies seem most promising: replacing short and wide and large volume glasses with tall and thin and smaller volume glasses, and replacing larger diameter and volume plates, bowls and serving utensils with smaller diameter and volume plates, bowls and utensils.

Portion sizes have increased since the 1970's in association with increased obesity in the U.S.,[31, 32] and some of the greatest increases have occurred among foods consumed in the home.[32] Several research groups have demonstrated that adults and children consume substantially more food and total energy when served larger portions, without compensating during the rest of the day or subsequent days.[33–38] Visual clues may serve as cognitive shortcuts and/or visual illusions that trigger decisions of how much to serve and when to stop eating.[39, 40] Bias in portion estimation of volumes for glasses is evident for both adults and children, appears to be resistant to practice and attention, and can have dramatic impacts on drink consumption.[39, 41, 42] A similar visual illusion occurs with food and plates, bowls and serving spoons. People overestimate the portion size when the food covers more of the area of the plate/bowl/spoon and they underestimate the portion size when the

food covers a smaller proportional area.[39, 43] These results suggest that people serve themselves and consume less drinks and food, without being aware of it, when drinking from taller and thinner glasses and when eating from smaller plates, bowls and serving utensils. Our Pilot study results suggested the feasibility and acceptability of substituting smaller bowls, plates, mugs, glasses, and serving utensils for families participating in a weight control program, and that smaller dishware appeared to result in serving smaller portions without evidence of increased hunger.[44]

During home visits the home interventionist helps families select smaller glasses and dinnerware from our samples and catalog. Pilot study data were used to select replacement dishware to produce 25% reduction in volume and/or surface area compared to families' existing dishware. Old glasses and dishware are packed into boxes for storage. At all subsequent visits interventionists monitor dishware use and provide positive reinforcement and continued and/or recurrent instruction and modeling to increase efficacy beliefs and promote maintenance or prompt additional attempts to make environmental changes.[7, 8]

Family-Based Behavioral Counseling for Diet, Physical Activity, and Screen Time Change—

The family-based behavioral counseling intervention consists of three modules: reducing energy intake, increasing physical activity, and reducing screen time. They can be delivered in any order, depending on the order preferences of the family. The content has been adapted from the Stanford Pediatric Weight Control Program (SPWCP) family-based, group, behavioral program, for use with individual families, and prior screen time reduction interventions. The SPWCP was originally adapted from the approaches used by Epstein et al, demonstrating long-term beneficial outcomes.[45–47] The diet module includes: categorizing foods and self-monitoring intake using traffic light colors (red, yellow, green) defined by energy density; setting goals to reduce red light foods; reciprocal contracting with parents/guardians, and instruction for parents about the appropriate use of praise, constructive criticism and rewards to build intrinsic motivation and methods to foster a growth mindset. Weight is also monitored and followed throughout these modules, with a goal of slowing weight gain, maintaining or slowly decreasing weight relative to height. The physical activity module similarly includes: categorizing and self monitoring physical activities using an activity point system based on energy expenditure, setting goals to increase activity points, earning a pedometer to set new step goals, reciprocal contracting, and instruction for parents.

The screen time reduction module focuses on environmental and behavioral strategies to build skills and self-efficacy for two main screen time reduction strategies, reducing eating while watching screens and reducing total screen time. Reducing screen time is one of the best-documented strategies to reduce weight gain in children. Children spend a substantial part of their lives in front of the television screens, averaging about 1/3 of their waking hours.[48] Low-income and ethnic minority children consume even more TV and other screen media than white children, and are more likely to have a TV set in their bedrooms. [49] Epidemiological studies of the associations between television viewing/screen time and childhood obesity have generally found a positive relationship.[50–71] Most importantly, a number of experimental studies of reducing screen time have also demonstrated that reducing screen time, as part of interventions to increase physical activity and improve diet, can promote weight loss in obese children,[72, 73] and reduce the prevalence of obesity.[74] Other randomized controlled trials have demonstrated the long-term effects of reducing screen time alone for preventing weight gain in children.[75, 76] The screen time reduction intervention for the current study is based on our successful interventions from prior studies, including using electronic screen time management devices.[75–81]

A particular emphasis of the intervention is on eliminating eating while watching television and other screen media. Children consume, on average, 17%–27% of their total daily weekday calories and 26%–32% of their total daily weekend calories while watching television.[82, 83] In our prior trials of reducing screen time, the intervention group significantly reduced the meals eaten while watching TV[75] and/or reduced energy intake.[76] These findings add to a growing body of research implicating effects of television viewing on eating behavior. Effects appear to be due to food advertising[84, 85] and distraction during eating, triggering eating independent of hunger, extending the duration of eating, and obscuring self-monitoring and/or habituation of eating/awareness of satiety cues.[86–88]

Family-Based Behavioral Counseling for Problem Solving and Maintenance of Behavior Change

The problem solving and maintenance intervention module is delivered as the last module during the three-year intervention. The content is based on methods used in the SPWCP, including instruction and practice in limit setting, modeling behavior, practice to promote enactive mastery, role-playing to overcome barriers, enlisting social support, and general problem solving to overcome environmental, social and cognitive barriers, especially those related to fast food, holidays, difficult family members, and lapses.

