TABLE OF CONTENTS

* Asterisk indicates items that are common across sites

1. EXECUTIVE SUMMARY

Increases in sedentary lifestyle and high calorie food consumption, among other factors, have contributed to epidemic levels of childhood obesity in the U.S. Children who are overweight during the preschool period are more likely to become overweight adolescents and obese adults. Food preferences and activity habits set in early childhood can profoundly influence lifelong trajectories for Body Mass Index (BMI) and health. Specifically, rapid BMI gain in early childhood has been established to affect adulthood mortality and morbidity. Unfortunately, the longer such unhealthy patterns are in place, the more difficult it can be to reverse them. Therefore, healthy lifestyle interventions targeted at children as early as preschool have enormous potential to affect lifelong health. Furthermore, nutrition and activity patterns are determined not only at the child level, but within the family and the community. Multi-level interventions are necessary to create and maintain health-promoting conditions. Building on the success of an existing partnership between Vanderbilt Pediatrics and Metro Parks and Recreation in Nashville, TN, the team in this proposal will conduct and evaluate an intervention intended to prevent obesity in preschoolers in an approach that affects multiple levels of risk and is both family-based and community-centered.

2. SPECIFIC AIMS AND OBJECTIVES FOR MAIN TRIAL

This research includes one primary and five secondary specific aims.

Primary Aim

Aim 1: Evaluate the efficacy of a multi-level intervention, addressing nutrition and physical activity, at public community recreation centers with high-risk parent-preschool child (ages 3-5) dyads to promote pediatric obesity prevention.

Hypothesis 1: The BMI trajectories of children in the treatment group will accelerate at a slower rate than those in the control group over time.

Secondary Aims

Aim 2: Evaluate the effect of the intervention on children's activity levels and dietary behaviors

Hypothesis 2: Either or both activity level and adherence to age-specific USDA nutrition recommendations will mediate the relationship between the intervention and child BMI trajectories. Specifically, relative to children in the control condition, children in the intervention condition will

2.1 Have lower sedentary activity levels (as measured by actigraphy data) after the intensive phase of the intervention (T2) and these lower levels will be associated with slower BMI growth rates and/or

2.2 Have better adherence to age-specific USDA nutrition recommendations, (e.g., age-appropriate total calories increased, fruits and vegetables, decreased sugar sweetened beverages [measured via diet recall data]), after the intensive phase (T2) and this better adherence will be associated with slower BMI growth rates.

Aim 3: Evaluate the effect of parents' physical activity levels and dietary behaviors on children's levels of the same.

Hypothesis 3: Parents' activity level and/or adherence to age-specific USDA nutrition recommendations will mediate the relationship between child levels of the same, the

intervention, and child BMI trajectories. Specifically, parents who have significantly lower sedentary activity levels (compared to baseline) after treatment and/or who have better adherence to USDA nutrition recommendations (age-appropriate total calories increased fruits and vegetables, decreased sugar sweetened beverages [measured via diet recall data]) will be more likely than parents who have higher sedentary activity levels or who do not adhere to USDA nutrition recommendations to have children who will show
3.1: Decreased sedentary activity levels post-treatment and
3.2: Better adherence to USDA nutrition recommendations (as measured in 2.2, above).

Aim 4: Explore the potential for developing new social networks and their effect on child nutrition and physical activity.
Hypothesis 4: Parents in the treatment group will develop new social networks and the strength of those social networks will be positively associated with reduced sedentary activity levels and improved dietary behaviors (measured as indicated above) among both parents and children. Specifically, the type (e.g., network of discussion partners where ties are weighted by how close they feel to each other) and total number of social networks will mediate the effect of the intervention on child and parent nutrition and physical activity level.

Aim 5: Evaluate the moderating relationship between genetic risk factors and child BMI trajectories over the course of the study.
Hypothesis 5: Higher levels of child genetic susceptibility to obesity (i.e., a higher genetic risk score(Kathiresan, Voight et al. 2009)) will be significantly associated with heavier-for-age BMI at baseline, and this susceptibility will moderate children's growth in BMI over time.

Aim 6: Assess the degree to which implementation of the GROW program encourages additional lifestyle programming for preschool children and their parents in the Metro Community Centers.
Hypothesis 6: The two Metro Community centers participating in the GROW trial will implement a higher number of activity or nutrition programs for families (as defined by the centers) with young children at the end of the study compared to the number they implemented at baseline, and they will also implement a higher number after the study compared to the number implemented by non-participating Metro Community Centers.

3. BACKGROUND AND RATIONALE

Early childhood is a critical time for obesity prevention.
Changes in physical activity and diet, among many other factors, have contributed to epidemic levels of childhood obesity in the U.S.(Zizza, Siega-Riz et al. 2001; Brantley, Myers et al. 2005; Carnell and Wardle 2008; Webber, Hill et al. 2008; Witkos, Uttaburanont et al. 2008) Obesity rates have tripled among children and adolescents over the past thirty years,(Ogden, Flegal et al. 2002; Ogden, Fryar et al. 2004) with Latino and African-American populations at disproportionately higher risk.(Suminski, Poston et al. 1999; Ogden, Fryar et al. 2004; Webber, Hill et al. 2008) At the current rates of childhood obesity, 30 to 40% of today's children may eventually develop type 2 diabetes and reduce their life expectancy.(Olshansky, Passaro et al. 2005) Nader et al demonstrated that children who were ever overweight during the preschool period were five times as likely to be overweight adolescents.(Nader, O'Brien et al. 2006) And the chances of overweight increase as the child ages. In that same study, 80% of school-age children who were ever overweight during

this period went on to become overweight adolescents. The significance of mounting risk for sustained overweight and its consequences cannot be overstated. In the Harvard Growth Study, overweight adolescents as adults had a two-fold increase in all-cause mortality and an increased morbidity due to cardiovascular disease.(Must, Jacques et al. 1992) It is not merely overweight/obesity in childhood that poses the risk for later increased mortality and morbidity as an adult, the slope of early weight gain is a potent predictor.(Barker, Osmond et al. 2005; Leunissen, Kerkhof et al. 2009) For example, Leunisson et al showed that rapid weight gain without concomitant growth in height during the first three months of infancy is linked with reduced insulin sensitivity in early adulthood. Furthermore, Barker et al demonstrated that the risk of adult coronary events was more strongly related to the rapid childhood gain in BMI than to BMI attained at any particular age.(Barker, Osmond et al. 2005) Consequently, this proposal will address prevention of rapid BMI gain during early childhood, fostering normal growth for those children who have a normal BMI (>50% and <85%) and improving BMI trajectories for those children who already have a BMI ≥ 85% <95% at ages 3-5 years. There is little evidence documenting successful behavioral interventions to *prevent* early childhood obesity (Summerbell, Waters et al. 2005; Kropski, Keckley et al. 2008; Birch 2009) and even less evidence concerning which factors may be crucial to success. Consequently, the Institute of Medicine (IOM)(Small, Jones-Gotman et al. 2003; Institute of Medicine 2011; Institute of Medicine 2012; Institute of Medicine. Committee on Progress in Preventing Childhood Obesity September 2006) and the *Strategic Plan for NIH Obesity Research*(Levine, Kotz et al. 2003; U.S. Department of Health and Human Services 2004) call for a community-engaged, culturally-relevant, family-centered approach to obesity prevention that can be sustainable.

Family plays a crucial role in pediatric obesity prevention.
Family influences normative expectations of how and what to eat as well as how often to be physically active.(Epstein, Wing et al. 1987; Crockett, Mullis et al. 1988) Moreover, families control the home environment that shapes children's early childhood choices, establishing behavioral habits.(Strauss and Knight 1999) For example, in the Viva La Familia study, random 24-hour dietary recalls of almost 1000 children showed that 67% of children's meals occurred at home and that most of these meals were high density, low nutrient foods, consistent with their parents' choices.(Wilson, Adolph et al. 2009) Parental involvement in programs to reduce overweight in children has been moderately successful, and is considered an important component of weight loss programs for children.(Epstein, Valoski et al. 1994; Epstein, Myers et al. 1998) Many of these programs focused on obesity treatment, however, the same association appears to exist for prevention efforts as reported in a meta-analyses of randomized trials to prevent childhood obesity.(Kamath, Vickers et al. 2008; Hesketh and Campbell 2010) Parents' role appears to be as both models to their children and as active participants in creating a healthy environment that encourages healthy lifestyles. Children are nearly six times more likely to be physically active if their parents are physically active.(Perusse, Tremblay et al. 1989)

One important component of parental involvement is the use of behavior change methods such as parents and children setting clear goals for nutrition and activity and self-monitoring of caloric intake and activity.(Barkeling, Ekman et al. 1992; Epstein, Valoski et al. 1994) Epstein's report of 10-year treatment outcomes for obese children indicates long-term success among families who set clear goals.(Epstein, Valoski et al. 1994) In a 2006 position paper, the American Dietetic Association (ADA)(Jansen, Theunissen et al. 2003; 2006)

recommended that effective, developmentally appropriate pediatric obesity interventions include the following elements:
1) Parent training/modeling (involving behavioral counseling targeted at parents to improve their parenting skills);
2) Behavior modification training (involving goal setting, problem solving, and self-monitoring);
3) Promotion of physical activity (including the reduction of sedentary behaviors); and
4) Nutrition counseling/education (including the provision of more general information on foods, shopping, and nutrition to promote healthful eating).

Obesity is impacted by both the physical and social environment.
It is not only the family that exerts influence over preschooler nutrition and physical activity habits, but both the physical and social environment.

Physical Environment: A developing area of research examines the impact of access to physical activity on increased activity levels. In a study by Wilson et al, access to physical activity such as neighborhood trails was associated with increased physical activity in low SES groups.(Wilson, Kirtland et al. 2004) Likewise, Sallis et al discovered that proximity of exercise facilities to one's home was associated with increased amounts of exercise.(Sallis, Hovell et al. 1990) Unfortunately, more physical activity barriers exist for residents living in poorer communities. For example, Estabrooks found that fewer free physical activity resources, such as parks and playground exist, in poorer communities.(Estabrooks, Lee et al. 2003) Lack of affordable, safe, and accessible recreation facilities and programs have been cited as contributing to children's watching more TV at home, which in turn is associated with increased rates of obesity.(Gordon-Larsen, Griffiths et al. 2004; Witkos, Uttaburanont et al. 2008) Creating links to free, accessible recreation would be especially important in areas where low SES populations live. Public community centers provide access to physical activity for those populations at highest risk for obesity.(Giles-Corti and Donovan 2002; Gordon-Larsen, Nelson et al. 2006) Through our existing partnership between the Department of Pediatrics at Vanderbilt University Medical Center (VUMC) and Metro Parks and Recreation, we have the opportunity to conduct and test a community center based intervention that can reach this high risk population.

Social Environment: Research now suggests that we have underestimated the influence of the social environment on shaping obesity-related behaviors. Social networks have been linked to obesity in adults and adolescents.(Christakis and Fowler 2007; Bahr, Browning et al. 2009; Valente, Fujimoto et al. 2009; de la Haye 2010). Social networks differ from social support. Social networks, the complex webs of social relationships and social interactions that connect individuals, have been shown to be strong influences on behaviors. Social support, however, is generally thought not to influence behavior, but rather be a mechanism to cope with challenges and facilitate recovery from illness, injury or disease. (Personal Communication, Dr. Thomas Valente, 10/25/2011). Social networks typically measure the presence or absence of friendships and task- or work-oriented relationships (which may or may not provide support) and treats the ties themselves as objects of study.(Smith 2008)

In our recently recently published work, we found that a new social network evolved among parents enrolled in a community-based obesity prevention RCT. Parents selectively formed friendship ties based on their child BMI z-score, (t=2.08, p<0.05). This reveals the tendency

for mothers to form new friendships with mothers whose children have similar body types.(Gesell 2012) Moreover,from a recently completed afterschool intervention (Gesell PI, manuscript in preparation), we notedspread of increased physical activity through a newly developed network. In this study with elementary school aged children from low SES neighborhoods,children's existing friendships heavily influenced their routine level of physical activity. The strongest influence on the amount of time children spent in moderate-to-vigorous activity in the afterschool hours was the activity level of their immediate friends. Children consistently made adjustments to activity levels of 10% or more in order to emulate the activity levels of their peers (OR=6.89, p<0.01).(Gesell 2012) This proposal explores the novel concept that by bringing groups of parents together regularly, the potential exists to create new social networks that can influence health behaviors. Therefore, this study will examine if new social networks are formed and if they mediate the effect of the intervention.. While many obesity interventions occur in a group setting, underlying group structure and group processes are not documented in the scientific literature. Systematic analysis of the network effects of the Growing Right Onto Wellness (GROW) study will elucidate the types of social ties that evolve among families participating in community-based trials, whether new social ties form in a predictable manner, and the effect they have on health behaviors and health outcomes under investigation

Genetic factors play a role in the development of obesity.
Research demonstrates that a genetic risk score (GRS) is a predictor of BMI. Family studies have demonstrated that genetic factors account for anywhere between 40% and 70% of the population variance in BMI for individuals with severe obesity. (Coady, Jaquish et al. 2002; Wardle, Carnell et al. 2008) Until recently, specific genes contributing to BMI in the general population had not been identified. It is now clear, however, that certain gene variants exert a substantial, clinically important effect on BMI in humans.(Willer, Speliotes et al. 2009) The GIANT Consortium reported the results from large scale studies to identify genetic variants contributing to the risk of obesity in both children and adults. In January 2009, this consortium reported a meta-analysis involving over 100,000 patients, in which 8 obesity-related risk alleles were conclusively validated far in excess of the standard (5 x 10-7) for genome-wide statistical significance.(Willer, Speliotes et al. 2009). A novel aspect of the present proposal is that it incorporates genetic data in relation to an interventional study to prevent early childhood overweight/obesity. We anticipate new discoveries over the course of the study, therefore we plan to bank saliva and determine our final approach to genetic analysis based on the latest scientific recommendations.

4. FORMATIVE RESEARCH – PHASE 1

4.1. Aims, Objectives, Interventions, Measurements
Before launching the Randomized Controlled Trial (RCT), we are conducting formative research to refine the intervention and control group procedures, protocols, and final content. The objectives include 1) refining the Growing Right Onto Wellness (GROW) curriculum and study protocol with African-American and Caucasian families via six focus groups and four focus groups with Metro Park leaders; 2) finalizing intervention study materials with English and Spanish speaking families with young children on health literacy and numeracy via cognitive interviews; and 3) conducting a pilot test with 60 eligible parent-child dyads (3-5 years) to test the revised components to create a final RCT protocol. A previous pilot study tested our proposed approach and content in Spanish-speaking

families, therefore in the current pilot, we focus on African-American and Caucasian families using English materials. Sixty families with pre-school-aged children from defined regions around East Community Center were recruited to participate in testing study elements (content and/or protocol) as directed by the focus group findings and with input from the larger UO1 Consortium. Refer to section 9 for measurement and quality control procedures. Data were collected at baseline and will be collected at 3 and 6 months for selective outcome and process measures that will be chosen based on focus group recommendations. The revised literacy-sensitive materials will be utilized, assessed, and finalized. We chose to include a larger pilot and feasibility number of sixty families as a test-run through the community center, since each center will need to accommodate three waves of 50 intervention families per center throughout the RCT. This pilot phase will prepare East Community Center and inform final protocol processes needed.

4.2. Results from Phase 1

Data Analysis: The data gathered from the pilot will help the GROW team to determine what final measures and processes will be used for the RCT. The following is baseline data collected prior to the beginning of the intervention phase. We will collect data two more times, after completion of the intensive phase and three months later after a brief maintenance phase.

Preliminary Findings: Preliminary baseline data from demographics, diet recall, and accelerometry are reported below. Resultant changes to study components based upon both the data presented and problems observed during the pilot are reported in section 4.3.

Demographics:

Table 4.1: Child and adult demographic data

Child	
Age, mean (SD)	4.69(0.74)
Gender, No. (%)	
Female	30(60.0)
Male	20(40)
Absolute BMI, mean (SD)	16.39(0.76)
Waist circumference (cm)	51.94(2.43)
Tricep skinfold (mm)	14.22(3.61)
Race, No. (%)	
Black	26(52)
White	15(30)
Multi/Other	9(18)
Hispanic or Latino/Latina	2(4)
Adult	
Age, mean (SD)	35.92(9.36)
BMI (kg/m^2), mean (SD)	35.39(12.46)
Waist (cm), mean (SD)	109.13(22.13)
Tricep (mm), mean (SD)	40.18(13.89)
Gender, No. (%)	
Female	48(96)

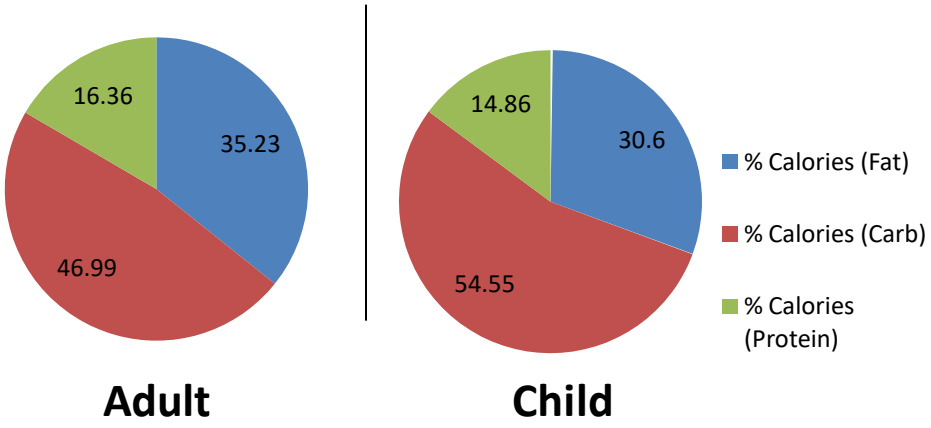
Male	2(4)
Race/Ethnicity, No. (%)	
Black	28(56)
White	19(38)
Hispanic or Latino/Latina	2(4)
Multi/Other	3(6)
Primary Caregiver Education, No. (%)	
9th - 12th grade	5(10)
High school graduate	9(18)
Some college	17(34)
Technical degree	1(2)
Associates degree	2(4)
College degree	9(18)
Higher degree	7(14)
Total Household Income, No. (%)	
$14,999 or less	16(32)
$15,000 - $24,999	13(26)
$25,000 - $34,999	4(8)
$35,000 - $49,999	2(4)
$50,000 - $74,999	5(10)
$75,000 - $149,999	8(16)
$150,000 - $199,999	1(2)
I prefer not to answer	1(2)

Diet Recall at Baseline: The following table and pie charts summarize the self-reported diet recall information of adults and children, respectively.