Primary Care Counseling Intervention—Pediatricians and other child health professionals rate childhood obesity as a top priority for treatment but identify lack of time, reimbursement, children's and parents' motivation, and support services, and limited effectiveness, confidence and self-efficacy in their own skills, as barriers to addressing the problem.[89–94] Ultimately, providers are left frustrated with few effective tools or resources to help them.[95] Our formative research and Pilot study identified a need for two types of resources: simple and quick tools and guidance to help them counsel patients and families, and community treatment programs/health promotion resources where they can refer their patients and families. The MMM treatment model is designed to address both of these needs in a way that does not add additional burden to primary care providers. First, community providers receive simple “prescription pads” to help them assess patients and identify those most appropriate for referral to the Stanford GOALS study. Second, the treatment intervention provides semi-annual Structured Encountered Forms (SEFs)/Progress Reports for each participant to guide counseling that is specifically tied to their participation and goals in the after school team sports and home interventions. SEFs are simple, brief tools found to be particularly easy and effective for integrating new skills into practice.[96] The SEFs/Progress Report are delivered to both the primary care providers and the families themselves, to take to visits with their primary care providers/clinics. This serves to further tie the providers to the ongoing community intervention and provides an opportunity to reinforce the messages and changes that are being implemented outside their clinic or office. Although the SEFs/Progress Reports are delivered twice yearly, participants and their primary care providers determine their frequency of visits. Based on the results of our formative and pilot studies, these intervention procedures were developed to function in a setting with substantial diversity and inconsistency in sources of, and access to, primary care. In addition, primary care providers and parents/guardians in both the treatment and control groups are sent the results of metabolic screening and blood pressure from the baseline and annual follow-up assessments.

Control Interventions

The choice of an appropriate control group for our study mandates a scientifically and ethically sound approach. First, we believe the evaluation of the entire MMM intervention is the research question of greatest clinical, practical and policy importance.[97] We also

believe that an untreated control condition is not warranted in children at risk for significant physiological, psychological and social morbidity. There also are practical reasons for not using an untreated control condition, which are particularly salient when working with a racially/ethnically- and socioeconomically-diverse sample of participants. In times past, the rights of ethnic minorities have occasionally been ignored and trampled upon in the pursuit of questionable scientific objectives. As a result, some groups and individuals have come to view the scientific enterprise with suspicion. Failure to attend to potential negative attitudes towards science can seriously jeopardize the ability of any research team to conduct a successful trial. Our experience convinces us that a no treatment control condition would likely deter recruitment and facilitate considerable contamination, or result in resentful demoralization or compensatory rivalry, serious threats to internal validity.[98] A 3-year waiting list control condition would be problematic for similar reasons and is not feasible. Instead, we chose to include certain “active” ingredients, such as health/nutrition education, which may influence behavior, but these ingredients differ from the conceptually relevant ingredients of concern to us.[99, 100]

Our comparison condition is an enhanced standard care/health education intervention. The enhanced standard care intervention includes notification of primary care providers about their metabolic measures and blood pressure but not SEFs/Progress Reports, and state-of-the-art information-based health education. The health education components include semi-annual home visits with a home interventionist for education about nutrition, separate monthly health education newsletters for children and for parents/guardians, and a series of quarterly evening health lectures and Family Fun Nights at neighborhood community centers or school sites. The newsletters and Family Fun Nights use standard educational materials from federal health agencies (USDA, CDC), health organizations (AHA, ACS, ADA), professional organizations (AAP, ADA) and our own research team.

This comparison intervention model worked well at keeping participants engaged for two years in a past trial.[81] Although this comparison intervention contains ingredients that may have specific effects on behaviors influencing weight gain, they are very different from the mechanisms operationalized in the experimental intervention. Finally, monetary incentives are included to enhance compliance with measurement protocols in both groups, and may have effects on behavior. The monitoring and incentive schedules employed for our experimental treatment procedures are also used to sustain participation of those assigned to our control condition. Thus, these “non-specific” and “specific” effects are equated for across the MMM intervention and active placebo control groups.

Participant Timeline, Assessments and Measures

Data collection is performed in a clinic, community or home setting at baseline, 12-, 24- and 36-months, by trained and certified, bilingual English and Spanish research assistants, *blinded* to experimental assignment. Data collectors are trained by the investigators and, for COPTR consortium common measures, by the RCU according to standardized protocols. COPTR uses a train-the-trainer model. “Master Trainers” who participate in a central training organized by the RCU are responsible for training and certifying the data collection staff at their field center. Data collectors must demonstrate high inter- and intra-rater reliability prior to data collection. All survey, interview and physical data are entered directly into laptop computers using a database designed for this project, including safeguards against illogical data entry and real-time data checking. Twice annually the Research RCU provides quality assurance tables for the common measurements and site-specific measurements for the Data and Safety Monitoring Board (DSMB). The measurement schedule was selected to satisfactorily model changes over time while minimizing potential “fatigue” in subjects resulting in poor quality participation over their three years of participation. We have chosen measures that can be feasibly, reliably and

validly assessed in clinic, community and home settings, to both maintain internal validity and also maximize generalizability. The schedule of assessments is included as Table 1.

Anthropometrics—Weight, height, waist circumference and triceps skinfolds are measured for all participating children and weight, height and waist circumference are measured for participating parents/guardians. Weight and height are measured with the participant in light clothing without shoes. Weight is measured to the nearest 0.1 kg using research precision grade, calibrated, digital scales and height is measured to the nearest 0.1 cm using a free-standing or wall mounted stadiometer. BMI (the primary outcome) is calculated as weight in kilograms divided by the square of height in meters. Waist is measured to the nearest 0.1 cm just above the uppermost lateral border of the right ilium using a Gulick II tape measure, model 67020. The triceps skinfold is measured using a Lange skinfold caliper in the midline of the posterior aspect (back) of the arm, over the triceps muscle, at a point midway between the lateral projection of the acromion process of the scapula (shoulder blade) and the inferior margin (bottom) of the olecranon process of the ulna (elbow). Triceps skinfolds are measured to the nearest 0.1 mm. For quality control, ten percent (10%) of the anthropometric measurements are measured by two different data collectors. BMI trajectory is the primary outcome measure. Trajectories of waist circumference, triceps skinfold thickness, BMI-z score, waist-to-height ratio and calculated percent body fat are included as secondary measures of body composition.

Dietary Assessment—Dietary intakes are measured from children using 24-hour recalls that are conducted on three randomly selected nonconsecutive days, including two weekdays and one weekend day using the Minnesota Nutrition Data System for Research (NDS-R) software (University of Minnesota Nutrition Coordinating Center). The first dietary recall is collected face-to-face and the second and third are collected over the telephone, in English or Spanish. The Food Amounts Booklet is used by the respondent to assist in identifying portion sizes. To capture variability of food supplies in the home, all three recalls do not occur within a seven-day period and the third recall is collected more than one week after the first recall. All three recalls are collected within 30 days. Full quality assurance checks are conducted on all recalls according to COPTR protocols.

Physical Activity—Accelerometry data are collected on all index children using the Actigraph GT3X+ monitor. Participants are instructed to wear the monitor on the right hip for seven complete days, including while sleeping, except during water activity (e.g., bathing, swimming, showering). The ActiGraph GT3X+ assesses acceleration in three individual orthogonal planes and is set to a frequency of 40-Hertz. Valid wear time minimums are 4 days (3 weekdays and 1 weekend day) of at least 6 hours of activity between 5:00am and 11:59pm.

Blood Pressure—An automated blood pressure measurement device (Carescape v100, GE Healthcare) is used to measure resting systolic and diastolic blood pressure and pulse. The participant's arm circumference is measured to ensure the correct cuff size is used. Participants sit quietly for 4–5 minutes before the first measurement is taken, and seated, resting blood pressure and pulse are measured three times. All readings are recorded to the nearest integer. The average of the second and third measurements is used in analysis.

Blood Measures—Fasting blood samples are collected by venipuncture from children at each assessment by a trained phlebotomist. All blood samples are analyzed by the Northwest Lipid Metabolism and Diabetes Research Laboratories (NWRL, Seattle, WA). The measures include: hemoglobin A1c (HbA1c), glucose, insulin, total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides, high-sensitivity c-reactive protein (hs-CRP), and alanine

aminotransferase (ALT). Children are instructed to fast for at least 8 hours prior to phlebotomy.

HbA1c levels are determined by an NGSP-certified auto-analyzer (G-8 Tosoh, Biosciences, Inc.) using non-porous ion exchange high performance chromatography to achieve rapid and precise separation of stable HbA1c from other hemoglobin fractions. Glucose is determined enzymatically on a Roche Hitachi Modular P chemistry autoanalyzer. Insulin is determined by a two site immuno-enzymometric assay performed using Tosoh 2000 auto-analyzer. The insulin assay is calibrated to WHO IRP 66/304 standard. Measurements of total cholesterol and triglycerides are performed enzymatically on the Roche Modular P autoanalyzer using methods standardized to the Centers for Disease Control and Prevention Reference Methods. Determination of HDL-cholesterol is performed after precipitation of apo B-containing particles by dextran sulfate Mg²⁺ (ref). LDL-cholesterol is calculated by the Friedewald equation. If triglycerides are >400 mg/dl then LDL-cholesterol is determined by a complete lipoprotein separation by ultracentrifugation which allows quantitation of the individual lipoprotein classes is performed using the Lipid Research Clinics Beta Quantification procedure. As an alternative in case of low sample volume, LDL-cholesterol is determined by a homogeneous enzymatic method using Roche LDL-C Plus 2nd Generation reagent on a Roche Modular P autoanalyzer. Levels of C-reactive protein (CRP) in plasma are measured immunochemically on a nephelometer autoanalyzer (BNII). The Alanine Aminotransferase (ALT) assay is performed on a Roche Double Modular P Analytics automated analyzer.

Surveys and interviews—Survey-measured demographic and household characteristics, secondary outcomes, and potential mediators and moderators measures are obtained from interviews in English of children and from interviews or self-administered surveys in English or Spanish from parents/guardians.

Demographic and household characteristics include: child's date of birth; child's sex; child's and parent's/guardian's ethnicity and race; child's and parent's/guardian's country of birth; years in the U.S.; parent's/guardian's employment and marital status; household configuration, including gender, age and relationship; frequency of speaking English at home; household participation in public assistance programs; parent's/guardian's education level; child care and after school care; household income; child's health insurance; receipt of free or reduce school meals; food security; and perceptions of child's and parent's/guardian's weight status; and home media environment.