Table 4.2: Adult and child diet recall

	Adult		Child	
Variable	**mean**	**SD**	**mean**	**sd**
Energy (kcal)	1911.27	707.72	1369.81	290.91
Total Fat (g)	74.72	26.07	49.04	17.28
Total Carb. (g)	231.73	109.73	186.6	39.63
Total Protein (g)	75.28	27.46	50.64	13.93
% Calories (Fat)	35.23	7.82	30.6	6.37
% Calories (Carb.)	46.99	10.01	54.55	7.61
% Calories Protein	16.36	4.04	14.86	2.76
Food Amount (g)	2858.95	1061.07	1451.21	335.11
Water (g)	2490.26	1013.53	1169.74	297.65
Sugars (g)	96.73	57.02	87.8	22.84
Fiber (g)	15.67	8.51	11.7	5.06

Figure 4.1: Adult and child calorie profile



Accelerometry: Our protocol asks both adults and children to wear accelerometry while awake and asleep.

Adult: Adult wear time information is based only on those participants with 4 or more valid wear days (any combination of weekday and weekend days) and ≥ 6 hours per day. Forty-two of 43 (97.7%) adults who wore an accelerometer met the minimum wear time criteria.

Table 4.3: Average adult wear time in hours

Variable	N	mean	sd	min	max
Adult wear time (hours)	42	157.29	20.05	83.78	185.5

The breakdown of physical activity during a typical weekday and weekend day for adults is shown in the following figures. These graphs show that the majority of time was spent doing sedentary activities, and that adults slept more on average on a weekend day as compared to a weekday. Additionally, adults spent almost no time participating in vigorous physical activity.

Figure 4.2: Adult weekday physical activity

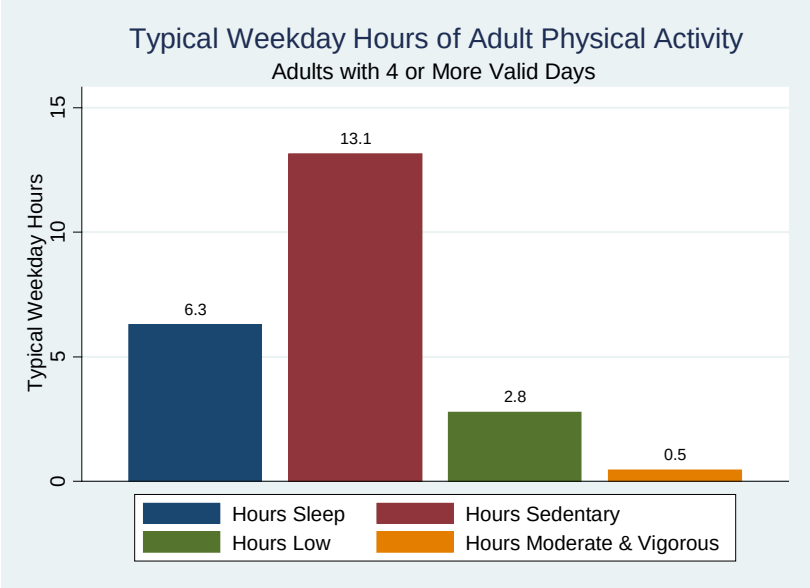
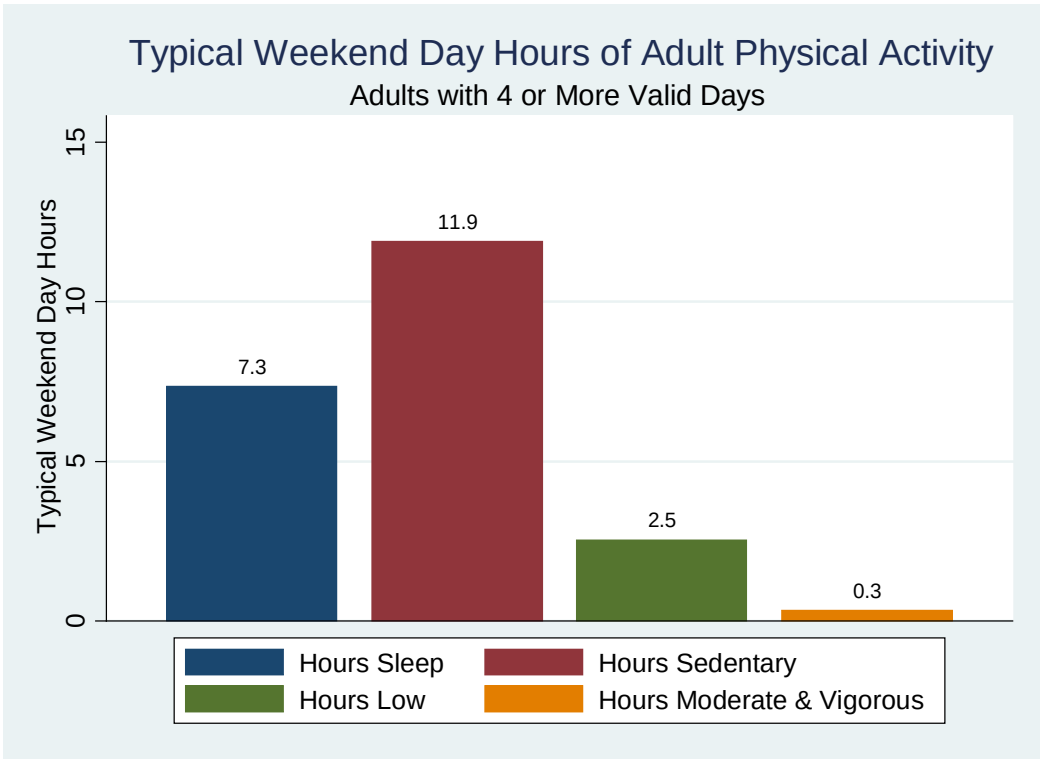


Figure 4.3: Adult weekend physical activity



Child: Child wear time information is based only on those participants with 4 or more valid wear days (any combination of weekday and weekend days) and ≥ 6 hours per day. Forty-one of 42 (97.6%) children (17 male, 25 female) who wore an accelerometer met the minimum wear time criteria.

Table 4.4: Average child wear time in hours by gender

Gender	N	mean	sd	max	min
Female	24	153.21	28.18	168	57.12
Male	17	163.55	19.79	191.87	94.78

Total	41	157.5	25.3	191.87	57.12

The breakdown of physical activity for a typical weekday and weekend day for children 3 to 5 years old is shown below. These graphs show that children spent more time participating in low, moderate, and vigorous physical activities than adults. They also appear to have slept more on weekends than during the week.

Figure 4.4: Child weekday physical activity

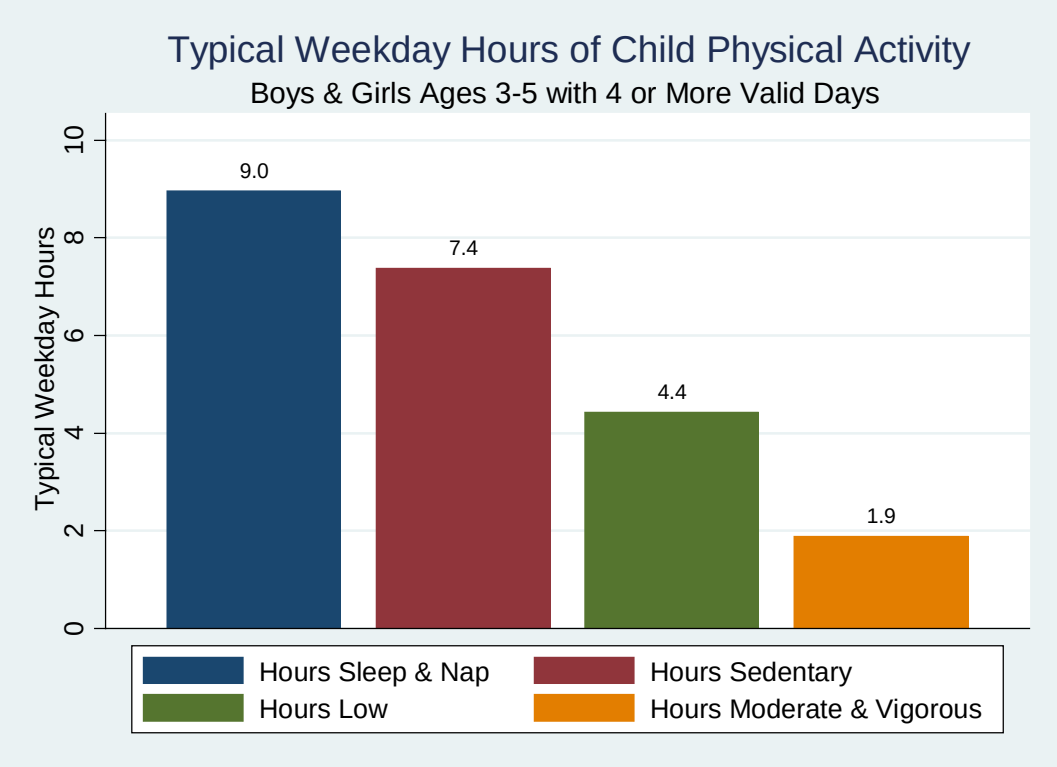
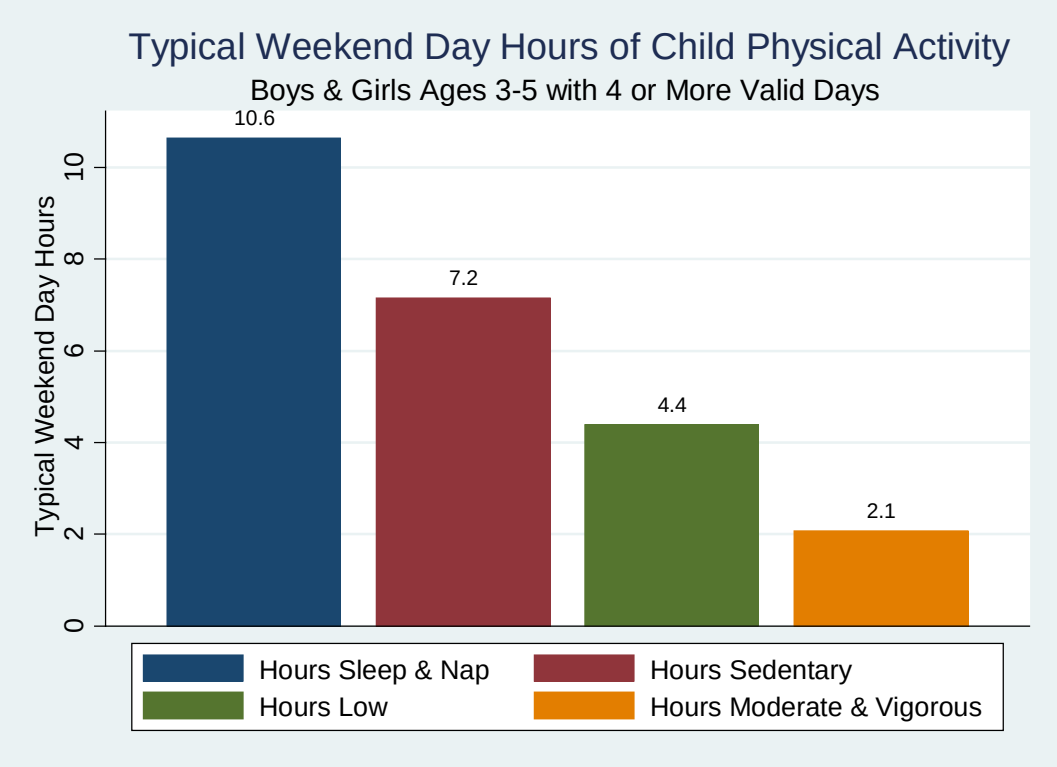


Figure 4.5: Child weekend physical activity



4.3. Key Recommendations for Phase 2

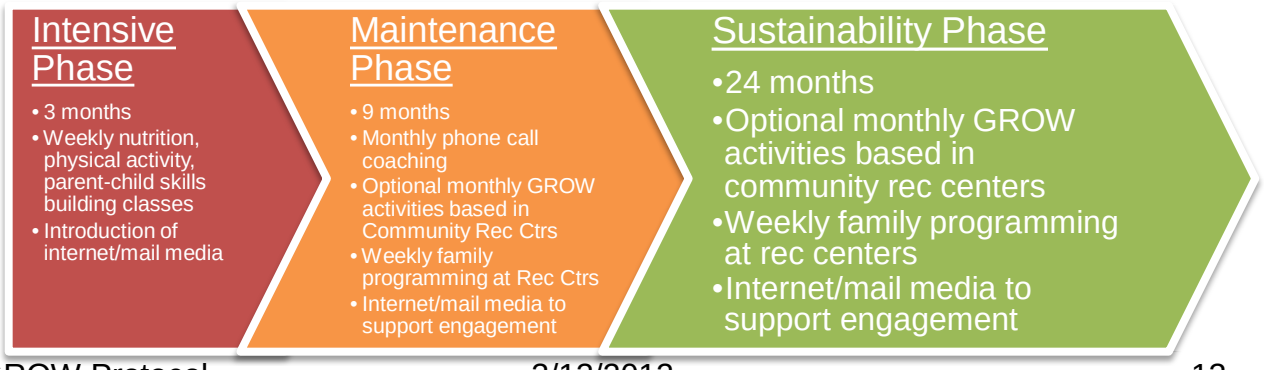
4.3.1. Major Changes from Proposal

Changes in place: The following adjustments were made in response to suggestions from the last DSMB update:

a) We have constrained our eligibility criteria to child's BMI of ≥50% and <95% in accordance to DSMB recommendations, allowing us greater ability to capture change over time.
b) We have reduced our stratified sampling technique to one criterion: parent dominant language use (English versus Spanish).

Revised intervention design: The following figure represents changes to the intervention design:

Figure 4.6: Revised intervention time frame and approach



For the intensive phase, our 12 weekly skills building sessions based at the local community center will be augmented by the introduction of Facebook/email/paper community information. Introduced in the intensive phase and carried throughout the duration of the intervention, this component will include Facebook/email/mail (see below for Facebook approach) to bring attention to activities or events occurring in the built environment to support healthy lifestyles (i.e. recreation center programming, grocery store sales).

Based on recent evidence(Appel, Clark et al. 2011) and our formative phase findings, we have changed our maintenance phase approach to 9 months of once monthly 30-minute coaching calls utilizing a motivational interviewing approach. The structure of these calls utilizes our theoretical framework of behavior change (goal setting, self monitoring, and problem solving) and the lessons learned in the intensive phase. In addition, participants will receive a 15-minute follow-up call one week later to track progress and goals set during the previous week's call (see below for phone call coaching design). Also, introduced in the maintenance phase and continued throughout the sustainability phase, recreation centers will provide weekly activity programming for parent-preschool child dyads and monthly 60-minute GROW events for families. Families can participate as their interest and availability dictates

The revised sustainability phase will include the same components as the maintenance phase EXCEPT for phone call coaching. Sixty-minute GROW activities and mail/internet media updates will continue monthly for the remaining 24 months of the 3-year RCT. Weekly parent-young child classes will be offered at the community recreation centers for families to participate as their interest and availability dictates. This approach will be refined and finalized as the formative phase is completed.

Revised control design: Utilizing the Vanderbilt Institute for Clinical and Translational Research (VICTR), we held an expert studio to provide input on our study design. Experts recommended that the intervention group should also be exposed to the school success component being offered to the control group to create a true control comparator. Thus, the 300 parent-child dyads of the intervention group will also be participating in the family school success program developed for the control group. Our partner in developing this curriculum is the Nashville Public Library. Currently, curriculum is being pilot tested and the final design will be informed by our findings. In the RCT, these 60 minute sessions will occur quarterly in a library setting. Control and intervention groups will attend different sessions to minimize contamination.

Revised "underserved" criteria: The regions selected for the GROW Trial were chosen because of the large proportion of low socio-economic status families residing near the built environment resource of freely accessible Metro Parks and Recreation facilities. However, in our pilot study we observed high level of gentrification in these regions resulting in participating family income ranging between $14,999 or less and $100,000-199,999 per year. Since the GROW Trial is explicitly designed for underserved families, we have redesigned our recruitment strategy to include a respectful approach to determining underserved status. This new approach will include adding a component to our prescreening process that asks if the participant or anyone in the participant's household utilizes a government-subsidized program such as TennCare, CoverKids, WIC, Food Stamps (SNAP), Free and Reduced Price School Lunch and Breakfast, or Families First (TANF). This method will allow us to better recruit from

our target population non-invasively and respectfully. A smaller pilot is underway to test this approach.

Phone call coaching: We are testing a phone coaching maintenance phase. Sessions include revisiting curriculum delivered in the intensive phase, 12-session modules related to healthy eating, physical activity and behavior modification techniques (i.e., goal-setting, self-monitoring, and problem-solving). Phone calls occur monthly, for approximately 30 minutes with a follow-up 15-min phone call in the subsequent week to ensure goals are on-track. These sessions are conducted by certified phone-based counselors with the Vanderbilt Integrative Health Center. For the larger study, we plan to train a pool of phone-call coaches to ensure continuity between coaches and specific participants that fosters trust, guided accountability, and a relationship towards a healthy lifestyle for the parent and preschool-aged child.

Facebook/email/mail: Currently, in 2012, one in two Americans have a Facebook account. In our participating low-SES population, 80% had a Facebook account and 95% had email accounts. To keep participants engaged throughout the 3 year study, we have planned to incorporate the widely popular social media tool, Facebook, into our study (for those without a Facebook account, a monthly mail and/or email equivalent of the information shared will be disseminated). The goal is to incorporate elements of GROW into the participants' Facebook newsfeed so that GROW is constantly visible and accessible in their day-to-day lives. All study participants in the intervention groups will be invited to join the private GROW Facebook group. Through our group page, members will receive reminders to upcoming sessions/community events, problem solving tools, polls to gauge satisfaction and curriculum understanding, posts that display recipes, pictures, and videos, and links to helpful websites for more information. In addition, Facebook group members will be able to post comments and pictures, and potentially strengthen their social network ties. A dedicated GROW employee will monitor the site daily.

4.3.2. Evolving Recommendations for Phase 2

In addition to the key recommendations discussed above, we are in the process of developing, testing, and incorporating the following elements for the RCT:

Community Liaisons: In consultation with Dr. Velma McBride-Murry, who has achieved 90% retention in family-/community-based trials involving African-American families, we learned of an innovative recruitment and retention strategy that utilizes community liaisons. For the purposes of the GROW trial, we define a community liaison as a well-respected person deeply integrated within a community who has the knowledge and resources to easily reach and effectively communicate with our target population. By May 2012, GROW plans to employ 2-4 community liaisons from each of the two communities served. Community liaisons will be expected to participate in the recruitment activities of the GROW study by spreading word about the study and referring potential interested individuals to the GROW staff for eligibility screening. Additionally, they will aid in identifying and attending community events to promote the GROW study. During recruitment, community liaisons will also be asked to assist the GROW staff in identifying potential session facilitators or providers for various study components. Once the trial is ready to begin, community liaisons will be assigned a list of participant names in his or her local community. They will aid the GROW staff if any of the participants on his or her list become difficult to contact by providing updated contact information or by making phone calls or home visits. In this process, the community liaisons must keep logs of all phone or in-person contacts made with participants for the purposes of

tracking and retention. When major events or transitions in the study occur, we will seek their input to help guide next steps.

Adaptive intervention for non-responders: We plan to utilize an adaptive intervention approach(Collins, Murphy et al. 2004) for children who are not responding to the intervention based on their BMI trajectories. For the purposes of this adaptive intervention, a child is considered a non-responder if her/his BMI categorization shifts negatively from T1 to T2 (e.g., normal weight shifts to overweight or obese, overweight shifts to obese – this is the tailoring variable). Child BMI change from T1 to T2 will be reported using an easily understandable and comprehensive growth feedback report and mailed to the parents after T2 measurements are collected. The adaptive intervention will occur at the first phone call coaching session of the maintenance phase. The coach will review the feedback report with the parent and solicit from the parent both the successes and barriers faced with incorporating GROW lessons into their everyday lives (responders will also receive feedback reports but will not receive a report explanation session with the phone call coach). These adaptive intervention report feedback sessions will occur again after BMI categorization/non-responder status is reassessed at the T3 data collection time point. This approach will be refined and finalized as the formative phase is completed.

Metro Parks and Recreation Programming: Parent-child physical activity programming is not widely available and programming that is low or no cost is virtually non-existent. To address this issue, we are working with Metro Parks and Recreation employees to develop parent-preschool child dyad programming. To date, three employees were awarded a stipend to develop a curriculum that is based on current literature and modeled after other best practice sites. These three Recreation Leaders have degrees in Exercise Science and other related disciplines as well as experience facilitating physical activity with pre-school aged children through their work on the GROW Trial pilot studies. Each Recreation Leader's curriculum will be tested with parent-preschool child dyads in March-May.

Social Network Measurement: The GROW trial is a social network intervention, utilizing social network data as a diagnostic tool to aid intervention implementation. The GROW intervention is designed to construct a new social network around each intervention participant to aid behavior change. A fundamental property of a network is cohesion. Our goal is to increase cohesion thought to accelerate the diffusion of ideas and behaviors through networks.

Because the intervention is designed to build a new social network, we want to ensure new social ties and cohesion increase during the intervention. At the beginning of the program, we expect no or very little network linkages and no or very low level of perceived cohesion. By week (session) 4, we anticipate some network structure should have emerged with participants able and willing to name others they go to for advice for healthy living behavior changes and those they have communicated with. They should also report some level of cohesion or belonging with the group. To measure this we will take a short 1-page assessment on intervention group participants after session 4. This survey will provide the social network data that will aid intervention implementation. Responses will be collected either in person as part of session 4 or by telephone before session 5 if participants were missing from session 4. These data will be analyzed before session 6 for each group.

Based on social network diagnostics (i.e., isolates, density, centrality, subgroups, transitivity, specific guidance will be given to the interventionist to increase cohesion during sessions 6-12 of the initiation phase (e.g., Connect Anne with any of these 5 group members; Ask Betty to review group goals at the start of the next session; Start all future sessions with ice breakers; etc). We expect change on all 5 diagnostic measures between baseline and session 12, and also on the self-reported measures of cohesion.

5. STUDY POPULATION AND ELIGIBILITY

5.1. Eligibility Criteria

Eligibility criteria for participation in this study are as follows:

- Three-to-five year old children
- English- or Spanish-speaking
- Child's BMI ≥ 50% and <95%
- Parental commitment to participate in a three year study
- Consistent phone access
- Parent age ≥ 18 years
- Parents and children must be healthy, without medical conditions necessitating limited physical activity as evaluated by a pre-screen (see Appendix 2)
- Child completion of baseline data collection on height and weight, two diet recall sessions, and at least 4 days of accelerometry and at least 90% of survey items completed by the parent
- Dyad must be considered underserved which will be indicated by the parents self-reporting if they or someone in their household participate in one of these programs or services: TennCare, CoverKids, WIC, Food Stamps (SNAP), Free and Reduced Price School Lunch and Breakfast, and/or Families First (TANF)
- Residence in one of two Nashville regions: **East Nashville/Region 1 (37206, 37207, 37208, 37213, 37216, 37228)**: surrounding the East Community Center and **South Nashville/Region 2 (37013, 37204, 37210, 37211, 37217, 37220)**: surrounding the Coleman Recreation Center

For the purposes of this study we define the participating index "parent" as the legal guardian of the child who identifies that they spend the majority of time with that child at home. Once height and weight, two diet recall sessions, and at least four valid days of accelerometry from the child are completed, and ≥ 90% of survey items been collected, parent-child dyads will be grouped into strata according to parent dominant language preference (English versus Spanish). Then dyads within the strata will be randomized to the intervention and control groups.

5.2. Exclusions

- Children who are <50% BMI or ≥ 95%

- Children outside the specified age range
- Families who do not speak English or Spanish
- Lack telephone contact
- Lack parental commitment to participate consistently for a three-year period
- Parents and/or children who are diagnosed with medical illnesses where regular exercise might be contraindicated
- Children who display dissenting behaviors
- Parents/children who do not otherwise meet the eligibility criteria listed in section 5.1. as determined by pre-screen

5.3. Inclusion Statement
The GROW study operationally defines participants using the following inclusion criteria:

Child: Developmentally normal three-to-five year old children with a BMI ≥ 50% and <95%.

Adult: Healthy (without medical conditions necessitating limited physical activity) adults age 18 or older and designated as the child's primary caregiver.

Family: Speaks English or Spanish, resides in the defined vicinity of the intervention community center or control library, has a commitment to the 3-year study, has phone access, and resides in a household that participates in an assistance program for the underserved (e.g. TennCare, WIC, SNAP, free/reduced price school lunch).

6. RECRUITMENT AND RETENTION
In order to preserve internal and external validity of the study, the success of any behavioral intervention is contingent on the researcher's ability to recruit and retain study participants. Successful retention begins at recruitment. Planning and budgeting for retention personnel and procedures prior to conducting longitudinal studies are critical.(Oman, Vesely et al. 2009) Prior effective approaches have included collecting as much data as possible from participants at the initiation of a study and outlining tracking procedures to follow-up with lost participants.(Tansey, Matte et al. 2007),(Velott, Baker et al. 2008). In our case, we will collect at least three phone numbers and/or internet contact information.

As a recruitment plan, the GROW team will use a plan revised from our pilot study experiences. As our pilot process was slow with a low return on investment (approximately 10% of those contacted participated), our primary strategy will include referrals from primary care providers at clinics and lists generated from sites with access to BMI, age, and zip code locations, which eliminate the need for on-site recruitment and an additional screening step. However, due to the large number of individuals that will need to be contacted in order to reach the eventual 600 participants in the RCT, the GROW team will continue to use the improved pilot plan, which includes contacting a variety of sites (e.g. daycares, pre-K programs, churches, community service programs) and an on-site eligibility pre-screening process. Follow-up calls will be made for all recruitment strategies to ensure participation. An additional measure the GROW team will be taking to increase the number of potential participants

reached will be to develop a variety of branding strategies. Ideally, this would include 8 different methods thereby enabling families to readily associate these materials with the program when contacted about participating. Methods employed may include: posters, flyers, mailed brochures/postcards, media spots on radio or TV, community liaisons (see section 4.3.2.), and a heavy presence at community events to spread the message about the GROW program. We are also in discussions with the Coordinated School Health program that supports health initiatives within the Metro Nashville Public School System to identify and follow GROW children in our regions of interest. This is a potentially mutually beneficial relationship that would afford us a combination recruitment and retention strategy.

6.1. Recruitment Tracking

Participant tracking databases will be reviewed monthly by the study's executive committee. If we note greater than anticipated attrition, the GROW trial study executive committee along with the UO1 COPTR Consortium recruitment and retention subcommittee, will discuss additional strategies. We will also ask participants and community liaisons for their suggestions as the study progresses.

To maximize recruitment results, we track our efforts through a REDCap database with the following domain entries: recruitment ID, site, staff contact, interest, eligibility criteria, participant contact information, session preference and limitations, transportation and supervision of children needs, and participant referrals of other potential participants to contact. This database also allows for tracking any contact information changes for later use with retention as well as recruitment which will be conducted over three waves. Each wave consists of a recruitment goal of 200 parent-child dyads over years 3-6 of the study period (100 intervention dyads and 100 control dyads / wave) to reach the goal of a total of 600 parent-child dyads in the study. Parent-child dyads will be recruited in three waves in clusters of two-hundred families to allow for completion of the intensive phase of the intervention prior to beginning the next wave of 200 parent-child dyads.

6.2. Recruitment of Minorities

While our study does not explicitly target specific minority groups, the six hundred parent-child dyads will be representative of the diverse ethnic backgrounds found in the low-income neighborhoods serving as our recruitment areas. Through a screening question related to assistance programs, we hope to recruit underserved families in these communities, which we expect to consist of a large percentage of minorities. To ensure recruitment of participants representing the racial/ethnic breakdown in our communities, we are targeting recruitment sites and site personnel who have direct contact and trusted connections to introduce our study recruiters to a variety of populations. Our study team's recruiters, data collectors, interventionists and retention specialists also include members of minority populations representative of our study's target population, including the ability for Spanish-English bilingual communication. Publicity and program (intervention and control) materials will be adapted for cultural relevance, fluency, and appeal, including radio program announcements and flyers at sites and in languages preferred by minority populations.

6.3. Procedures for Obtaining Informed Consent

Recruiters will pre-screen dyads on-site to verify study eligibility before the dyad can begin the baseline data collection process. At the eligibility station, child BMI% will be double-checked along with other key criteria for eligibility. Those eligible will be invited to complete the informed

consent process with a study team member who will provide a written consent form in the language of the participant and verbally review that form. The study member will respond to any questions in the language of the participant, English or Spanish. If the participant gives consent, they will sign and date one copy of the form and keep another for their reference; both forms are also signed and dated by the study team member obtaining the informed consent.

6.4. Randomization Procedures

Randomization Strata: Randomization will occur after participants complete height and weight, two diet recall sessions, at least four valid days of accelerometry, and ≥ 90% of survey items. Within the first cohort of the trial, parent-child dyads will be grouped according to parent dominant language use (English versus Spanish), resulting in two strata within each region. Dyads within the strata will be randomized to the intervention and control groups within each of the two regions (region 1: 50 intervention/50 control; region 2: 50 intervention/50 control; total N = 200/enrollment year). Dyads will not be stratified by child age in the first cohort but child age distribution will be examined within this cohort such that, if the desired distribution of the various child ages are not reached, the child age stratum will be introduced in cohort two and beyond, so as to adjust the size of the age groups as desired (see below).

Because the primary hypothesis of the study stipulates a curvilinear model that crosses the period of adiposity rebound projected to occur for the age group under study (evidence indicates that adiposity occurs between approximately age 5-6,(Whitaker, Pepe et al. 1998; Rolland-Cachera, Deheeger et al. 2006; Williams and Goulding 2009) we anticipate by study's end to have enrolled a higher proportion of 4-year olds than either 3- or 5-year olds. Obtaining a higher number of 4-year old children than either 3- or 5-year olds will ensure that the majority of the sample will reach adiposity rebound during the study and that either end of the curve will also be modeled adequately. That is, some 3 year olds, who will be in the study until age 6, may *not* reach adiposity rebound during the study, some 5 year olds may have *already* reached rebound by the time they enter the study, and most 4 year olds, who will remain in the study until age 7, *will be expected to reach* rebound during the study years. By enrolling a higher proportion of 4-year olds compared to 3- or 5-year olds, we will increase the chance that we will capture the curve that is under study (that of adiposity rebound) and be able to model that curve appropriately. Within the first cohort (to begin August 2012), however, we will not stratify by child age or pre-determine the size of any age group. Results of our earlier Salud study and our current pilot indicated that a higher number of 4-year-olds matriculated into the study compared to either 3- or 5-year olds. In the on-going pilot, for example, of the 61 children whose parents agreed to participate, 44% (27/61) were age 4, whereas 34% (21/61) were age 3 and 21% (13/61) were age 5. We expect that a similar age distribution may occur by chance in the trial, thus initially, within the first cohort, we will rely upon simple randomization to ensure our desired age group proportions. Before the second cohort is recruited, however, we will assess the proportion of dyads within each age group within cohort one, and, if needed, introduce an age stratum during randomization of cohort two to ensure the desired proportions of the age groups across the combined total of cohort one and two participants. In a similar fashion, we will introduce an age stratum during randomization of cohort three, as needed. By not stratifying by age within the first cohort, we will be able to maximize our recruitment efforts such that children are not turned away within the first (or second) cohort because an 'ideal' or target age stratum may be filled.

In addition, we expect to have both English-speaking (i.e., English language dominant) as well as Spanish-speaking (i.e., Spanish language dominant) families in both study regions. Because our group size within region will be approximately 17 dyads (see analysis plan), we expect to have a total of 6 groups within region (three groups within treatment and three within control [17x3=51] x 2 = 102 per region]). Within region, provided sufficient numbers of participants are recruited with respect to language usage, we will strive to create at least one Spanish-dominant group and one English-dominant group within each arm (treatment and control). The language use of the third group will be determined by the language of the majority of the remaining participants recruited.

Randomization Schedule: An identical randomization procedure will be followed for each of the three successive cohorts. Available software (e.g., SAS, Stata) will be used to generate a blocked randomization schedule per each strata, within both regions, resulting in 4 total schedules (2 language conditions x 2 regions = 4). If dyads were enrolled equally across the strata, we would expect 100/6 = 17 dyads within region per stratum. Because we will allow for flexibility among the language-use assignment, each randomization schedule will accommodate 100 dyads. Block size will be randomly permuted with the software procedure (although no larger than 10), thereby insuring equal representation at intermittent recruitment points while minimizing the probability of correctly guessing subsequent condition assignment

Each schedule will be identified by stratum and loaded into the recruitment database. The database security settings will be specified so that once loaded no one on the study team will have write privileges for the schedules, and only the statistician will have read privileges. These settings will prevent anticipation (except for the statistician) or subversion of the randomization process by any member of the study team.

Random Assignment: Each potential dyad's contact information, including child age and dominant language use, will be loaded into the recruitment database upon identification as a potential participant and assigned a unique study identification number (family id). The recruitment database will follow each potential dyad from the point of identification through eligibility assessment and enrollment through disqualification or randomization. The recruitment database will track all eligibility and enrollment criteria and include a utility that checks still-eligible study candidates for criteria that must be met prior to randomization. Upon identifying dyads who have met all of these criteria, recruitment staff will engage a database utility that performs randomization by identifying the stratum into which each potential dyad should be randomized, and populating the next available slot in the appropriate randomization schedule with the dyad's family id. The database user will not be able to see, and will be unlikely to anticipate, the arm assignment (treatment versus control) for each dyad, especially when multiple dyads within a stratum are randomized at once. Once the dyad is assigned to an arm, a link is established between family id and arm assignment (treatment versus control). This link will not be writable by any study staff and will be viewable by the study statistician in the randomization schedules. Dyad's assignments will be viewable by all study staff on a case by case basis so that the daily activities of managing participants, both parents and their children, may be done without hindrance.

Randomization Data Management: The link between family id and arm assignment will be stored in the randomization schedule, to which only the statistician will have read access. All

randomized dyads will remain in the recruitment database for the duration of the study so that recruitment and enrollment reports can be generated on demand by all study staff. By viewing a dyad's record, any study staff can view but not edit the dyad's arm assignment.

All dyads' family ids will be exported into a measurement database along with the fields necessary to conduct timely data collection and on-demand reporting by any study staff. Arm assignment will not be exported to the measurement database. As such, it will not be possible for measurement staff to know a dyads's arm assignment based on the information available in the measurement database.

In addition, once randomized, the family ids (both treatment and control) will be exported into an intervention database along with the fields necessary to conduct the treatment and control procedures and allow on-demand reporting. Arm assignment will not be exported to the intervention database, although its value is implicitly known. As such, intervention staff (in both the control and treatment conditions) will know which dyads have been assigned to which arm, but this knowledge is unavoidable and redundant with knowledge that will be apparent from contact with the dyads within each arm.

Randomization Data Safety: All databases (recruitment, measurement, etc.), will be stored within a password protected shared drive within the university computer system. All study staff will have access to the databases upon submitting the required password. Access to tables within these databases will be made available as needed to perform job responsibilities and in accordance with COPTR policies. The randomization schedule will not be stored in the intervention database making it impossible to access in this manner.

6.5. Techniques for Retention

While the literature of best community-based interventions often have a 65-70% retention rate at the end of one year, (Economos, Hyatt et al. 2007) we strive to achieve an 80% retention rate with our recruitment and retention strategies outlined above. Retaining this large cohort of largely underserved families is our greatest anticipated challenge. Our retention plan derives from best practice approaches and includes: 1) employing a retention specialist for consistent personal contact with participants; 2) developing a clear protocol that outlines the collection of contact information, systematic contacts, financial incentives, and a participant tracking database; 3) creating the RCT to allow for scheduling around participant's other needs and offering childcare and transportation to remove barriers to consistent study participation; and 4) utilizing other methods of staying in contact with participants, such as employing community liaisons and taking advantage of social media applications like Facebook.

Retention Specialist: As one retention methods, all participants will receive a dedicated mobile telephone number to contact the study team 24-7. A staff member will be dedicated to monitoring this phone number and tracking all information and question reported by participants. Additionally, the GROW team will collect multiple contact numbers and the contact numbers of others who may help us re-establish contact with participants. A phone call protocol is in place to respond immediately after a family misses a session and to problem-solving for continued participation of all participants.

Incentives: We plan to include regular participant incentives provided in sessions and after data collection periods. After each data collection session, each dyad will receive a $20 gift

card. Additionally, when returning the Actigraphs, we will give the dyad a gift valued at $10. During the 12 core intensive phase sessions, we will provide families small practical gifts related to session topics. Based on attendance of these sessions, we will also hold various door prize drawings, increasing in value as the sessions continue. Finally, we will provide free family memberships to the community center (this provides half off swimming lessons, a key motivator in our prior work). In strong support of this work and partnership, Metro Parks is providing in-kind support that equals more than $250,000 to provide annual memberships to the intervention group. The grant will provide free family memberships to control participants who complete all three years. In addition, we will use a punch card system to track and reward participants for their attendance at optional community sessions during the maintenance and sustainability phases. Once participants attend a certain number of sessions, they will exchange their punch card for a small incentive. During our formative phase, we will finalize our incentive approach.

Community Liaisons: As another retention (as well as recruitment) strategy, the GROW team plans to hire community liaisons from each of the two communities served. Please see section 4.3.2. for details on the role and function of the community liaison as a retention tool.

Facebook/email/mail: To keep participants engaged throughout the 3 year study, we will use Facebook, email, and mail media to bring attention to healthy lifestyle information. Please see section 4.3.1. for details on this approach.