Screen time is assessed during the baseline interview using self-report based on instruments with high test-retest reliability ($r = 0.94$)[61], accuracy compared to direct videotaped observation,[78] and sensitivity to change in response to prior interventions.[28, 75] Children first perform time-estimating exercises, to try to improve their time estimates, before reporting their minutes of screen time, separately, by screen type, before school and after school, "yesterday" and "last Saturday." The instrument includes newer types of screen media. The same instrument is used to assess other sedentary behaviors. *Eating Meals with the Television* is assessed by children's reports of their past week's frequencies of eating breakfast, lunch, dinner and snacks in a room with the television turned on, using previously validated items,[78] proved sensitive to change,[28, 75] *Household Television Use* is reported by parents/guardians using Medrich's constant TV households measure.[75, 101]

Sexual maturation is self-assessed using drawings and descriptions of the standard pubertal stages, [102] with demonstrated past accuracy[102–105] and clinical validity.[106–111] Girls also report their age at menarche. *Overconcern with weight and shape* is assessed using the McKnight Eating Disorders Risk Factor Survey.[112] *Depressive Symptoms* are assessed using the 10-item short form of the Children's Depression Inventory (CDI).[113]

School Performance is self-reported as “most recent school grades” on a 9-point scale ranging from “mostly A’s to mostly F’s.”[28]

Child transportation to School, child after-school physical activity programs and sports teams, child meals eaten outside the home and at school, and child’s unsupervised time for typical weekdays and weekend days are self-reported.

Parents/guardians complete the abbreviated Children’s Sleep Habits Questionnaire (CSHQ) to report *children’s sleep habits* and *Parent/guardian physical activity* is assessed using questions on frequency and intensity developed and validated by Washburn, et al.[114, 115]

Both children and parents/guardians complete assessments of *implicit theories of body weight, general habit formation, sports ability and eating habits* to measure tendencies toward a “growth mindset” versus a “fixed mindset” regarding the possibility of change, based on measures of implicit theories of intelligence among adolescents.[21, 22]

Process Measures—We assess the success of intervention implementation to describe intervention delivery and exposure and explain potential variations in individual responses. This includes attendance and participation rates for each element of the experimental MMM intervention, observations of team sports (direct observation/checklists) and home visits (checklists) to estimate the fidelity of intervention delivery, home observations of the extent of adoption and maintenance of changes in dishware, and installation and use of electronic TV time managers, achievement of goals, and use of SEFs/progress reports. Only intervention staff (unblinded) collect implementation data, to maintain data collector blinding.

Participant Safety

Adverse events are assessed systematically at each data collection visit with direct queries for all injuries, illnesses or other medical problems requiring a visit to a medical care provider and related to participation in the study. Serious Adverse Events (SAEs) are specifically monitored. Adverse events are also recorded and evaluated when they come to the attention of study staff between the data collection visits.

Clinical Monitoring—As an additional safety feature, we also screen participants for preexisting or incident conditions that may pose a risk to their health, but are not expected to result from participation in the study. These include poor stature growth, hypertension, dyslipidemias, impaired fasting glucose, pre-diabetes and diabetes mellitus, and excessive weight loss. Results are explained to parents/guardians and they are referred to their primary care medical professional for further evaluation.

An external, independent *Data and Safety Monitoring Board* has been appointed by NIH to review study protocols and provide twice-yearly formal reviews and continuous oversight of recruitment and study progress, data quality and completeness, and participant safety.

Study Design, Statistical Considerations and Analysis Plan

Stanford GOALS is a two-arm, parallel group, randomized controlled trial. The primary hypothesis is: compared to enhanced standard care/health education controls, children randomized to the MMM intervention will have significantly attenuated BMI trajectories.

The primary objective of the proposed intervention is to reduce BMI to a degree that has clinical and/or public health and policy significance. We are assessing results by comparing changes in the treatment and control groups over the course of the entire 36-month study, using an analytic strategy that takes full advantage of the prospective nature of the data

collected. BMI is assessed at baseline, and at approximately 12-, 24- and 36-months after baseline. Our primary outcome is a derived measure of change in BMI values, estimated by computing a slope for each child by regressing BMI on time, where each child may have up to 4 BMI measurements. For this analysis we assume BMI behaves linearly over time. Children with at least 2 measurements have a corresponding derived slope. Children with only one BMI measurement at baseline, however, have missing outcome values (slopes), which will be imputed via multiple imputation techniques. Multiple imputation allows inclusion of all children randomized to each experimental condition, to perform an intent-to-treat analysis. One important, practical advantage of this approach is that it incorporates BMI measurements obtained at varying intervals. While we intend to assess follow-up BMI at 12, 24 and 36 months after baseline, experience suggests this does not always occur. In contrast to other possible functional forms of the outcome, the proposed approach allows and accounts for deviation from the ideal measurement schedule without unrealistic assumptions about timing that may introduce substantial additional error into the outcome.