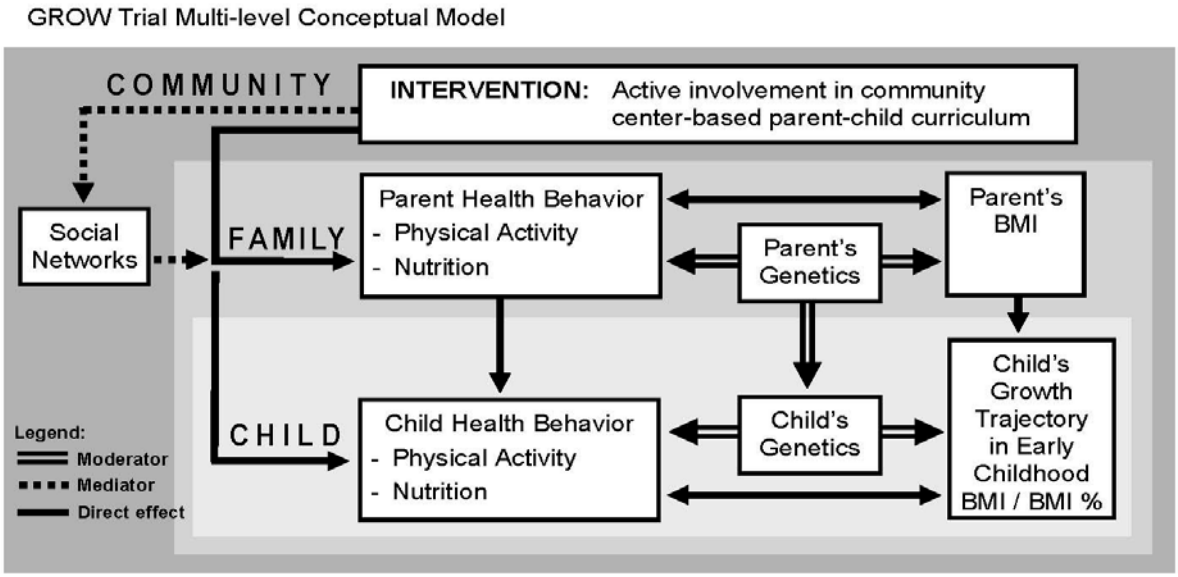
Additional Retention Strategies: Finally, the GROW team hopes that both the intervention and control sessions themselves will create an experience that leaves participants wanting to come back for more through: hands-on, practical, and meaningful session topics; reliable child supervision and activities; transportation to and from sessions; and new social connections.

7. INTERVENTION

7.1. Conceptual Framework

We base our conceptual model on the Centers for Disease Control and Prevention's theory that obesity is affected over time at sensitive windows of development, and by both micro- and macro- level systems.(Glass 2006; Huang 2009) The micro- level system includes one's personal characteristics down to their genetic makeup. The macro-level system moves first into the level of familial influences and then farther up into the level of societal influences. In this proposal, the main intervention will be aimed at the level of child within family, focusing on an index parent-child dyad, and connecting into the larger built environment. This built environment serves as a community-centered location to build healthy lifestyle skills (both routine physical activity and nutritional habits). The micro- level individual genetics will be captured and included in the final analysis as a moderating variable and the macro-level exploration of the creation of new social network influences through study participation will be included as a mediating variable.

Figure 7.1 Conceptual framework

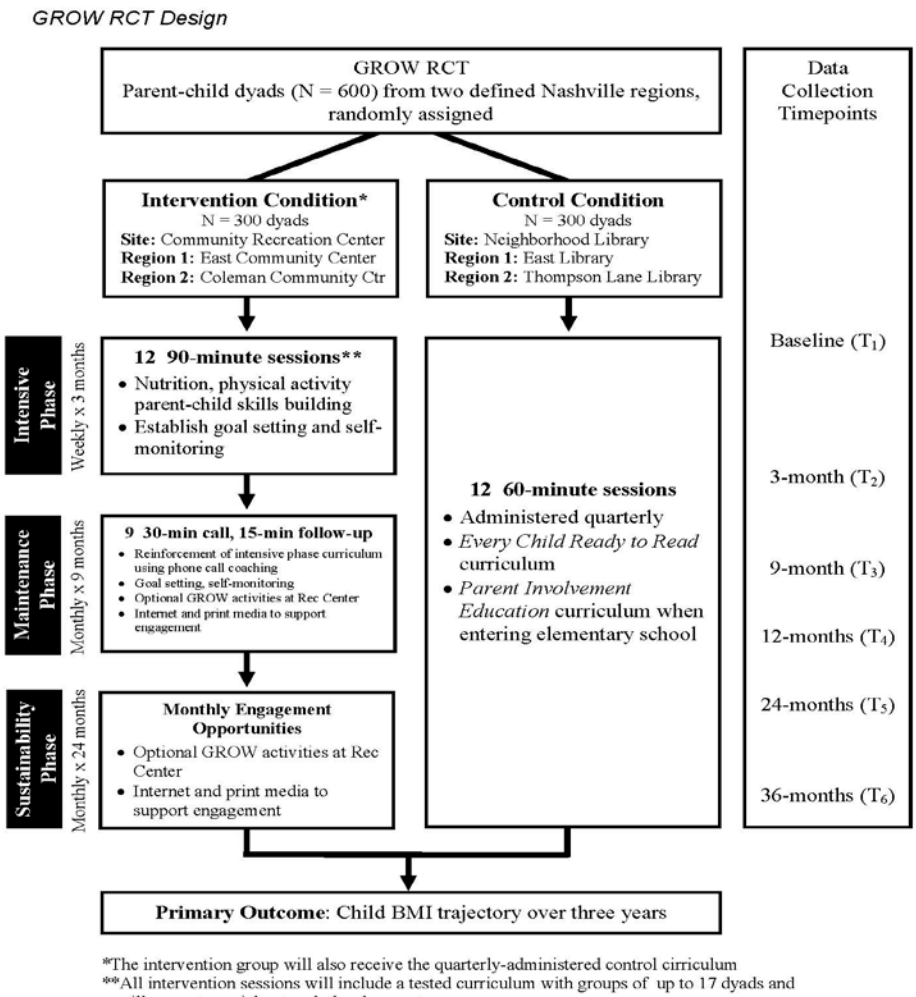


At the level of the child and the child within the family, we rely on principles of Social Cognitive Theory (SCT),(Bandura 1986) with a focus on health literacy and effective health communication. According to SCT, individuals are more likely to engage in behaviors they see modeled or rewarded, as well as those for which their engagement receives direct reinforcement.(Brantley, Myers et al. 2005) Thus, a key component of our intervention for young children is to involve parents in modeling health-promoting behaviors to children in the earliest years. Health literacy and effective communication are important components of health behavior change and central to our intervention. Factors contributing to health literacy and the potential impact of health literacy on direct and indirect health effects have been well elucidated by Rootman,(Rootman 2004) Baker,(Baker 2006) Rothman,(Rothman, DeWalt et al. 2004; Rothman, Housam et al. 2006; Rothman RL 2009) and members of the Institute of Medicine (IOM) Committee on Health Literacy, and others.(Institute of Medicine Committee on Health Literacy 2004) Our proposed study will focus on the interaction between study interventionists (including phone call coaches), community center leaders, and participating parent-child dyads.

7.2. Description of the Intervention

Six hundred parent-child dyads with children ages 3-5 years and representative of diverse ethnic backgrounds from low income neighborhoods will be randomly assigned to either a three-year lifestyle (nutrition and physical activity) intervention delivered at a community center or a control condition that delivers a language/ school success program. All modules involve a parent only skills building component and a parent-child applied learning component. Integrated within our intervention is the intentional building of new social networks. Three study waves, each with 200 parent-child dyads, will occur over years 3-6 of the study period (100 intervention dyads and 100 control dyads/wave). To ensure equal representation in intervention and control groups, parent-child dyads will be grouped into strata according to parent dominant language preference (English versus Spanish). Then dyads within the strata will be randomized to the intervention and control groups. Both regions (Region 1 in East Nashville or Region 2 in South Nashville) will have an intervention site (community center) and a control site (local library). Measurement protocols will be finalized with input from the UO1 Consortium to facilitate meta-analysis whenever possible.

Figure 7.2: Study design and timeline



7.2.1. Intervention Dose

The GROW intervention phases include: 1) an intensive phase: weekly nutritional and physical activity skills building sessions that promote new social networks. We provide encouragement to utilize the built environment for routine family physical activity and nutritional advice using Facebook, email, and mail media (three months); 2) a maintenance phase: monthly phone coaching calls to reinforce concepts from phase one, continued encouragement through internet and mail media, the availability of weekly activity programming for parent-preschool child dyads through the recreation centers, and monthly 60-minute GROW events for families (9 months) for families to participate as their interest and availability dictates; and 3) a sustainability phase: discontinuation of phone call coaching and continuation of the other elements in the maintenance phase that occurs monthly (24 months). The three main pillars of

behavior change will be applied at each face-to-face and phone coaching session: 1) goal setting; 2) self-monitoring to achieve those goals; and 3) problem solving. Additionally, after each measurement point in the intervention group, both the parent and child participants will receive a feedback report on growth in the form of an age- and gender-appropriate BMI curve.

7.3. Process Measures

The GROW trial process measures will include: participation rates collected via attendance logs; data collection process collected via timed logs and identification of any issues that arise during the data collection procedures; retention barriers and facilitators via call logs conducted by the study retention specialist; session fidelity checks to ensure consistency and accuracy of content administration (see Appendix 3); logs to assess use of recreation center and library outside of mandatory GROW-related sessions; Metro Parks and Recreation facility staff satisfaction surveys to assess barriers and facilitators of conducting the research program within their facility; library facility staff satisfaction surveys to assess barriers and facilitators of conducting the research program within their facility; and parent-child satisfaction with study participation.

Table 7.1: Vanderbilt process evaluations

Fidelity "The extent to which the intervention is delivered as intended; quality of the intervention; how well an intervention is being implemented compared to its original design; could include, but not limited to, content & quality of messages, adherence to protocol, and intervention staff skill/training/certification."

Fidelity	Fidelity Construct	Data Collection Method	Completed By	Timing of Data Collection
Intervention Component #1				
Group Sessions	Content and quality of messages delivered (Number of sessions offered, length of sessions, staff attendance, materials used as directed, adherence to session outline, full delivery of key messages, location of sessions per protocol)	Session Fidelity Plan	Fidelity Monitor	Every module of every interventionist
Group Sessions	Family satisfaction with content and length of group sessions	Family Satisfaction Survey	Intervention Parent	Every 4 weeks of intensive phase; T3; T6
Group Sessions	Use of social network data as diagnotistic tool to build group cohesion	Social Network Survey Network Action Plan	Intervention Parent Co-I	Week 4 Week 6
Intervention Component #2				
Coaching Calls	Process (Number of calls made, number of calls completed,	Call Log	Phone Coach	Every call

	number of calls followed schedule, length of calls) Content (Adherence to call outline, goal attainment)	Recorded Calls scored on Utterance scale	Fidelity Monitor	First call and 10% of calls thereafter
Intervention Component #3				
Parks GROW Programming	Frequency of programming (Number of sessions, length of sessions, type of program)	Attendance Sheets	Session Leader	Monthly
Library GROW Programming	Content and quality of messages delivered (Number of sessions offered, length of sessions, staff attendance, materials used as directed, adherence to session outline, full delivery of key messages, location of sessions per protocol)	Session Fidelity Plan	Fidelity Monitor	First session and 10% of sessions thereafter
Staff Training Component				
Intervention Component #1				
Training of Parent and Child Interventionists	Attendance at required training sessions; Certification of knowledge/skills	Session Attendance Log Interventionist Certification	Research Coordinator	After each training session
Training of Fidelity Monitor	Attendance at required training sessions; Certification of knowledge/skills	Session Attendance Log Fidelity Monitor Certification	Research Coordinator	After each training session
Intervention Component #2				
Training of Phone Coaches	Attendance at required training sessions; Certification of knowledge/skills	Phone Coach Certification	Research Coordinator	After each training session

Dose Delivered "The amount of intervention that was delivered; could include, but not limited to, number and length of sessions implemented"

Dose Delivered	**Dose Delivered Construct**	**Data Collection Method**	**Completed By**	**Timing of Data Collection**

Intervention Component #1				
Group Sessions	Content and quality of messages delivered (Number of sessions offered, length of sessions, staff attendance, materials used as directed, adherence to session outline, full delivery of key messages, location of sessions per protocol)	Session Fidelity Plan	Fidelity Monitor	Every session
Group Sessions	Provision of action plan to interventionist	Network Action Plan	Co-I	Week 6
Intervention Component #2				
Coaching Calls	Process (Number of calls made, number of calls completed, number of calls followed schedule, length of calls) Content (Adherence to call outline, goal attainment)	Call Log Recorded Calls scored on Utterance scale	Phone Coach Fidelity Monitor	Every call First call and 10% of calls thereafter
Intervention Component #3				
Parks GROW Programming	Frequency of programming (Number of sessions, length of sessions, type of program)	Attendance Sheets	Session Leader	Monthly
Library GROW Programming	Content and quality of messages delivered (Number of sessions offered, length of sessions, staff attendance, materials used as directed, adherence to session outline, full delivery of key messages, location of sessions per protocol)	Session Fidelity Plan	Fidelity Monitor	First session and 10% of sessions thereafter

Dose Received "The amount of intervention that was received; could include, but not limited to, participant engagement, and intervention messages or materials received"

Dose Received	**Dose Received Construct**	**Data Collection Method**	**Completed By**	**Timing of Data**

				Collection
Intervention Component #1				
Group Sessions	Attendance of index parent and index child	Session Attendance Log	Interventionist	Every session
Group Sessions	Module booklet received	Module Booklet Tracker	Interventionist	Every session
Intervention Component #2				
Coaching Calls	Number of calls completed on schedule	Call Log	Phone coach	After each call
Intervention Component #3				
Parks GROW Programming	Attendance of index parent and index child	Session Attendance Log	Session Leader	Every session
Library GROW Programming	Attendance of index parent and index child	Session Attendance Log	Session Leader	Every session

Program Design "The assessment of non-specific treatment effects, could include, but not limited to participant satisfaction with, feasibility, and costs of intervention"

Program Design	Program Design Construct	Data Collection Method	Completed By	Timing of Data Collection
Intervention Component #1				
Group Sessions	Recreation Staff Satisfaction	Staff Satisfaction Survey	Parks Staff involved in programming and Facility Coordinator	Quarterly
Group Sessions	Family Satisfaction	Family Satisfaction Survey	Intervention Parent	Every 4 weeks of intensive phase;T3;T6
Group Sessions	Interventionist Satisfaction	Interventionist Satisfaction Survey	Interventionist	Quarterly
Intervention Component #2				
Coaching Calls	Retention call process (number of attempts and length of calls)	Call Log	Retention Specialist and Interventionist	After each call

Reach "The proportion of intended recipients who actually participate in an intervention; the extent to which the intervention is reaching the target population; could include, but not limited to, attendance, participation, and engagement by group (e.g. race, gender, SES, intervention group)"

Reach	Reach Construct	Data Collection Method	Completed By	Timing of Data Collection
Intervention Component #1				
Group Sessions	Demographics of those who consent	Study Survey	All Parents	T1
Group Sessions	Attendance of index	Session	Interventionist	Every session

	parent and index child; Demographics of those who attend	Attendance Log Study Survey	All Parents	T1
Group Sessions	Retention Barriers	Call Log	Retention Specialist and Interventionist	After each call
Group Sessions	Recruitment Reach (screened, eligible, consented, attended)	Recruitment Flow Chart	Recruitment Specialist	Weekly
Intervention Component #2				
Coaching Calls	Demographics of participants vs. non participants	Study Survey	All Parents	T1
Intervention Component #3				
Parks GROW Programming	Attendance of index parent and index child; Demographics of those who attend	Session Attendance Log Study Survey	Interventionist All Parents	Every session T1
Library GROW Programming	Attendance of index parent and index child; Demographics of those who attend	Session Attendance Log Study Survey	Interventionist All Parents	Every session T1

2. 7.4. Unblinded Process Measures

The following table lists the unblinded variables, process, access point, and justification for unblinding for the RCT.

Table 7.2: Unblinded process measures

Variable(s)	Arm(s)	When	Purpose
Retention (adult-child dyad)	Each arm separately	Every data collection time point	Need for robust population to answer research questions. Retention data will be examined separately for each arm in order to address differential attrition, and because the barriers may be different for each arm. However, any procedures implemented to address retention will be the *same in both arms*, therefore, eliminating the potential for bias between arms.
Attendance (adult-child dyad)	Each arm separately	Every session	
Fidelity of implementation:	Each arm separately	Every session	Monitor implementation and ensure proper/consistent delivery of the intervention and control conditions.
Number of sessions delivered	Each arm separately		
Length of sessions	Each arm separately		
Key session components delivered	Each arm separately		

Adherence to outline of sessions	Each arm separately		
Social Cohesion Survey/Advice Questions	Small subgroups intervention arm only	4 weeks into program	A component of the social networking intervention to create responsive group sessions that increase social cohesion.
Use of recreation center outside of sessions	Intervention arm only	Continuously	Attrition prevention during maintenance and sustainability phases. Adjust incentives (according to *a priori* plan) if necessary.
Coaching call implementation:	Intervention arm only	Continuously	Monitor implementation and efficiency of calls. Make adjustments to call rate if necessary.
Calls made	Intervention arm only		
Calls completed	Intervention arm only		
Length of calls	Intervention arm only		

8. CONTROL CONDITION

Three hundred (300) parent-child dyads will be randomly assigned to receive only a program for school success based upon formative phase pilot findings. Participants will attend twelve 60-minute sessions over a period of 3 years to be delivered quarterly at the public library in their zip code region. The core curriculum training will involve developing parental skills while also creating a practice-based learning environment for parent-child dyads around school success utilizing key elements of *Every Child Ready to Read*,(Neuman 2011) a project of the Association for Library Service to Children and the Public Library Association. These sessions will be led by bilingual facilitators who are trained educators that work with the Nashville Public Library Foundation to enhance outreach efforts. Sessions will occur quarterly for three years and will be provided for both the control condition and the intervention condition. The intervention participants and control participants will not participate in the same sessions. As children age in the study and enter elementary school, the control parent-child dyad will receive a curriculum that integrates core elements from the *Parent Involvement Education* curriculum, tested and implemented by the Parent Institute for Quality Education (PIQE) to improve school success.(Chrispeels JH 2000) Data will be collected from both groups on early literacy and executive functioning (working memory and inhibition/decision making).