Primary Analysis—ANCOVA will be applied for the primary analysis. The proposed model can be expressed as:

$$\text{BMI Slope} = \text{beta0} + \text{beta1 treatment} + \text{beta2 baseline BMI (centered by average BMI)} \\ + \text{beta3 baseline BMI (centered by average BMI)} \times \text{treatment} + \text{epsilon},$$

where epsilon is the random error term assumed to follow a normal distribution.

We will test the primary hypothesis corresponding to overall treatment effect. All tests will be two-sided and conducted at the 0.05 level of significance.

The Treatment $\times$ baseline BMI interaction is included as a covariate in the primary analysis of treatment effects because we have occasionally found evidence of greater intervention effects among participants with relatively higher or lower BMI at baseline.[28, 29, 75] We therefore include the baseline BMI and Treatment $\times$ baseline BMI interaction effect as a term in the model to obtain an unbiased estimate of treatment effects, as has been recommended in the statistical literature.[116–119] To ignore a meaningful interaction in the model has three effects: (1) Part of the interaction effect (in non-orthogonal designs) is remapped into the main effects, thus producing a biased estimate of the main effect of treatment; (2) Part of the interaction effect (whether or not the design is orthogonal) is remapped into the error sum of squares, with a possible substantial reduction of power; and (3) Since the residual variance used in estimating effect sizes is inflated, it is quite possible that the effect size of treatment would be attenuated, thus misleading consideration of the clinical significance of the treatment. If our expectation is wrong, and there is no non-zero Treatment $\times$ baseline interaction, then this analysis still results in an unbiased estimate of the main effect of Treatment, and we only lose one degree of freedom. Thus the risks of ignoring a strong interaction generally far outweigh the risks of including an unnecessary interaction. It insures that we will have an unbiased estimate of the main effect of treatment and potentially increases our power.

Detectable Difference, Sample Size, and Power—For clinical or public health significance, we have estimated the minimum acceptable difference between the MMM intervention compared to the enhanced standard care control condition is an effect size (Cohen's d) = 0.4, the equivalent of about 27% non-overlap of two normal distributions, or 50% of one group's distribution being greater than about 66% of the other group's distribution,[120] a Number Needed to Treat for one additional success (NNT) of 4.49, a Standardized Risk Difference (SRD) of .223, and an Area Under the ROC Curve (AUC) of .611.[121, 122] Examples of scenarios that corresponds to a Cohen's d of 0.4 include: an average decrease in MMM intervention children of 0.1 BMI units per year while controls

increase at a rate of 0.4 BMI units per year with a standard deviation of BMI of 1.2; MMM intervention children decrease by 0.4 BMI units per year while controls have no change in BMI per year with a standard deviation of 1.0; both groups increase in BMI each year where MMM intervention children increase by 0.2 BMI units per year and controls increase by 0.6 BMI units per year with a standard deviation of 1.0.

For a two-tailed 5% alpha level test, the planned sample size of 120 children per group would provide approximately 90% power to detect intervention effects of that magnitude or greater.[120, 123] Based on simulation studies (1000 simulations per scenario) we also have assessed power for detecting meaningful treatment effects in the presence of an interaction between treatment and baseline BMI. The results demonstrated excellent power (83% to 95%) for detecting clinically relevant differences between treatment arms.

Analysis for Possible Moderators and Mediators of Treatment Effects—

Variables from several domains (i.e. demographic, socio-cultural, psychological, biological) are used in analyses to shed light on the potential moderators and mediators of treatment response. We use the MacArthur Network approach.[124–126] Moderators are pre-randomization factors useful to allow appropriate targeting of treatment, as well as in research to identify appropriate inclusion/exclusion criteria in future studies, or factors on which a study should be stratified to amplify power. A mediator is a post-randomization event or change during treatment that is correlated with treatment (thus possibly an outcome of treatment). Mediators are useful in giving clues to what direction might be most profitable in the search for causal chains. All baseline (pre-randomization) measures will be tested as potential moderators and all post-randomization changes will be tested as potential mediators. Moderator and mediator analyses are necessarily exploratory, hypothesis-generative secondary analyses.

Secondary Hypotheses and Additional Analysis—In addition to the primary analysis, we will pursue further descriptive analysis of the primary outcome, to better characterize the clinical significance of the results. In this analysis we examine treatment effects based upon thresholds of BMI. Changes in waist circumference and triceps skinfold thickness are also assessed to further characterize changes in adiposity resulting from the intervention. Effects of the MMM intervention are also assessed on secondary outcomes. We use a similar analysis approach as used with the primary analysis to examine the effects of the intervention on all secondary outcome measures.

Additional secondary analyses include: descriptive analyses to assess distributional assumptions, analyses to assess the success of randomization/description of population/ effect of attrition, correlate/risk factor studies, process/delivery of intervention studies/ success of intervention studies.