9. MEASUREMENTS

9.1. Methods

9.1.1. Primary Outcome

Background and Rationale: The measure used as the primary outcome variable of all four COPTR trials is body mass index (BMI). BMI assesses body weight adjusted for height and is correlated with percent body fat as assessed by dual energy x-ray absorptiometry.(*Daniels, Khoury et al. 1997*; *Pietrobelli, Faith et al. 1998*; *Dezenberg, Nagy et al. 1999*; *Bray, DeLany et al. 2001*) (When calculated using measured anthropometrics BMI is highly reliable. BMI has demonstrated clinical validity in its associations with type 2 diabetes mellitus,(*Pinhas-Hamiel, Dolan et al. 1996*; *Scott, Smith et al. 1997*) hyperinsulinemia,(*Freedman, Dietz et al. 1999*)

blood pressure and hypertension,(*Daniels, Khoury et al. 1997*; *Dwyer, Stone et al. 1998*; *Freedman, Dietz et al. 1999*) adverse lipoprotein profiles(*Dwyer, Stone et al. 1998*; *Freedman, Dietz et al. 1999*; *Teixeira, Sardinha et al. 2001*) and early atherosclerotic lesions.(*Mcgill, Mcmahan et al. 1995*; *Berenson, Srinivasan et al. 1998*) among children and adolescents Importantly, BMI can be assessed easily in clinical and public health settings and is generally accepted and well understood.

Objective: The objective of the BMI measures is to provide a precise and accurate measure of the impact of the intervention on relevant aspects of body size in the children studied in COPTR.

Methods: All consented index children in the COPTR study have weight and height measured at the beginning and end of the intervention (36 months) and at two common interim time points (12 and 24 months). All baseline anthropometric data will be collected prior to randomization. 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 is calculated as weight in kilograms divided by the square of height in meters.

All height and weight measurements are collected by trained and certified staff. COPTR will use a "train the trainer" model. Each field center will designate one or more "Master Trainers" who participate in a central training organized by the RCU at the University of North Carolina at Chapel Hill on April 16-18, 2012. These Master Trainers are responsible for training and certifying the data collection staff at their center.

9.1.1.1. Other Anthropometric Secondary Outcomes

Anthropometric secondary outcomes differ by site as detailed in Table 9.1. Variables measured in the index child at all sites include waist circumference and triceps skinfold. All sites are measuring height and weight in at least one adult family member of the index child and some sites are measuring siblings. Secondary outcomes that will be calculated from anthropometry in at least one site include BMI z-score, waist-to-height ratio (WtHR), and percent body fat.

Table 9.1: Anthropometric Common Measures by Research Center

Anthropometric Measure	Case	Minnesota	Stanford	Vanderbilt
Index Child				
Weight	x	x	x	x
Height	x	x	x	x
Waist circumference	x	x	x	x
Triceps skinfolds	x	x	x	x
Other Children				
Weight	--	x*	x†	--
Height	--	x*	x†	--
Waist circumference	--	--	x†	--

Anthropometric Measure	Case	Minnesota	Stanford	Vanderbilt
Triceps skinfolds	--	--	x†	--
Other Adults				
Weight	x	x*	x	x
Height	x	x*	x	x
Waist circumference	--	--	x	x
Triceps skinfolds	--	--	--	x

* Minnesota: All children and adults in household.
† Stanford: Only study eligible children

Background and Rationale: BMI z-scores provide a method for evaluating the weight status of children adjusted for age and gender. The measure is commonly used in clinical practice to track body size trajectory. However, several authors have cautioned against the use of BMI z-scores for research using longitudinal designs citing concerns that their use could result in spurious differences between groups.(*Cole, Faith et al. 2005*; *Berkey and Colditz 2007*) One reason for this problem is that children at the extreme ends of the BMI distribution require substantially greater changes in weight than their thinner counterparts for the same change in z-score. Also because the BMI z-score curves were constructed using only data between the 3rd and 97th percentiles, the CDC recommends extreme caution when using the growth curves outside this range.(*Kuczmarski, Ogden et al. 2000*) Finally, Berkey et al. noted that the difference between z-scores reflect larger differences in BMI in older compared to younger children.(*Berkey and Colditz 2007*) For these reasons the COPTR investigators have chosen to study BMI z-score as a secondary rather than a primary outcome.

Abdominal adiposity is associated with metabolic risk factors in children,(Freedman, Srinivasan et al. 1987; Freedman, Srinivasan et al. 1989; Caprio, Hyman et al. 1995; Caprio, Hyman et al. 1996) although evidence to date suggests that anthropometric measures tend to only moderately predict visceral fat.(Goran 1998; Goran, Gower et al. 1998) Waist circumference is a feasible non-invasive measure of abdominal fatness for community-based assessments of children. It has also been shown to be sensitive to change in response to prevention interventions.(Robinson 1999)

Waist-to-height ratio (WtHR) is a simple index that has recently received increased interest from investigators.(Browning, Hsieh et al. 2010) After the age of four years, waist and height appear to simultaneously increase during childhood and adolescence.(Kahn, Imperatore et al. 2005) Thus, WtHR could provide a practical estimate of adiposity that could be consistently applied to a wide range of age groups. Recently Browning et al. published a systematic review of waist to height ratio as a screening tool for cardiovascular and diabetes-related outcomes.(Browning, Hsieh et al. 2010) In their examination of 13 cross-sectional studies in children they found that waist-to-height ratio compared favorably with waist circumference and BMI. In a cross-sectional study of 1,511 youth 8 to 17 years of age McMurray et al. found that waist circumference performed well as a predictor of insulin resistance in boys but not girls.(McMurray 2010) Better performance was observed when waist circumference was divided by height, producing an index that was highly associated with insulin resistance in both genders and over a range of ages. Kahn et al. and Savva et al. have suggested a WtHR cut point of 0.49 to distinguish high and low levels of risk, however, McMurray et al. suggest that a WtHR of 0.54 may result in fewer misclassifications.(Savva, Tornaritis et al. 2000; Kahn,

Imperatore et al. 2005; McMurray 2010) WtHR can also be analyzed in the continuous form. COPTR can provide an opportunity to further evaluate this index using both cross-sectional and longitudinal designs.

Triceps skinfold thickness is a measure of subcutaneous fat and is a component of equations used to predict percent body fat. COPTR investigators are using data from the NHANES study to develop a prediction equation for percent body fat that uses triceps skinfold along with other anthropometric variables collected in COPTR (height, weight and waist circumference) together with demographic variables to predict percent body fat (see section 4.8. in RCU protocol). Equations were developed in children in the age ranges being studied by Case Western and Stanford. Preliminary work indicates that this equation has an R^2 of over 0.8. Unfortunately estimates of percent body fat from DEXA are not available in children less than 8 years of age in NHANES. Therefore Vanderbilt and Minnesota will estimate percent body fat in younger children in their study using the prediction equation created by Dezenberg (R^2=0.95 as compared to DEXA, Model SEE=0.46) using data from White and African American 4 to 11 year old children.(Dezenberg, Nagy et al. 1999) This method has been shown to have higher validity across subgroups than other equations(Slaughter, Lohman et al. 1988; Goran, Driscoll et al. 1996) and has been validated in 3 to 8 year old White and Hispanic children.

Obesity has been shown to cluster in families such that having obese parents increases the risk of obesity in children.(Barness, Opitz et al. 2007; Macfarlane, Cleland et al. 2009; Silventoinen, Rokholm et al. 2010) This clustering is due to both shared environment and genetic factors. The collection of anthropometric variables in the families of the index children in COPTR provides an opportunity to examine longitudinal changes within families in the family members and to assess any impact of the intervention on family members.

Objective: The anthropometric secondary outcomes are assessed to provide a richer understanding of the changes in body size characteristics associated with the COPTR interventions.

Methods: Waist circumference and triceps skinfolds will be measured at the beginning and end of the intervention (36 months) and at two common interim time points (12 & 24 months). Measurement details have been determined with guidance from the 2007 NHANES anthropometry procedures manual.(*Center for Disease Control and Prevention 2007*) 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 (or a Harpenden caliper if the measurement exceeds capacity of the 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). Skinfolds are measured to the nearest 0.1 mm.

9.1.2. Demographic Variables

Background and Rationale: Self-reported information will be collected from COPTR index children and other household members by obtaining responses to written or verbalized questions. Although we refer to “questionnaires”, as discussed in the methods section below,

several methods are used to collect these data, and only a minority of the data is collected through the use of paper questionnaires. The information obtained is used to describe the study population or as a confounder, mediator, moderator or secondary outcome of intervention effects.

In general, the mediators chosen for measurement are targeted by the intervention, are expected to change as a result of the intervention and to result (directly or indirectly) in change in BMI. In COPTR, each Field Site's intervention is unique and many of the mediator variables are site-specific because they serve as explanatory constructs for the site-specific theoretical model. A moderating variable is defined as a variable that could influence the primary or secondary outcomes because the variable interacts with the intervention to change study outcomes. In other words, the intervention affects people differently, depending on their status on the moderator variable. These variables are evaluated at the beginning and the end of the intervention, and in some cases as interim measurements.

Objective: The purpose is to describe the characteristics of participants, to determine possible mediators and moderators of intervention effects and to study secondary outcomes that are impacted by the intervention.

Methods: The demographic, household, mediators and moderators survey is administered to parents/primary caregivers of the participating child and/or to the participating child. Table 9.2. summarizes the location where the questionnaire will be administered and administration format in each site. To accommodate the sample being studied some sites administer questionnaires in Spanish.

Table 9.3. lists the questions used to collect common questionnaire data and shows which sites are collecting each item. All of the common survey questions are not administered at all Field Sites. The source of the 55 common questions and the responses are listed in Table 9.4. In addition to the common survey questions, each Field Site has site specific mediator and moderator questions (Tables 9.5 -9.8). There will be four common measurement time points – baseline, 12 months, 24 months and 36 months. All common data collection will occur between May 2012 and February 2017. All baseline data collection will occur prior to randomization. Measurement data collectors are not intervention staff unless data are collected prior to randomization.

A “train the trainer” model is used to prepare staff to collect questionnaire data. Each Field Site designates two or more “Master Trainers” who participate in central trainings conducted by the RCU at the University of North Carolina at Chapel Hill on April 16-18, 2012. These Master Trainers are responsible for training and certifying the data collection staff at their Field Site. To be certified, Master Trainers attends the central training, reads the protocol and manual of procedures, complete the questionnaire and administer the questionnaire. The data collectors are certified by a Master Trainer who will describe the data collection process, insure that the protocol and manual of procedures are read and observe the questionnaire being administered to a volunteer.

Table 9.2: Characteristics of questionnaire administration by Field Sites

	Field Sites			
	Case Western	**Minnesota**	**Stanford**	**Vanderbilt**
Administration Location	Clinic	Home	Community center, Home, or Clinic	Community center
Administration Format	Interviewer administered	Interviewer administered	Interviewer administered (child) and mix of interviewer and self-administered (parent)	Interviewer administered
Data collection format	Computer	Computer	Paper Computer	Computer
Languages	English	English Spanish	English and Spanish (parents) and English (child)	English only in pilot; English and Spanish in main trial
Respondent	Parent or primary adult caregiver and participating child	Parent or primary adult caregiver	Parent(s) or primary adult caregivers and participating child	Parent or primary adult caregiver

Table 9.3: Questionnaire Common Measures by Field Site

Construct	**Item**	**Case**	**Minnesota**	**Stanford**	**Vanderbilt**
Household Configuration	For all children and adults living in your household, please tell me:				
	Gender,	X	X	X	
	Birth date, or age	X	X	X	
	Relationship to the participating child.	X	X	X	
Child's date of birth	Child's date of birth	X	X	X	X
Child Sex	What is this child sex?	X	X	X	X
Child Ethnicity	Is this child Hispanic, Latino/a or of Spanish origin?	X	X	X	X
Child Race	Which of the following best describes your child?	X	X	X	X
Parent Ethnicity	Are you Hispanic, Latino/a or of Spanish origin?	X	X	X	X
Parent Race	Which of the following best describes you?	X	X	X	X
Parent Country of Birth	In what country were you born?		X	X	X
Child Country of Birth	In what country was this child born?		X		X
Years Parent Lived in USA	How many years total have you lived in the United States?		X	X	X
Employment Status	What is your employment status?	X	X	X	X
Marital Status	What is your current marital status?	X	X	X	X
Access to Car	Is there a car that you can use whenever you need to?	X	X		X

Construct	Item	Case	Minnesota	Stanford	Vanderbilt
Frequency of Speaking English at Home with Family	How often do you speak English at home with your family? (Choose one.)		X	X	
	If you do not always speak in English at home with your family, what languages do you speak the rest of the time?	X	*X*		
WIC	Do you participate in WIC? WIC stands for Women, Infants, and Children, a Federal assistance program.	X	X		X
Food Stamps/ SNAP	Does anyone in your household receive food stamps or SNAP? SNAP stands for Supplemental Nutrition Assistance Program.	X	X	X	X
Unemployment/ Social Security/ Disability	Does anyone in your household receive Unemployment, Social Security, or Disability Benefits?	X	X	X	
Education Completed	What is the highest degree or level of school that you have completed?	X	X	X	X
	What is the highest degree or level of school that your child's other parent living in the household or adult caregiver living in the household has completed?	X	X	X	X
Child Care	In a usual week, how much time does this child spend being cared for by someone other than parent/guardian?				
	in your own home		X	X	X
	in someone else's home		X	X	X
	in childcare center/after school program		X	X	X
Household Income	What was your total household income from all sources before taxes last year? By "household", we mean that you should report the combined income of everyone in your home.	X	X	X	X
Child Health Insurance	Is your child covered by a health insurance plan?	X	X	X	
	Which type of plan are they covered by?	X	X	X	
Free or Reduced Price Breakfast or Lunch	Does any child in your household receive free or reduced price breakfast or lunch at school?		X	X	
Maturation Status	Has your daughter started having her menstrual period?	X		X	

Construct	Item	Case	Minnesota	Stanford	Vanderbilt
	When did she have her first menstrual period?	X		X	
Breastfeeding/ Pregnancy Risk	Did <this child> breastfeed for more than a month?	X	X		X
	How old was <this child> in months when he/she first received a bottle of formula, cow's milk, water, juice, tea, or cereal at least once a day?	X	X		X
	How much did this child weigh at birth?	X	X		X
	Did a doctor say that <you/birth mother> had diabetes when pregnant with <this child>?	X	X		X
	Did a doctor say that <you/birth mother> had hypertension (high blood pressure) when pregnant with <this child>?	X	X		X
Food Security	"The food that (I/we) bought just didn't last, and (I/we) didn't have money to get more." Was that often, sometimes, or never true for (you/your household) in the last 12 months?	X[3]	X	X	X
	"I/we couldn't afford to eat balanced meals." Was that often, sometimes, or never true for (you/your household) in the last 12 months?	X[3]	X	X	X
	In the last 12 months, since (date 12 months ago) did (you/you or other adults in your household) ever cut the size of your meals or skip meals because there wasn't enough money for food?	X[3]	X	X	X
	How often did this happen -- almost every month, some months but not every month, or in only 1 or 2 months?	X[3]	X	X	X
	In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money to buy food?	X[3]	X	X	X
	In the last 12 months, were you ever hungry but didn't eat because you couldn't afford enough food?.	X[3]	X	X	X
TV & Media	How many working TVs do you have in your home?	X[1]	X	X	
	Is there a working TV in the room where <this child> sleeps?	X[1]	X	X	X

Construct	Item	Case	Minnesota	Stanford	Vanderbilt
	Is there a computer in your home?	X[1]	X	X	X
	Is there a computer in the room where <this child> sleeps?	X[1,2]	X	X[2]	X
	Is there a video game player in your home?	X[1]	X	X	
	Is there a video game player in the room where <this child> sleeps?	X[1]	X	X	X
	Do you have Internet access in your home?	X[1]	X		
	On an average WEEK day, how many hours does <this child> watch TV?		X		X
	On an average WEEKEND day, how many hours does <this child> watch TV?		X		X
	On an average day, how many hours does <this child> play video or computer games, or use a computer for something that is not school work? (Include activities such as Play Station, Xbox, hand held video games, computer games, and the Internet.)		X		X
Food Norms	During the past seven days, how often did your family eat breakfast together?		X		X
	During the past seven days, how often did your family eat lunch together?		X		X
	During the past seven days, how often did your family eat dinner together?		X		X
Weight Status	How would you classify your own weight?	X	X	X	X
	How would you classify <this child's> current weight?	X	X	X	X

1 – The TV/Media questions for Case are derived from a group of embedded scale questions
2 – Case and Stanford uses the term "desktop" computer in their question.
3—Case questions are embedded into a survey and are not administered as an interview.