Sensitivity Analyses—To address whether trajectories of BMI over time (that may be non-linear) may differ between treatment arms, we will perform a secondary analysis through use of a mixed effects linear regression model that includes a child-specific random intercept. In this model we will make use of all the individual BMI measurements within a child. We allow BMI to behave non-linearly over time by fitting and evaluating three possible models: one where the four time points are represented by three indicator variables, one where a linear and quadratic term are included, and one where a linear, quadratic, and cubic term are included. Model selection among these three choices will be done using the likelihood ratio test. Product terms between time and treatment group will be included in each model, as the parameters representing these interaction terms are of interest and represent the differential trajectories of BMI over time across treatment arms. For example the first model can be written as:

$$\text{BMI}_{ij} = \text{beta0} + \text{gamma}_i + \text{beta1 treatment}_i + \text{beta2 time2}_{ij} + \text{beta3 time3}_{ij} + \text{beta4 time4}_{ij} + \text{beta5 treatment}_i \times \text{time2}_{ij} + \text{beta6 treatment}_i \times \text{time3}_{ij} + \text{beta7 treatment}_i \times \text{time4}_{ij} + \text{epsilon}_{ij}$$

where BMI_{ij} is the BMI measurement for the i^{th} child at the j^{th} visit, where $j=1,2,3$, or 4 , gamma_i is the child-specific random intercept term assumed to follow a normal distribution, epsilon_{ij} is the random error term corresponding to the i^{th} child at the j^{th} visit. Such a model allows flexibility in how BMI behaves over time. Our hypothesis of interest is whether the trajectories differ. This involves testing whether $\text{beta5}=\text{beta6}=\text{beta7}=0$

To assess the sensitivity of the primary findings to assumptions of independent errors across participants, we will repeat the primary analysis applying a mixed effects model to assess whether treatment impacts BMI change after accounting for potential clustering of responses. Appropriate clusters will be defined by examining patterns of after school community center attendance and other intervention features such as home intervention staff and primary care professional/clinic. We do not expect this analysis to be different from the primary analysis.

To assess the sensitivity of the primary findings to assumptions of missingness, We will explore active and passive approaches and, in addition to considering multiple models under the MAR assumption, we will also consider MI models under the NMAR missing data mechanism. Varying the imputation methods and the assumptions about the missing data mechanisms allows us to gain insight into the robustness of our findings across assumptions.

DISCUSSION

Stanford GOALS is a large-scale, community-based randomized controlled trial of a multi-component, multi-level, multi-setting approach to treating overweight and obese children. The study includes many attributes of both an *efficacy trial* and an *effectiveness trial*. The intervention model was designed to overcome the major barriers to children's participation and adherence in standard treatment models. The novel treatment model is: *innovative*, drawn from past successful approaches, attempting to avoid the pitfalls of past failures, and taking advantage of recent advances in knowledge of biological and physiological, psychological, social, and environmental influences on eating, activity, sedentary behavior, and energy balance, *multi-component*, targeting eating behaviors, physical activity, inactivity, and screen time, in multiple ways and in multiple contexts, and *multi-level*, targeting individual children, families, groups, primary care providers, and community youth-serving organizations, in *multiple settings*, including primary care clinics, community centers, and homes. This MMM approach is also potentially generalizable to real world communities and populations, by using infrastructure and resources that already exist in many communities, and particularly relevant to an ethnically-and socioeconomically-diverse population at increased risk for obesity and obesity-related morbidity and mortality.

The MMM intervention was developed through community based participatory research, involving collaborations with community leaders, health professionals, our partner youth-serving community organizations, and overweight children and their families. Childhood obesity and risk of future diabetes were identified as the highest priority health concerns in these communities. These groups requested better linkages between medical providers and community programs/resources, direct help for parents/families to improve children's behaviors in the home, and greater availability of community-based programs to provide a safe place for children after school and to enhance children's health, social development and academic achievement. As a result, the MMM intervention includes: a theory-based, community-based, after school team sports program designed specifically for overweight and obese children; a home-based family intervention to alter the home food/eating

environment, reduce screen time, and promote self-regulatory skills for eating and activity behavior change; and a primary care provider behavioral counseling intervention linked to the community and home interventions.

Most of the MMM intervention components have individually demonstrated the potential to reduce weight gain or produce weight loss on their own. However, the MMM intervention was conceptualized as more than the sum of exposures to individual intervention activities. Rather, to produce greater magnitude and more durable effects on individual and group BMI trajectories, the MMM intervention is conceptualized as a collection of mutually reinforcing opportunities across multiple components, multiple levels and multiple settings (MMM) to shift energy balance in a negative direction (energy intake less than energy expenditure). The multiple components aim to decrease energy intake, increase physical activity and reduce sedentary and screen time behaviors – each individually capable of producing effects on energy balance and BMI. As a result, the MMM model (1) increases the probabilities of being exposed to an intervention element that prompts a behavior change, (2) increases opportunities for reinforcing messages and skills across different intervention elements and, we propose, (3) increases opportunities for synergies that substantially magnifies the resulting effects, in the intervention group as a whole, beyond what could be produced by summing single-component, single-level or single-setting interventions.

For example, reducing dietary energy intake is promoted through the home-based environmental interventions by reducing dishware sizes, eliminating eating with screens, and behavioral counseling for diet changes, at the team sports program through the snack policies, displacement of opportunities for snacking at home afterschool, and social norms promoted during after school team sports, and in the primary care counseling intervention through positive reinforcement of specific dietary changes. Physical activity is also promoted in the after-school team sports intervention, the home-based behavioral intervention to increase physical activity, and the primary care counseling intervention. Reducing sedentary behavior and screen time is promoted through the home-based behavioral and environmental interventions to eliminate eating with screens and reduce overall screen time, the after school team sports program that displaces afternoon discretionary time, and reinforced through primary care counseling. Therefore, an individual participant may be exposed to multiple elements, each capable of shifting his or her energy balance, serially and/or simultaneously, as part of any one or more intervention elements.