Table 9.4: Source and Response Sets of Questionnaire Common Measures

Construct	Item	Response Options	Source
Household Configuration	For all children and adults living in your household, please tell me:		Developed
	Gender,	Male; Female	
	Birth date or age	MMDDYYYY; __ __ yrs	
	Relationship to the participating child.	Mother; Father; Stepmother; Stepfather; Other male CG, (list); Other female CG, (list)	
Child's date of birth	Child's date of birth	MMDDYYY	Developed
Child's sex	What is this child's sex?	Male; Female	HHS data standards (Dorsey & Graham, 2011)
Child Ethnicity	Is this child Hispanic, Latino/a, or of Spanish origin? (Choose all that apply.)	No, not of Hispanic, Latino/a or Spanish origin; Yes, Mexican American, Chicano/a; Yes, Puerto Rican; Yes, Cuban; Yes, Another Hispanic, Latino/a or Spanish origin	HHS data standards (Dorsey & Graham, 2011)
Child Race	Which of the following best describes your child? (Choose all that apply.)	American Indian or Alaskan Native Asian; Black or African American; Native Hawaiian or Pacific Islander; White; Other (please describe)	U.S. Census, 2010
Parent Ethnicity	Are you Hispanic, Latino/a, or of Spanish origin? (Choose all that apply.)	No, not of Hispanic, Latino/a or Spanish origin; Yes, Mexican American, Chicano/a; Yes, Puerto Rican; Yes, Cuban; Yes, Another Hispanic, Latino/a or Spanish origin	HHS data standards (Dorsey & Graham, 2011)
Parent Race	Which of the following best describes you? (Choose all that apply.)	American Indian or Alaskan Native Asian; Black or African American; Native Hawaiian or Pacific Islander; White; Other (please describe)	U.S. Census, 2010
Parent Country of Birth	In what country were you born?	USA; Mexico; Somalia; Laos/Thailand/Vietnam; Other (please describe)	Marin Acculturation Scale
Child Country of Birth	In what country was this child born?	USA; Mexico; Somalia; Laos/Thailand/Vietnam; Other (please describe)	Modified Marin Acculturation Scale
Years Parent Lived in USA	How many years total have you lived in the United States?	_ _ yrs	Marin Acculturation Scale
Employment Status	What is your employment status?	Working full time; Working part time; Not working for pay	Developed
Marital Status	What is your current marital status?	Married or living as married; Single	Developed
Access to Car	Is there a car that you can use whenever you need to?	Yes and I drive; Yes but I don't drive; No	Developed

Construct	Item	Response Options	Source
Frequency of Speaking English at Home with Family	How often do you speak English at home with your family? (Choose one.)	Never; Sometimes; About ½ the time; Most of the time; Always	Marin Acculturation Scale
	If you do not always speak in English at home with your family, what languages do you speak the rest of the time?	*Free text*	
WIC	Do you participate in WIC? WIC stands for Women, Infants, and Children, a Federal assistance program.	Yes; No; Don't know	Developed
Food Stamps/ SNAP	Does anyone in your household receive food stamps or SNAP? SNAP stands for Supplemental Nutrition Assistance Program.	Yes; No; Don't know	Developed
Unemployment/ Social Security/ Disability	Does anyone in your household receive Unemployment, Social Security, or Disability Benefits?	Yes; No; Don't know	Developed
Education Completed	What is the highest degree or level of school that you have completed? (Choose one answer.)	6th grade (elementary school) or less; 7th - 8th grade (attended some middle school/junior high); 9th - 12th grade (attended some high school); High school graduate (received diploma or the equivalent, GED for example); Completed some college credit, (or technical school) but no degree; Technical degree; Associate's degree; College degree; Master's, Professional, or Doctoral degree	Modified U.S. Census, 2010
	What is the highest degree or level of school that your child's other parent living in the household or adult caregiver living in the household has completed? (Choose one answer.)	6th grade (elementary school) or less; 7th - 8th grade (attended some middle school/junior high); 9th - 12th grade (attended some high school); High school graduate (received diploma or the equivalent, GED for example); Completed some college credit, (or technical school) but no degree; Technical degree; Associate's degree; College degree; Master's, Professional, or Doctoral degree	Modified U.S. Census, 2010
Child Care	In a usual week, how much time does this child spend being cared for by someone other than parent/guardian…		Developed

Construct	Item	Response Options	Source
	in your own home?	0 Hours; 1-10 Hours; 11-20 Hours; 21-30 Hours 31-40 Hours; 41+ Hours	
	in someone else's home?	0 Hours; 1-10 Hours; 11-20 Hours; 21-30 Hours 31-40 Hours; 41+ Hours	
	in childcare center/after school program?	0 Hours; 1-10 Hours; 11-20 Hours; 21-30 Hours 31-40 Hours; 41+ Hours	
Household Income	What was your total household income from all sources before taxes last year? By "household", we mean that you should report the combined income of everyone in your home.	$14,999 or less; $15,000 - $24,999; $25,000 - $34,999; $35,000 - $49,999; $50,000 - $74,999; $75,000 - $149,999; $150,000 - $199,999; $200,000 or more; Don't know; I prefer not to answer	Developed
Child Health Insurance	Is your child covered by a health insurance plan?	Yes; No; Don't know	
	Which type of plan are they covered by?	Medicaid, Medicare, CHIP, state funded, or other federally funded; Private - through work or purchased individually; Military; Other, type unknown; Don't know	
Free or Reduced Price Breakfast or Lunch	Does any child in your household receive free or reduced price breakfast or lunch at school?	Yes; No; Don't know	Modified from TAAG2
Maturation Status	Has your daughter started having her menstrual period?	Yes; No; Don't know	Developed
	When did she have her first menstrual period?	MMYYYY	Developed
Breastfeeding/ Pregnancy Risk	Did <this child> breastfeed for more than a month?	Yes; No; Don't know	Schwarz et al. 2010
	How old was <this child> in months when he/she first received a bottle of formula, cow's milk, water, juice, tea, or cereal at least once a day?	_ _ mos.	Schwarz et al. 2010
	How much did this child weigh at birth?	_ _ lbs _ _oz	Schwarz et al. 2010
	Did a doctor say that <you/birth mother> had diabetes when pregnant with <this child>?	Yes; No; Don't know	Schwarz et al. 2010
	Did a doctor say that <you/birth mother> had hypertension (high blood pressure) when pregnant with <this child>?	Yes; No; Don't know	Schwarz et al. 2010
Food Security	"The food that (I/we) bought just didn't last, and (I/we) didn't have money to get more." Was that often, sometimes, or never true for (you/your household) in the last 12 months?	Often true; Sometimes true; Never true; Don't know; Refused	USDA (Bickel, 2000)

Construct	Item	Response Options	Source
	"I/we couldn't afford to eat balanced meals." Was that often, sometimes, or never true for (you/your household) in the last 12 months?	Often true; Sometimes true; Never true; Don't know; Refused	USDA (Bickel, 2000)
	In the last 12 months, since (date 12 months ago) did (you/you or other adults in your household) ever cut the size of your meals or skip meals because there wasn't enough money for food?	Yes; No; Don't know; Refused	USDA (Bickel, 2000)
	How often did this happen -- almost every month, some months but not every month, or in only 1 or 2 months?	Almost every month; Some months but not every month; Only 1 or 2 months; Don't know; Refused; Not asked	USDA (Bickel, 2000)
	In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money to buy food?	Yes; No; Don't know; Refused	USDA (Bickel, 2000)
	In the last 12 months, were you ever hungry but didn't eat because you couldn't afford enough food?.	Yes; No; Don't know; Refused	USDA (Bickel, 2000)
TV & Media	How many working TVs do you have in your home?	*text*	Derived from Borzekowski, 1999; Robinson, 1999; Robinson et al., 2010
	Is there a working TV in the room where <this child> sleeps?	Yes No	
	Is there a computer in your home?	Yes No	
	Is there a computer in the room where <this child> sleeps?	Yes No	
	Is there a video game player in your home?	Yes No	
	Is there a video game player in the room where <this child> sleeps?	Yes No	
	Do you have Internet access in your home?	Yes, No, Don't Know	
	On an average WEEK day, how many hours does <this child> watch TV?	None Less than 1 hour per day 1 hour per day 2 hours per day 3 hours per day 4 hours per day 5 or more hours per day	Schmitz et al., 2004
	On an average WEEKEND day, how many hours does <this child> watch TV?	None Less than 1 hour per day 1 hour per day 2 hours per day 3 hours per day 4 hours per day 5 or more hours per day	Schmitz et al., 2004

Construct	Item	Response Options	Source
	On an average day, how many hours does <this child> play video or computer games, or use a computer for something that is not school work? (Include activities such as Play Station, Xbox, hand held video games, computer games, and the Internet.)	None Less than 1 hour per day 1 hour per day 2 hours per day 3 hours per day 4 hours per day 5 or more hours per day	Modified Schmitz et al., 2004
Food Norms	During the past seven days, how often did your family eat breakfast together?	0 times 1-2 times 3-4 times 5-6 times 7 or more times	Developed
	During the past seven days, how often did your family eat lunch together?	0 times 1-2 times 3-4 times 5-6 times 7 or more times	Developed
	During the past seven days, how often did your family eat dinner together?	0 times 1-2 times 3-4 times 5-6 times 7 or more times	Developed
Weight Status	How would you classify your own weight?	Very Underweight Underweight Normal Overweight Very Overweight	Modified Birch et al., 2001
	How would you classify <this child's> current weight?	Very Underweight Underweight Normal Overweight Very Overweight	Modified Birch et al., 2001

Table 9.5: Vanderbilt University Site-Specific Mediators and Moderators

Construct	Respondent	# Questions
Acculturation	Parent	4
Behavior change/goal setting/monitoring	Parent	6
Daily Physical Activity	Parent	2
Parenting around eating	Parent	45
Healthy Snacks and Drinks	Parent	2
Daily Serving of Fruits and Vegetables	Parent	2
Monitoring Sugar and Fiber	Parent	1
Meal Planning	Parent	1
Portion Control and Plating	Parent	2
Sleep	Parent	6
Group Cohesion	Parent	8
Social Network	Parent	8
Parenting Self-efficacy	Parent	16
Eating Location	Parent	2
Community Center Use	Parent	3
Stress	Parent	10
Parent Depression	Parent	21
Built Environment	Parent	85
Time Spent with Child	Parent	2
Exclusive Breastfeeding	Parent	1
Preterm Birth	Parent	1
Fast Food	Parent	1
Cognitive Functioning	Child	Series of tasks

9.1.3. Common Mediators, Moderators and Secondary Outcomes

9.1.3.1. Accelerometry

Background and Rationale: Physical activity (PA) will be measured objectively using a commercially available ActiGraph GT3X+ (all youth). For parents and other adults GT3X+ accelerometers (Vanderbilt) or GT3X accelerometers (Minnesota) will be used. (ActiGraph, Pensacola, FL). The rationale for using ActiGraph is that among currently available devices it provides consistent and high quality data supported by feasibility, reliability, and validity testing in children and adults.

ActiGraph monitors have been used in numerous studies to assess PA in children (Freedson, Pober et al. 2005; Cliff, Reilly et al. 2009; De Vries, Van Hirtum et al. 2009; Reilly 2010). The

validity of the ActiGraph has been examined in several studies involving children aged 2 to18 years. ActiGraph has been validated using direct observation (Kelly, Reilly et al. 2004; Sirard 2005; Hands 2006), doubly labeled water (DLW) (Montgomery, Reilly et al. 2004; Reilly, Kelly et al. 2006), indirect calorimetry (Garcia 2004; Schmitz, Treuth et al. 2005; Pate, Almeida et al. 2006; Trost, Way et al. 2006; Choi, Chen et al. 2010) and other accelerometers (Garcia 2004; Kelly, Reilly et al. 2004) as reference methods. Correlations between ActiGraph counts and observed activity was moderate to high (r = 0.52-0.77) in older ActiGraph models (Kelly, Reilly et al. 2004; Sirard 2005; Hands 2006) and higher in a newer ActiGraph (GT1M) model and when using more advanced algorithms (Choi, Chen et al. 2010). Although the validity of ActiGraph GT3X and GT3X+ models in populations including children has not be reported, it is expected to be at least as high or higher than the GT1M and older ActiGraph models.

The GT3X+ and GT3X contain electronic motion sensors consisting of piezo-electric sensors that generate an electric charge in response to a mechanical force, thus, acceleration. They do not respond to constant acceleration. Their major advantage is that no power supply is required, except for data storage, resulting in a considerable reduction in the size and weight of the device. Both monitors provide activity counts, vector magnitude, and inclinometry data. Other data calculated by the ActiGraph manufacturer-provided software includes activity intensity levels, energy expenditure (METs) and number of steps.

The GT3X+ collects data in the raw format at a pre-defined sample rate from 30 to 100 Hertz (Hz). When collecting data at 40 Hz, the battery life is stated to be 13 days and the data memory lasts for 16 days. The GT3X has the ability to collect 1-second epoch data for at least 7 days. The GT3X does not have adequate data storage capacity to collect raw data for multiple days.

Accelerometry technology is still improving and mathematical models to predict PA and PA-related energy expenditure are being developed. We expect these advances to continue. Thus, COPTR investigators will collect raw acceleration data in the index child that could be used to measure physical activity and sedentary behavior using both currently existing algorithms and new algorithms/approaches that emerge during the study (next 6 years). Table 9.6 summarizes the specifications of the GT3X devices.

Table 9.6: Specifications of the GT3X devices

Specifications	**GT3X+**	**GT3X**
Transducer	Tri-axis, solid state accelerometer	Tri-axis, solid state accelerometer
Dynamic Range	+/- 3G	+/- 3G
Dimensions	4.6cm x 3.3cm x 1.5cm	3.8cm x 3.7cm x 1.8cm
Capacity	16 Days (Raw data at 40 Hz)	16MB or 400 Days (60 sec epoch)
Battery Life	13 Days (Fully Charged at 40 Hz)	20 Days (Fully Charged)
Weight	19 g	27 g
Resolution	12-bit A/D conversion; 1.46 mG (Raw Data)	12-bit A/D conversion; 1.46 mG (Raw Data)
Sample Rate	30Hz-100 Hz	30 Hz

Limitations of accelerometry.

Accelerometers are the best currently available relatively simple and precise device for objectively assessing physical activity and sedentariness. However, they do not provide

information on types of activities, nor can they be used to assess lifestyle activities such as raking and shoveling, static activities such as bicycling and weight lifting, and aquatic activities such as showering and swimming. These limitations may be addressed as new algorithms emerge during the course of the study. Other limitations are related to use and application of collected data in device-specific arbitrary counts (PA counts) or more comparable approach of using acceleration (m/sec^2) to summarize accelerometry data.

Objective: Accelerometry monitoring will provide an objective measurement of the amount and patterns of physical activity and sedentary behavior.

Methods: Accelerometry data on children and parent (Minnesota and Vanderbilt) will be collected at four common data collection time points – baseline, 12 months, 24 months and 36 months. All baseline accelerometer data will be collected prior to randomization. The GT3X+ will be set to 40-Hertz frequency and the GT3X will be set to 1-second epoch.

The index children in the study will wear the GT3X+ monitor on the right hip for seven complete days (including while sleeping and naptime) except during water activity (e.g., bathing, swimming, showering). The responding parent in Minnesota and Vanderbilt will also wear the GT3X and GT3X+ monitor, respectively for seven days on their right hip. A consensus has been reached that the monitoring period should include two weekend days and five weekdays. In some cases, participants may be able to provide only 6 days of data, which is acceptable. If the participant does not wear the activity monitor for four days, it may be necessary to have the participant wear the monitor again in order to get valid data. The valid wear time criteria (minimums) are 4 days (3 weekdays and 1 weekend day) of at least 6 hours of awake time with 33% non-zero epochs per hour. For some participants, accelerometer data for the 2 wears will be combined in order to meet the minimum wear time criteria.

Any major updates in the ActiLife software version used during the trial will be made as a collaborative decision by the Diet and Physical Activity Working Group. If a change does occur, it will be on the same calendar day for all Field Sites. Regular (minor) updates in the ActiLife software will be done by each Field Site as they are released by ActiGraph. The Accelerometer Manual of Procedures will be updated only after major updates in the ActiLife software (e.g. Version 6.0 to Version 7.0).

COPTR will use a “train the trainer” model. Each field center will have at least two activity monitor master trainers who will participate in a central in-person training organized by the RCU at the University of North Carolina at Chapel Hill on April 16-18, 2012. Following part 1 of the training session, the master trainers will wear the accelerometer for at least 8 hours. The certification process requires the master trainer to successfully initialize, download and transfer accelerometer data. The master trainers will train and certify additional research staff at their site. Data collectors/staff do not initialize or download accelerometer data until after they have been trained and certified.

9.1.3.2. Dietary Assessment

Background and Rationale: The 24-hour recall is the most widely used method to assess diet in studies of populations, and is used in national food consumption surveys such as the NHANES. This method allows assessment of all foods, beverages and dietary supplements

consumed during the 24-hour period obtained – typically beginning with the first item consumed the previous day. The 24-hour method, which can be performed face-to-face or by telephone, has been validated in lean and obese individuals.(Conway, Ingwersen et al. 2004) In face-to-face interviews, the use of visual aids such as food models, food portion booklets and measuring utensils improves the accuracy of estimation of quantities consumed.(Moshfegh 1999) For telephone interviews, visual aids and instructions are often mailed to subjects.(Posner, Smigelski et al. 1992) In addition, with a trained interviewer, they are relatively quick and easy to administer. An important strength of the 24-hour recall method is that it allows comparison of groups of individuals by demographic variables such as age, gender, race/ethnicity or geographic region. Another strength is that the 24-hour recall (Nutrition Data Systems for Research or NDSR) has been used to generate Healthy Eating Index scores, and thus to assess dietary quality.(Miller, Mitchell et al. 2011) The main limitations of capturing quantitative dietary intake information by use of 24-hour recalls are: 1) the variability in day-to-day dietary intakes; 2) reliance on subject memory; and 3) the potential of over or underreporting of intakes. To compensate for these possible limitations, interviewers typically capture data on more than one day of the week which includes both weekdays and weekend days, and use the USDA 5-step multi-pass method.(Moshfegh 1999)

Objective: The purpose of performing dietary intake assessment is to capture quantitative nutrient information on all the foods, beverages and dietary supplements that study subjects consume. The dietary intakes are analyzed for: volume of food, total energy, macronutrients, micronutrients, water, dietary fiber, added sugars and specific food groups. We will also examine glycemic load, dietary energy density, nutrient adequacy ratios, and dietary pattern and quality. Examples of diet quality indices used in children are shown in Table 9.7.

Table 9.7: Examples of dietary quality indices used in children

Citation	Subjects			Diet Assessment	Group/Index	Methods
	N	Sex	Age			
Daniels, EJCN, 2009	1,810	m/f	2y	24 hr recall	Diet Diversity score(DDS-10g) - FAO (score 1-9)	Cross-sectional: 1 pt per 10g of a each food group or 1 pt for 1g oil.
Feskanich, JAmDietAssoc, 2004	16,452	m/f	9-14y	132 item FFQ	Youth HEI- 13 components (score 0-100)	Modified HEI and compared to YHEI (Note: YHEI not strongly related to energy intake).
Freedman, JNutr, 2010	17,311	m/f	□2y	24hr recall	HEI-2005: 12 dietary components	NHANES ('01-'04) data- 3 part model (they create) based on Tooze 2- part model(Tooze, Midthune et al. 2006) in >1000 subjects.
Guenther, JAmDietAssoc, 2008	8,650	m/f	□2y	24 hr recall	HEI-2005	NHANES ('01-'02) compared HEI-2005 assessed validity through 4 methods (concluded valid).
Kennedy, JNutr, 2007	3,164	m/f	24-71 mo	24 hr recall	Diet Diversity Score (DDS) – 10 food group & DDS-10g	Filipino Nutrition Database. DDS summed unique food groups for score. DDS-10g required minimum amounts (see: Daniels, 2009).
Manios, JAmDietAssoc, 2009	2,287	m/f	2-5y	24 hr recall + weighed records + food diaries	HEI- 10 component	Weighed records were used in nurseries and recalls or diaries were used outside nurseries. Summed individual scores- used quartiles of the scores for analysis.
Steyn, Public Health Nutr, 2006	2,200	m/f	1-8y	24 hr recall	DDS- following FAO guidelines Food Variety Score (FVS) (Score 0-45)	Secondary analysis of NFCS in South Africa. 1 24 hr recall by caregivers. Also used nutritional adequacy ratio and mean adequacy ratio.
Serra-Majem, EJCN, 2003	3,166	m/f	6-24y	24 recall +16 item FFQ	KIDMED- Mediterranean diet measure (Score: -3 to 12)	Assessed diet from Spanish children has high, med, low KIDMED.
Kranz, JAmDietAssoc, 2006	5,437	m/f	2-5y	24 recall	Created new- RC-DQI	Continuing Survey of Food intakes by individuals (1994-1996, 1998) components chosen based on My Food Pyramid, ADA, and APA recommendations (Nutrient-based)
Hurley, JNutr, 2009	317	m/f	11-19	131 item- youth/ adolescent FFQ	Compared HEI and YHEI	Compared the indices to body composition and found HEI better correlated with body composition and disease risk.
LaRowe, JAmDietAssoc, 2010	135	m/f	2-5	24 hr recall	My Food Pyramid	Great Lakes Inter-Tribal Council Head Start programs- baseline data from HCSF intervention.