Another novel enhancement to the intervention design is applying recent findings from neuroscience, behavioral economics and social, developmental, and cognitive psychology, to increase motivation, performance, and perceived self-efficacy. We particularly focused on strategies found to raise educational achievement among underserved and/or stigmatized youth. These strategies are used to frame the intervention content and delivery both within and across individual intervention elements. For example, a unifying implicit theory/growth mindset framing[21, 22] appears throughout all of the home-based modules and also in the after school team sports intervention components. This approach provides children with coping mechanisms to overcome perceived barriers or failures and turns set backs into opportunities to promote behavior change. Similarly, results from research about how to design intrinsically motivating educational interventions greatly influenced the design and planned delivery of intervention components consistently across the study.[20] These innovations are expected to further magnify the effects of the intervention components themselves – resulting in a greater *effective dose*, to produce greater effects from all exposures.

Finally, Stanford GOALS is able to benefit from a broad, interdisciplinary team of investigators, strong collaborations with community partners and policymakers to translate

the interventions into real world practice, a supportive and entrepreneurial research environment, the opportunity to pilot test most of the procedures, measures and interventions during Phase 1, and the opportunities for real-time collaborations with the other investigative teams participating in the COPTR consortium.

The primary research question is whether a 3-year, multi-component, multi-level, multisetting community-based intervention to treat overweight and obese children will reduce BMI compared to an enhanced standard care/health education active placebo control intervention? We hypothesize that compared to controls, children randomized to MMM intervention will have a significantly attenuated body mass index trajectory. Both the MMM intervention and the health education control intervention last for 36 months, and all participants complete assessments at baseline, 12 months, 24 months and 36 months. The primary outcome measure is BMI trajectory over the entire 3-year study. If successful, the MMM intervention would represent a potentially generalizable new model for shifting the treatment of overweight and obese children from the medical care setting to the community.

Acknowledgments

We thank Sally McCarthy, Connie Watanabe, Susan Bryson, MS, Michelle Fujimoto, RD, Kelly I. Burke, Marite Carrasco Valdez, Ernesto T. Ceja, Jesenia Contreras, Tania Davila, Maria DeGuzman, Rosa Gill, Esmeralda Gomez, Flor Larios, Karla L. Martinez-Tavera, Natalie M. Masis, Christin New, Antonio Nunez, Marie E. Sanjines, Jessica R. Whalen, Molly Wolfes, MPH, Mark Lepper, PhD, Paul Wise, MD, Jay Bhattacharya, MD, PhD, and Greer Murphy, MD, the Stanford GOALS community advisory board and community partner organizations, the Boys and Girls Club of the Peninsula, The Police Activities League of Redwood City, CA, and the City of Redwood City, CA Parks, Recreation, and Community Services Department, and the participating children and families who participated in the Stanford GOALS formative and pilot studies, for their contributions to the design of the Stanford GOALS trial. We also thank the rest of the COPTR consortium and Data and Safety Monitoring Board/Protocol Review Committee for their valuable and ongoing input.

Funding Source: Research reported in this publication was supported by the National Heart, Lung, and Blood Institute of the National Institutes of Health under Award Number U01HL103629. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The National Institutes of Health is represented on the Steering Committee and subcommittees of the Childhood Obesity Prevention and Treatment Research (COPTR) consortium that participated in the decision to submit manuscripts describing the design of the COPTR trials for publication.

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Table 1

Schedule of assessments

	baseline	12-mos	24-mos	36-mos
Child Anthropometrics 10% duplicate measurement (Quality Control)				
Height	X	X	X	X
Weight	X	X	X	X
Waist Circumference	X	X	X	X
Triceps Skinfold Thickness	X	X	X	X
Blood Pressure and Resting Heart Rate	X	X	X	X
Child Physical Activity				
Activity Monitoring (Accelerometers) – 7 days	X	X	X	X
Child Diet				
24-hour Dietary Recalls (3 days, 1 st in person, 2 nd & 3 rd over phone)	X	X	X	X
Child Survey				
Ethnicity/Race (of the child by parent) (2Qs)	X			
Transportation (4 Qs) How many days per week do you usually walk to school? How many days per week do you usually ride a bike, ride a non-motorized scooter, skate, rollerblade or skateboard to school? How many days per week do you usually walk home after school? How many days per week do you usually ride a bike, ride a non-motorized scooter, skate, rollerblade or skateboard home after school?	X	X	X	X
Eating with acreens / homework (4Qs) Breakfast, Dinner, Snacks while: Watching TV, using computer, game player or cell phone Snack while doing homework	X	X	X	X
Self-reported wake-up/fall asleep time (Sat, Sun, Yesterday/last Thursday) (6Qs)	X	X	X	X
Time spent in sedentary behaviors (36Qs) Sedentary behaviors include: TV, Videotape/DVD, video games, computer, portable media device, cell phone use. Six behaviors for before noon and after noon on both Saturday and Sunday and weekday (Yesterday/Last Thursday).	X	X	X	X
Hunger after eating / 2nd, 3rd helpings (3Qs): How often do you still feel hungry after finishing dinner? Dinner - How often do you take 2nd servings? 3rd servings?	X	X	X	X
McKnight Over-Concern with Body Size & Shape – (5 Qs) Worried about fat on your body, felt fat, thought about wanting to be thinner, worried about 2 lb gain, weight made a difference in how you feel about yourself.	X	X	X	X
Children's Depression Index, short form (Depressive Symptoms) – (10 Qs)	X	X	X	X
Implicit Theory questions regarding Body Weight, Sports Ability, and Eating Habits (12 Qs)	X	X	X	X
Compared to other things in your life, how important is it for you to be an athlete, someone who plays sports? (1Q)	X	X	X	X
Self-report pubertal/sexual maturation (2Qs per gender)	X	X	X	X
Parent/Guardian-Child Survey Completed together with child or parent/guardian fills out about child.				
Parent relationship to child, parent DOB, Survey Date	X	X	X	X

	baseline	12-mos	24-mos	36-mos
Child Date of Birth	X	X	X	X
What Country child was born in?	X			
Child covered by health insurance plan? Type of Plan	X	X	X	X
Child's sex	X	X	X	X
Menstrual period? Yes/no (girls only) Calculated age of Menarche - Month/Year first period	X	X	X	X
Child's most recent grades in school (1Q)	X	X	X	X
Does this child have another parent/caregiver living in same household? Yes/No, If Yes: Country born, Years living in us, Employment status, Education, Physical activity	X			
Child's participation in afterschool physical activity/sports program, months in past year (1Q) Participation on a sports team, months in past year (1Q)	X	X	X	X
Home TV/Media Environment (24Qs) Number of working TVs (1Q) Number of TVs hooked to cable or satellite; DVD or VCR; TIVO or DVR (3Qs) Working TV in room where child sleeps (1Q) Computer in home (1Q) How many working desktops in your home (1Q) Does child use desktop computer in home (1Q) Desktop computer in the room where child sleeps (1Q) How many laptops computers in your home (1Q) Does child use laptop computer in home (1Q) Laptop computer allowed in the room where child sleeps (1Q) sleeps (1Q) Internet access in your home (1Q) Does child use internet in your home (1Q) WIFI internet access in your home (1Q) Does child use WIFI in your home (1Q) Video game players in home (1Q) Number of video game players connected to TV (1Q) Number of handheld video game players (1Q) Video game player in room where child sleeps (1Q) Number of iPod touch, iPad or tablet computers in home (1Q) Number of iPods or MP3 players in home (1Q) Does child personally own a mobile phone (no, smart phone, other than a smart phone) (1Q) Does your child use a mobile phone that is not personally his or hers (no, smart phone, other than a smart phone) (1Q)	X	X	X	X
Sleep Habits Questionnaire – (17Qs)	X	X	X	X
Child's Unsupervised time at home on typical weekday and both Saturday and Sunday (3Qs)	X	X	X	X
Childcare arrangements – in home, other's home, childcare center/after school program (3Qs)	X	X	X	X
Life Events (10Qs)	X	X	X	X
Household Membership (up to 8 adults and 8 children): Sex, Relationship to child, Age Overweight, normal weight, underweight	X			
Weight Status (1Q) How you would classify this child's current weight? (5-pt scale)	X	Y	Y	Y
Parent/Guardian Household Survey				
Parent/guardian DOB	X			
Parent/guardian marital status	X	X	X	X
Home ownership	X			
How often English is spoken at home (1Q)	X			

	baseline	12-mos	24-mos	36-mos
Country Born Years lived in US respondent completed	X			
Employment Status respondent completed	X	X	X	X
Parent/guardian education levels (1Q): Highest degree or level of school respondent completed	X			
Government Assistance (2Qs) Food Stamps/Snap Unemployment, Social Security or Disability benefits	X	X	X	X
Total household income before taxes	X	X	X	X
Does any child receive free/reduced price breakfast or school lunch?	X	X	X	X
Food Security (5Q) Food lasting Afford to eat balanced meals Cut size of meals or skip meals not enough money How often did this happen? Eat less than you felt –no money to buy food	X	X	X	X
Constant TV Household: How often TV on in home-typical week (morning, afternoon, dinner, evening) (4Qs)	X	X	X	X
Implicit Theory Qs regarding body weight, sports ability and eating habits (12Qs)	X	X	X	X
Physical activity	X	X	X	X
Health Literacy	X	X	X	X
Parent/Guardian Anthropometrics 10% duplicate measurement (Quality Control)				
If Female: Are you pregnant?	X	X	X	X
Adult Ethnicity Adult Race	X			
Parent Weight	X	X	X	X
Parent Height	X	X	X	X
Waist Circumference (Iliac Crest)	X	X	X	X
Child Biomedical Measures				
Fasting (8 hours) Total Cholesterol, LDL-C, HDL-C, VLDL, Triglyceride, Glucose, Insulin, Hemoglobin A1c, Alanine Aminotransferase (ALT), High Sensitivity C-Reactive Protein	X	X	X	X
Adverse Events				
Child adverse events - asked of primary parent/guardian in primary household about child		X	X	X
Parent/guardian adverse events (asked of parent/guardian about themselves)		X	X	X
Adverse events between data collection visits		When it occurs	When it occurs	When it occurs