Citation	Subjects			Diet Assessment	Group/Index	Methods
	N	Sex	Age			
Cheng, JNutr, 2010	376	m/f	6-8y	3-day weighed record	Nutritional Quality Index (NQI)- Density measure RC-DQI- nutrient based	German Cohort

Methods: Dietary Intakes will be measured using 24-hour recalls that are conducted on two weekdays and one weekend day per study time-point using NDS-R version 2012. Any update in the NDS-R version during the trial will be made as a collaborative decision by the Diet and Physical Activity Working Group. If a change does occur, it will be on the same calendar day for all Field Sites with one caveat. Participants who have already completed 1 or 2 recalls in the old version of NDS-R will have their remaining recalls conducted using the same older version of NDS-R such that all 3 recalls are collected using the same version of NDS-R.

Dietary assessment data will be collected at baseline, and 12, 24 and 36 months during the study. All baseline dietary assessment data will be collected prior to randomization. Table 9.8 summarizes the specific data collection plans for each Field Site. To avoid collecting days with similar foods, recalls should not be conducted on consecutive days. In addition, in order to capture variability of food supplies in the home, all three recalls should not occur within a seven day period. The third recall needs to be collected more than one week after the first recall. All three recalls must be collected within 30 days. This is a hard deadline.
While the goal is to collect three dietary recalls per participant, it is possible that a limited number of participants at each Field Site may only have two dietary recalls completed within the 30 day window. All efforts will be made to obtain a minimum of two recalls (1 weekday and 1 weekend) for each participant. All dietary intakes (i.e., food, and beverages including water) will be collected. For Diet Recall of young children, those responsible for child feeding (e.g. parents, daycare providers) will be the reporter. Details of the procedures to be used in dietary assessment are in the COPTR Manual of Procedures for Dietary Assessment.

COPTR will use the "train- the- trainer" model. Each field center will have two diet master trainers who will participate in a central in-person training organized by the RCU at the University of North Carolina at Chapel Hill on April 16-18, 2012. Following the training session, the master trainers will complete two dietary recalls for certification by the RCU. The master trainers will train and certify additional research staff at their site. No diet recalls will be conducted until after the trainer has been trained and certified.

Table 9.8: Site specific 24 hour dietary recall data collection plans

	Case	Minnesota	Stanford	Vanderbilt
Number of recalls	3	3	3	3
# weekdays	2	2	2	2
# weekends	1	1	1	1
Recaller	Child & parent	Parent & day care provider	Child & parent	Parent & day care provider
How collected (1^{st}, 2^{nd}, 3^{rd})	In-person Telephone Telephone	In-person In-person/Telephone In-person/Telephone	In-person Telephone Telephone	Telephone Telephone Telephone
Announced/ Unannounced	Announced	Announced	Unannounced	Announced
Language administered	English	English, Spanish	English, Spanish	English, Spanish
Use of Portion Size Devices	Food Booklet	Food Booklet	Food Booklet	Food Booklet

9.1.4. Site-Specific Mediators, Moderators and Secondary Outcomes

All data will be collected at the intervention or control site by trained bilingual study personnel. Prior to collecting data, all study personnel will undergo training certification to ensure consistent, standardized data collection methods.

Table 9.9: Vanderbilt secondary outcomes

Item	Measurement Tool	Description	Respondent [Parent (P) or Child (C)]	Method	Collection Time	Site-Specific?
BMI	Scale, stadiometer	Change in BMI over time	P	Weight (kg)/height (m^2)	$T_1 – T_6$	No
Body Fat % (Triceps Skin Fold)	Caliper	Change in % body fat over time	P	Staff measured	$T_1 – T_6$	No
Waist Circumference	Measuring tape	Change in waist circumference	P	Staff measured	$T_1 – T_6$	No

Table 9.10: Vanderbilt mediators and moderators

Domain	Measurement Tool	Description	Respondent [Parent (P) or Child (C)]	Method	Collection Time	Site-Specific?
Physical Activity	Accelerometer (GT3X+)	Sedentary activity (% sedentary mins/total wearing time)	P, C	Parent and child accelerometer wear (≥4 days, ≥6 hrs/day)	T_1, T_4, T_6	No
	GROW developed survey questions related to intervention messages	Self-reported physical activity habits	P	Computerized Survey (2Q)	$T_1 – T_6$	No
Nutrition	Diet Recall Parent's Child's	Total calories and macronutrient content (% fat, protein, carbohydrate) adherent to USDA recommendations	P	3-day parent and child diet recall (parental report for child)	T_1, T_4, T_6	Yes No
	GROW developed survey questions related to intervention messages	Parent and child eating and feeding habits	P	Computerized Survey (8Q)	$T_1 – T_6$	Yes

Social Network	GROW developed Social Network Survey	Assessing social networking and its influence on behavior modification	P	Computerized Survey (20Q)	T_1 – T_6	Yes
	Bollen & Hoyle Perceived Cohesion Scale	Assessing group cohesion	P	Computerized Survey (2Q)	T_1, Wk 4, T_6	Yes
			P	Computerized Survey (3Q)	T_1, Wk 4, T_6	Yes
Parenting Practices	GROW developed Advice Scale Comprehensive Feeding Practices Questionnaire (CFPQ)	Assessing information sharing Parenting approaches to child feeding	P	Computerized Survey (45Q)	T_1 – T_6	Yes
Eating Together	HHHK - Eating Behaviors subscale	How often meals are eaten together	P	Computerized Survey (3Q)	T_1 – T_6	No
	GROW developed survey questions related to intervention messages	Where meals are eaten together	P	Computerized Survey (3Q)	T_1 – T_6	Yes
Sleep	GROW developed survey questions related to intervention messages	Parent and child sleeping habits	P	Computerized Survey (6Q)*	T_1 – T_6	Yes
Media Use	Stanford (GEMS/ ECHALE) developed questions	Media available in household	P	Computerized Survey (3Q)	T_1 – T_6	No
	YRBS subscale	Child's media use	P	Computerized Survey (3Q)	T_1 – T_6	No
Use of Rec Center	GROW developed survey questions related to intervention messages	Parent and child knowledge and use of rec center outside of GROW activities	P	Computerized Survey (3Q)	T_1 – T_6	Yes
Perception of the Built Environment	Participant Physical Activity and Neighborhood Supports Survey	Parent knowledge of the resources in the built environment	P	Computerized Survey (40Q)	T_2	Yes

Stress	Cohen's Perceived Stress Scale (PSS)	Assesses current levels of parental stress	P	Computerized Survey (10Q)	T_1 – T_6	Yes
Depression	Center for Epidemiological Studies-Depression Scale (CES-D)	Assesses levels of parental depression	P	Computerized Survey (21Q)	T_1 – T_6	Yes
Goal Setting and Monitoring	GROW developed survey questions related to intervention messages	Ability to set and track goals	P	Computerized Survey (6Q)	T_1 – T_6	Yes
Working Memory	Stroop Day-Night Task & 9 Box Test	Executive functioning/ working memory	C	Hands-on Tasks	T_1, T_6	Yes
Literacy	Peabody Picture Vocabulary Test III (PPVT-III)	Child literacy aptitude	C	Survey (1Q)	T_1, T_6	Yes
Weight Perception	COPTR common survey questions	Current perception of parent's and child's weight	P	Computerized Survey (2Q)	T_1 – T_6	No
Self-Efficacy	Parenting Sense of Confidence (PSOC)	Confidence around parenting decisions	P	Computerized Survey (16Q)	T_1, T_2, T_4, T_6	Yes
[redacted]						
Demographics	See section 9.1.2.	See section 9.1.2.	P	Computerized Survey (17Q)	T_1	No**
Genotype	Oragene kit (adult), baby brush (child)	Genetic risk score	P, C	Genotyping saliva	T_1	No
Perinatal Health	Updated questions from KA Dept of Health WIC intake	Maternal gestational health, birth weight, and breastfeeding habits	P	Computerized Survey (5Q)	T_1	No**
Health Literacy	The Newest Vital Sign (NVS)	Understanding food label information	P	Computerized Survey (5Q)	T_1	Yes
Food Security	USDA 2008 subscale	Financial barriers affecting availability of food in the home	P	Computerized Survey (7Q)	T_1	No
Intelligence	Stanford-Binet Intelligence Scales (Early SB5)	Standard intelligence measurement	C		***	Yes

Q = Survey Questions
*** Some accelerometry data will be used to assess sleeping behaviors**
****Some site-specific questions have been added in addition to the common questions in these areas**
*****Timing to be determined**

In addition to the above, we will also monitor Metro Community Center programming and policy changes. The tools utilized for these assessments will be finalized with input from the formative research phase.

9.2. Quality Control

9.2.1. Primary Outcome

Ten percent (10%) of the measurements (height and weight) that compose the primary outcome (BMI) and the other anthropometric measurements (waist circumference and triceps skinfold) are measured by two different data collectors. Ideally one of the data collectors is a Master Trainer. The method used to select the 10% sample is site specific and is incorporated into the site's data management system to track who requires the second measurer. Duplicate measures are recorded to confirm inter-rater reliability, but the first data collection staff's measurements will be used in the analysis. To be acceptable, the absolute difference between the calculated values by the two data collectors must be less than 0.5 cm for height, 0.3 kg for body mass, 1 cm for waist, and no larger than 2 mm if the skinfold is less than 10 mm or greater than 10% if the skinfold is 10 mm or larger. If a data collection staff's agreement on a measurement (height, weight, waist circumference or skinfold) is outside this range in more than two out of ten individuals, then he/she must complete retraining.

Range checks are built into the data management system to prevent the collection of erroneous data. The 2003-2010 NHANES was used to determine age and gender-specific range checks for the anthropometric variables. Range checks are set so that participants with extreme and erroneous values are brought to the attention of the data collection staff for scrutiny.

The bounds for range checks in the baseline data collection vary by center since the anthropometric eligibility criteria for enrollment of index children vary.

9.2.2. Demographic Variables

The demographic variables are collected via questionnaires along with additional mediator variables (e.g. food security, tv and media). The survey collection, review and editing procedures are site specific. The RCU monitors for missing and out of range values on the common questions across the Field Sites.

9.2.3. Common Mediators, Moderators and Secondary Outcomes

Physical activity is measured by accelerometry. Because activity levels change daily and the test retest relationships would be low, participants are not asked to wear the activity monitor twice for quality control. In addition, an interview is not a good quality control check since it does not provide the necessary data for a comparison, and thus are not used for quality control. The RCU monitors and reports the amount of data (e.g. the number of valid days, number of re-wears). The valid wear time criteria (minimums) are 4 days (3 weekdays and 1 weekend day) of at least 6 hours of awake time with 33% non-zero epochs per hour. For some participants, accelerometer data for the 2 wears will be combined in order to meet the minimum wear time criteria.

The dietary interviewer reviews and edits the 24-hour dietary recall as soon as possible after its administration. During editing, special attention is paid to NDS-R Missing Foods, Priority

Notes and all other Notes. Full quality assurance must be conducted on at least 10% of recalls. The quality assurance checks include ensuring information is entered correctly in header tab, meal information window, food tab and trailer tab. In the header tab the goal is to make sure information is filled in correctly (e.g. ID, Date of intake, Site ID). The meal information window should have meals in order by time and the eating and activity codes entered correctly. The quality assurance checks in the food tab include checking that foods entered correctly, amounts match code, missing foods and priority notes are resolved. Recalls that have issues that need to be resolved are put into the FIX project. All data must be cleaned and missing foods, or priority notes must be resolved before the output file is run and sent to the RCU on a quarterly basis. All missing foods are discussed at diet interviewer staff meetings. There will be quarterly reviews of data entry issues and shared user recipes to standardize the data entry process across all sites.

In SAS or other statistical package a quality assurance report is run to generate for each record total energy, percent kilocalories from fat, fruit servings, vegetable servings and grams of fluid. Ranges are set for school aged children and preschool aged children. Records with values beyond the cutoff points below are printed and checked.

	School Aged Samples	Preschool Samples
Total Energy	<500; >2500	<250; >1200
% kcal from fat	<25%; >45%	<25%; >45%
Fruit Servings	>3	>2
Vegetable Servings	>3	>2
Grams of Fluid	<300; >2000	<200; >1500

9.2.4. Site-Specific Mediators, Moderators and Secondary Outcomes
Please see the Process Evaluation table in section 7.3. for specific evaluation and quality control procedures for mediators, moderators, and secondary outcomes.

9.3. Measurement Schedule
The table and figure in this section outline and illustrate the measurement collection schedule. Refer to the tables in section 9.1. for specific measurement schedule information.

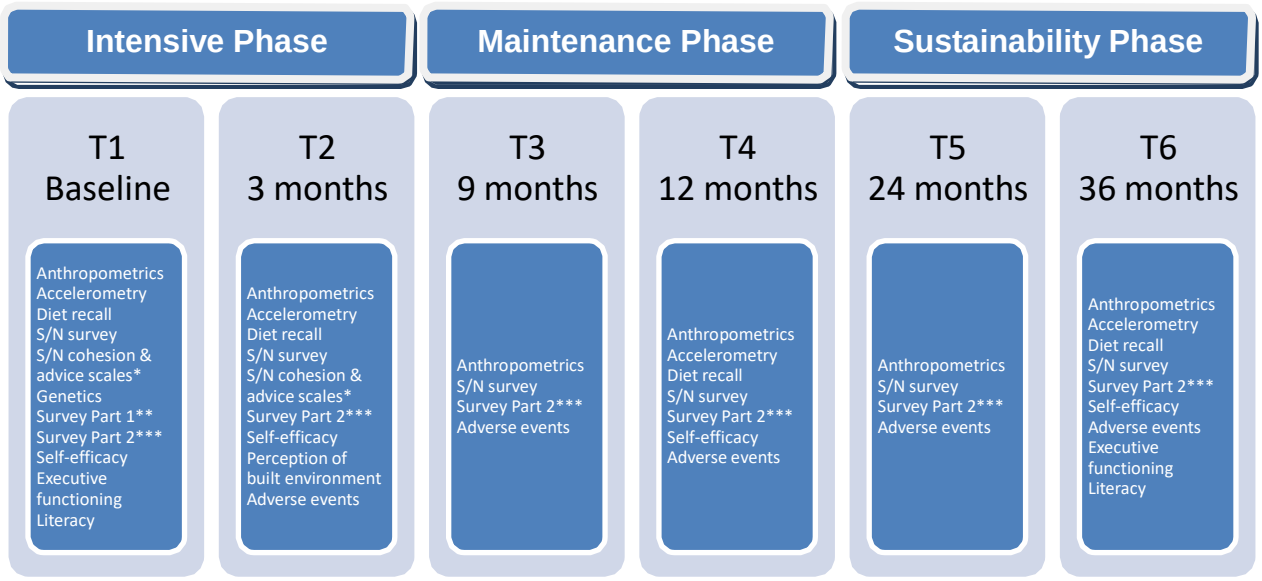
Table 9.11: Data collection schedule

Item	T1 Baseline	Wk 4	T2 3 months	T3 9 months	T4 12 months	T5 24 months	T6 36 months
Anthropometrics	☐		☐	☐	☐	☐	☐
Accelerometry	☐		☐		☐		☐
Diet Recall	☐		☐		☐		☐
Social Network Survey	☐*		☐	☐	☐	☐	☐
Social Network Cohesion/Advice Scales	☐*	☐	☐				
Genetics	☐						
Survey Part 1: Demographics, Perinatal Health, Food Security, Health Literacy, Intelligence	☐						

Survey Part 2: Nutrition, Eating Together, Media Use, Sleep, Parenting Practices, Rec Center Use, Goal Setting/Monitoring, Problem Solving, Depression, Stress, Weight Perception	☐		☐	☐	☐	☐	☐
Self-Efficacy	☐		☐		☐		☐
Perception of Built Environment			☐				
Adverse Events			☐	☐	☐	☐	☐
Executive Functioning	☐						☐
Literacy	☐						☐

*"T1" social network surveys will not be administered until session 1

Figure 9.1: Data collection schedule by phase



*In addition to T1 and T2, social network cohesion/advice will be surveyed on Week 4 of the intensive phase

**Survey Part 1 = Demographics, Perinatal Health, Food Security, Health Literacy

***Survey Part 2 = Nutrition, Eating Together, Media Use, Sleep, Parenting Practices, Rec Center Use, Goal Setting/Monitoring, Problem Solving, Depression, Stress, Weight Perception

10. PARTICIPANT SAFETY AND ADVERSE EVENTS MONITORING

10.1. Potential Risks and Protection against Risks

Although adverse events are not anticipated from the nature of this low-risk study, all volunteers will be covered by the Vanderbilt policy to provide all necessary care to subject volunteers who experience an adverse event during a study. The investigator or designate is responsible for the detection and documentation of adverse events (AE) and serious adverse events (SAE) in persons participating in this study. At each data collection point during the study period, the investigator or site personnel will document any AEs or SAEs, as detailed in this protocol. AEs and SAEs will be reported to National

Institutes of Health as outlined in the following sections. A telephone number will be provided to participating parent-child dyads who will be asked to immediately report any adverse events. At Vanderbilt, any potential adverse events (such as physical injuries, excessive weight loss, malnutrition, hypoglycemic events, ER visits, and hospitalizations) and any concerns from participants will formally be assessed monthly by Dr. Barkin and forwarded to the RCU and DSMB as per COPTR protocol. Dr. Barkin will be responsible for responding to these phone calls or concerns. If a subject concern is reported, Dr. Barkin will consult with the Independent Safety Monitor to assess severity and determine if the event is related to participation in the study. If the study intervention is implicated in the adverse event the caregiver and their child will be removed from the study, an adverse event report will be generated, and notifications of the Vanderbilt IRB and other appropriate authorities will occur. The report will include a description of the event, when and how it was reported, as well as any official chart records or documentation to corroborate the event or the reporting of the event. All adverse events will be graded as mild, moderate, or severe. The level of attribution to the protocol will also be documented. Any severe and/or unanticipated adverse event will be immediately reported to the IRB. All other adverse events will be reported in a timely fashion to the IRB, preferably within 2 weeks of the date of the event. All adverse events will be summarized annually and submitted to the IRB and NHLBI. Any action resulting in a temporary or permanent suspension of this study (e.g. IRB actions, or actions by the investigators or co-investigators) will be reported to the appropriate NIH program official. The final protocol will be refined through the relevant COPTR subcommittee.

10.2. Potential Benefits

There are no direct benefits to the families for their participation in this study. Indirect benefits include: adults will learn things they can do as parents to improve their child's wellbeing, be introduced to other families with children, and spend time with their children.

10.3. Safety Monitoring Plan

The following section outlines the respective action responsibilities of different study parties:

PI:

1. Evaluate AE for attribution to study, severity, action taken and outcome.
2. Report all SAEs and unexpected events to RCU, DSMB, IRB and NHLBI.
3. Notify DSMB and IRB of any new safety information.
4. Provide written response to DSMB and IRB action plans, if required.
5. Provide meeting minutes and AE reports to DSMB.
6. Respond to any DSMB recommendations.
7. Evaluate study components and content for appropriateness and report AE associated with these components to DSMB.
8. Evaluate need for participant referral to community resources for support and treatment.

Research Coordinator:

9. Complete IRB AE Report for each event.
10. Provide PI appropriate documentation for review and recommendations.

DSMB:

11. Insure protocol has specified guidelines regarding the identification and procedures for reporting AE.
12. Review summary reports and tabulations of AE.
13. Recommend continuation, modification, suspension of study based on event significance.
14. Notify IRB of recommendations to modify or suspend study.
15. Maintain written record of all communication, assessments and recommendations as well as materials reviewed.
16. Ensure review process is free from conflicts of interest.

Subjects who consent:

17. Provided with phone contact info for immediate reporting to PI and IRB.
18. Assured in informed consent document of care and insurance coverage for usual and customary fees for treatment of injuries related to study.
19. AE reports and annual summaries will not include subject-identifiable material, only subject identification number.
20. Will be given an opportunity to answer AE and SAE questions for themselves and their child who is the focus of the study.
21. Will be alerted and provided appropriate resources for treatment if CES-D total score indicates severe depression (i.e., a CES-D total score of 27 or greater).

.

10.4. Informed Consent Documents

Please see Appendix 1 for the current informed consent documents.

11. STUDY DESIGN, STATISTICAL CONSIDERATION AND ANALYSIS PLAN

11.1. Study Design

The design of the study is a longitudinal non-blinded (open) randomized control trial, comparing participants in an obesity prevention treatment program to those in a non-specific literacy-based educational control group. The trial will take place over six years and consist of three overlapping cohorts who will enter the study 9 months apart and each remain in the trial for three years. The trial will be conducted at two separate sites (region One, East Nashville, and region Two, South Nashville). Within each site, 100 parent-child dyads with children ages 3-5 years will be randomly assigned, stratified according to parent language use (English or Spanish), to either the three-year prevention program or the control condition, yielding 200 dyads per cohort (100 per region/site), and a total sample size of 600 (200 per 3 cohorts). Assessments will occur over 6 time points within each cohort, beginning at baseline and including assessments post-intervention (at 12 weeks/3 months), and at 9, 12, and 36 months from baseline.

11.2. Primary Research Question and Hypothesis

Our primary research question is about the impact of the GROW trial on the growth rate of children's BMI over time. Specifically, we hypothesize the following:

Hypothesis 1: The BMI trajectories of children in the treatment group will accelerate at a slower rate than those in the control group over time.

11.3. Primary Outcome

Although childhood obesity is a well-documented public health concern, most studies have assessed the obesity outcome (e.g., BMI) using only a single time point or incorporating a pre-post design, leaving us with little knowledge about the actual shape or growth rate of trajectories of BMI during this critical period of development. Indeed, few studies have taken a developmental perspective in order to understand how and when obesity develops in early childhood. By measuring BMI at multiple time points, we will examine growth trajectories in early childhood. This will allow us to examine the effect of a prevention program on these varying trajectories.(Agras, Hammer et al. 2004; Pryor, Tremblay et al. 2011) As Barker et al. demonstrated, it is the change in BMI over time in early childhood, rather than BMI at any one time point, that is linked with health consequences in adulthood.(Barker, Osmond et al. 2005) Moreover, an earlier childhood adiposity rebound is associated with an increased risk of later obesity.(Rolland-Cachera, Deheeger et al. 1984; Cole 2004) Because clinical literature about childhood obesity indicates that the shape of the BMI trajectory across ages 3 to 8 is curvilinear, we will account for this in our analytic plan.(Kuczmarski, Ogden et al. 2002; Cole 2004) (see below).

11.4. Primary Analysis

11.4.1. Statistical model and approach

For our primary analysis, which will be an intention-to-treat analysis, we will fit the following quadratic mixed model equation (some subscripts suppressed for readability):

$$BMI = \beta 0C+\beta 1I+\beta 2(age-X)C + \beta 3(age-X)2C + \beta 4(age-X)I + \beta 5(age-X)2I + ... + error\ terms$$

where:

1. "I" is an indicator for group and equals 1 for the intervention group and 0 for the control group; "C" is an indicator for group and equals 1 for the control group and 0 for the intervention group; there is no intercept in this model in the 'traditional sense' (see point 2 below);
2. "X" is the value at which we center age; we plan to use age at enrollment as our centering term, which will make the indicator variables interpretable (β_0 as the mean BMI at enrollment for those in the control group and β_1 as the mean BMI at enrollment for the intervention group);
3. "..." stands for other predictors; at the present time, we believe that the predictors for the main model will be gender (coded, e.g., as 1 for female and 0 for male) and ethnicity (we expect there to be 3 ethnicity groups and thus 2 indicator variables for these); in addition, gender by age interaction terms will be included, since the literature indicates that trajectories may differ by gender;

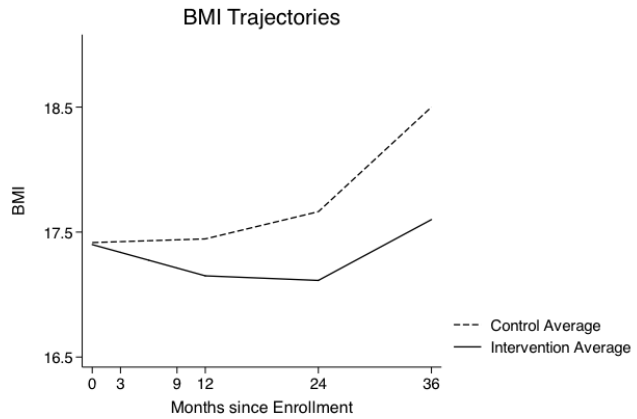
4. For the primary analysis, "error terms" will include subject, subject X age, and the covariance between these random effects, using a heterogeneous variance structure for the fitted model (Roberts & Roberts, 2005). For the primary analysis, we will not include a random effect for subject X age2, given that, with our proposed unstructured covariance matrix, the inclusion of this additional random effect would result in 13 random-effects components and may lead to convergence problems (see Rabe-Hesketh & Skrondal, 2012, page 348). We will examine the consequences of this choice via planned secondary analyses (see below, section 11.8).
5. A post-hoc test of whether β3 = β5 will allow us to examine whether the quadratic terms differ between arms of the trial, thus answering our primary research question.

Interpretation of some terms: the indicator variable for trial arm, the linear term (age) for trial arm, and the quadratic term $(age)^2$ for trial arm jointly describe the trajectory (and starting point) for each group (intervention and control), and each can be interpreted as follows: the constant is the mean BMI at age on entry into the trial; the linear term indicates the rate of change at entry age; and the quadratic term indicates change in rate of growth (acceleration). In our specification, this model allows each child to have her/his own BMI intercept at baseline and own BMI trajectory. Accordingly, we do not include BMI at baseline as a predictor in our model. Additionally, we do not include a BMI by treatment interaction, because BMI is an outcome and treatment is a predictor. We plan to examine a baseline BMI by treatment interaction (as well as other interactions) in our secondary analysis (see below).

Our hypothesis is that β_5, the quadratic term for the intervention group, will be significantly different from β_3, the quadratic term for the control group, at the 0.05 level. We do not have an hypothesis about the linear terms. Note that we expect the sign of β_5 to be positive, and we expect the coefficient to be smaller than the coefficient for β_3.

A graphical view of the above description is provided below in Figure 11.1 (we have suppressed the lines for the individual age groups for readability); note that the actual model will produce smooth curves instead of the piece-wise linear curves shown in the graph.

Figure 11.1: Projected BMI trajectories over time



11.4.2. Assumptions with justification

Assumptions Pertaining to Potential ICC among BMI Trajectories:
We will have three waves of recruitment with 200 parent-child dyads/wave (100 dyads/arm). The control group will gather in unchanging groups in local libraries, where we expect little-to-no correlation even though children will stay in their original session for the entirety of the study. The intervention group utilizes a social network building component and will have pre-specified parent groups that will continue throughout the study. The intervention group will attend one of two community recreation centers (50 dyads/community recreation center/wave). Typically, we will divide these dyads evenly across three weekly sessions. **The session is our subgroup (cluster) of interest.** Each session will have approximately 17 families in it. If the size of the subgroup remains constant over time, the total number of subgroups we will have is 36, i.e., 600/(50/3).

It is also worth noting that we will further subdivide the 17 families of an intervention session into 2 smaller subgroups of 8-9 families. This division is done to facilitate our activities and encourage interaction among these smaller subgroups. It will also likely facilitate the development of social networks among these groups, which we hypothesize to be related to improved health outcomes for the treatment group over the course of our intervention. If we take this smaller subgroup as the unit for the intervention group, our total number of subgroups is 54, i.e., 18+36, or [300/(50/3)]+[300/(50/6)], where the first square bracket is the number of subgroups in the control group (where subgroups are not broken down into smaller subgroups), and the second square bracket is the number of subgroups in the intervention group.

The social networking aspect within the intervention group and the smaller group size lead us to predict a positive but small ICC that may be higher than what we expect to be a small ICC in the control group. Note, however, that session membership is well-defined for both the intervention arm and control arm, as participants will have minimal movement between sessions. This leads us to propose a heterogeneous variance structure for the primary analysis, allowing the ICC at the level of session to be estimated separately for the intervention and control arms.

Checking and Sensitivity Analyses: Once a model has been estimated, we will need to investigate its properties not only to ensure that any data idiosyncrasies do not impact the results but also to help ensure that the results are generalizable. The first issue is to check for systematic differences between the model and the data using graphs, such as comparisons of predicted and observed values of BMI, and other standard diagnostics.(Snijders 2008) An extension of this idea is to simulate new sets of outcomes, based on our model, and use the simulated data as a reference test group by comparing this set to the observed result; in this case, we would look for situations in which the data appear different from what we would expect by using the model to predict the data.(Gelman 2007)

A second issue is whether we have left out important features of the model, including, for example, (1) age at randomization, (2) measurement occasion, (3) study wave (by which we mean enrolled in first year, second year, or third year of the program), or (4) other demographic variables (e.g., SES, parent level of education) or substantive covariates (e.g., maternal depression). Some of these variables will be tested explicitly as moderators or mediators (see previous sections pertaining to moderators and mediators as well as sections 11.6 and 11.7 below). In addition, trajectories may vary by baseline BMI; this possibility will be checked by estimating a model with a baseline BMI by treatment group interaction. We will estimate additional models that include one or more of these additional features to check whether inclusion of any of these predictors is both statistically reasonable and affects our conclusions.

A third issue is whether age is correctly specified. With 6 data points, a limit exists as to what can reasonably be done. We suggest that the quadratic model should be checked in two ways: (1) substitute linear splines with a break between, for example, ages 4 and 5 (anticipated adiposity rebound timing); (2) substitute non-linear splines, in particular, restricted cubic splines with 4 knots chosen following Harrell's default positions.(Harrell 2001)

11.4.3. Missing data including level of attrition, lost to follow-up, and missing data treatment

Estimated Attrition: Within each planned cohort of 200 dyads per three cohorts, six waves of data collection will occur, with shorter time intervals between the earlier waves and longer time intervals later. According to prior community-based studies, subject dropout decelerates over time, with the worst losses occurring early. We will make every effort to reduce attrition, with particular focus on the earlier waves of the study, to ensure that we retain at least 80% of our sample within each cohort, yielding a cohort size of at least 160 and a total sample size, at study end, of at least 480. This level of attrition would leave us sufficiently powered (.90) to be able to detect a standardized effect size of .40 (a respectable and common effect size unique to the analytic method we are using--see sample size and power analysis section). An even larger sample size will increase the power to detect a meaningful difference, as explicated in the power analysis and sample size section below, and we will strive to ensure that the sample is

as large as possible at each successive wave. In addition, it is important to note that our analysis is an intention-to-treat analysis. Accordingly, we will use all cases in our analyses, even those with as few as one wave of data, such that attrited cases will not truly be lost but instead retained in our analytic procedures.

Missing Data: Conceptually, we anticipate two types of missing data: (1) people who drop out after a measurement occasion and never return [i.e., lost to follow up]; and (2) people who miss one or more particular measurement occasions (e.g., occasion 3) but are present for each of the others, at least one of which is later in time than the one (or more) that they missed.

With 6 repeated measurements, some participants inevitably will miss one or more occasions of outcome data collection. One advantage of the mixed models over older repeated measure ANOVA models is the use of all available data without dropping any subjects.(Nich and Carroll 1997) We begin by assuming that the missing occasions meet MCAR or MAR assumptions.(Little and Rubin 2002) If so, the results of the mixed model (e.g., the effect of time, group by time) are robust.

To guard against missingness biasing results, we will also conduct secondary analyses of missingness to see how realistic the assumption of MAR or MCAR may be. This check can be done in several ways. We will start with descriptive statistics comparing the characteristics of observations with and without missing values (e.g., gender, baseline BMI, age at enrollment, etc.). The first analysis will use standard multiple-imputation with 100 imputations.(Little and Rubin 2002) Three possible directions, in addition to standard diagnostics,(White, Royston et al. 2011) can be pursued when checking whether being missing is non-random (i.e., in checking the results of the multiple imputation):

1) The first method is our primary suggestion: we will impute the data using standard multiple imputation (MI) software but with constraints on the values that can be imputed. These constraints arise because our prime concern regarding non-random missingness is that either those who don't need the program (i.e., those who are lean) or those who perceive that they are not seeing an effect (i.e., who are, and remain, overweight) will miss occasions. For example, in one set of imputations we would constrain all imputed BMIs to be below, say, “a”; in a different set, we would constrain the imputed BMIs to be above, say, “b”; this type of constrained MI is discussed in An and Little(An, Little et al. 2010) and Jenkins, Burkhauser, Feng, and Larrimore(Jenkins, Burkhauser et al. 2011). One hundred imputations will be used for each such constrained MI. We will examine the BMI pattern of those who drop out and, if we see evidence of either "a" or "b", use the values we observe to set the constraints.
2) A second possible type of sensitivity analysis was originally suggested by Rubin (1987) and has been extended by Carpenter, Kenward, and White,(Carpenter, Kenward et al. 2007) who suggest weighting each imputed result (rather than Rubin's standard simple averaging of the results), where the weight depends on the assumed departure from the MAR assumption. Their technique relies on at

least one strong assumption, but they provide a graphical diagnostic to help check this assumption.

3) If drop-outs (situation 1 above) are much more common than missing an occasion and then returning (situation 2 above), we will estimate a pattern-mixture model.(Little 1993; Hedeker and Gibbons 1997) If missing one or more occasions and then returning is relatively common, however, we will not pursue this strategy.

11.5. Detectable Difference, Sample Size, and Power

Power and Sample Size Estimation: The power analysis was performed on our primary analysis (see below): a quadratic model of the BMI trajectories. For our sample size estimation, we used the OD(Spybrook 2011) software so that we would be consistent with our planned analysis. This software allowed us to examine two-group repeated-measures trials with quadratic change, the same model being used for the analysis.

This software uses a standardized effect size as defined in Raudenbush and Liu, namely, the group difference on the polynomial trend divided by the "population standard deviation of the polynomial trend of interest" (p. 391; the "population standard deviation" refers to the square root of the variance of the random effect).(Raudenbush and Xiao-Feng 2001) This specification, particularly the denominator, is quite different from cross-sectional standardized effect sizes such as Cohen's D, given that, with a polynomial model (here quadratic), the difference between groups depends on the point in time examined. In particular, given our hypothesis (see below), we expect that, after adiposity rebound is reached, the BMI of children in the intervention group will grow more slowly than that of children in the control group such that the differences between their mean BMIs will increase over time**.** Our expectation implies that we are interested in the significance of the quadratic term in the model, and expect that the difference between the control and treatment group quadratic effect will be significantly different from zero.

We note one difference between the OD program's assumptions and our study: the OD program assumes that the measurement occasions will be equally spaced over time, which is not the case in our study. As a result, specifications from the OD program may lead us to overestimate power and underestimate sample size. Power is high in the current study, as can be seen in the table below, thus we expect that these potential mis-estimations are not problematic.

To determine the power and effect size of the current study, we need estimates of the standardized effect size, which we obtained from a subset of our previous Salud Con La Familia study. We used only a subset of the Salud subjects because the inclusion criteria for that study (i.e., children at any level of baseline BMI) were broader than for the current study (i.e., children whose baseline BMI is between the 50th and 95th ([or 99th] percentile). For our estimations, then, we used only the Salud data for those from the 50th to the 95th percentile (and then again from the 50th to the 99th percentile [see below]). Other important differences exist between Salud and the current study,

however, that limit our ability to estimate power and sample size based solely on Salud: (1) the Salud subjects had only 3 measurement occasions which covered 15 months rather than 6 occasions over 3 years (the GROW trial) and (2) the Salud intervention was comparable only to the 12-week intensive phase proposed in the GROW study and did not include a maintenance or sustainability phase as proposed in the GROW trial. We expect that the increased number of sessions as well as the intensity of the intervention in the GROW trial will serve only to increase the power of the GROW study.

When using the OD software, the user can set various values, the most important of which is the standardized effect size discussed above. Other possible values to set include the duration of the study (here, 3 years), the number of measurement occasions (here 6), and the variance of the residuals and the variance of the random effects. We found that even fairly sizable changes in value used for the residuals and the variance of the random effects had little effect on the projected sample size (e.g., holding other elements constant and changing the variance of the random effect of age-squared from the observed standard deviation of 2.8 [based on the Salud data] to the OD program's default of 1, only increased the sample size at a power of 0.8 by about 20 subjects). Using the program defaults for residuals and variance of the random effects was a conservative (i.e., produced larger estimates of sample size) approach compared to using the results based on Salud, thus we used these defaults in the table below. Changing the standardized effect size does have important consequences for the estimated sample size, however (see Table 1).

As previously stated, we used the Salud data to estimate our primary model (see below) for those within that study who were between the 50th and 95th BMI percentiles at baseline. The control group in the Salud data showed unexpected results with virtually no non-linearity (i.e., their BMI trajectories increased but in a linear fashion over a 15 month period), therefore we believe that the effect size from that model, which was quite large and based on different assumptions, is an overestimate of the effect that we will see in the GROW study. Instead we used the OD program default for the effect size of 0.4, a commonly used effect size in longitudinal studies and thus the OD program default, to estimate our required sample size. Accordingly, Table 1, below, indicates, for powers of 0.7, 0.8, and 0.9, the estimated sample size using the OD program for the default effect size (0.4) and for two additional effects sizes, a smaller and more conservative effect size (0.3) and a larger and more liberal effect size (0.5). As the table below indicates, we estimate that recruiting a sample size of at least 480 will leave us adequately powered to determine this middle/medium effect size of 0.4.

Table 11.1: Estimated required sample size for given standardized effect sizes

Power/Effect Size	Sample size for Standardized Effect size = 0.3	Sample size for Standardized Effect size = 0.4 *(OD program default)*	Sample size for Standardized Effect size = 0.5
70.00%	500	285	186
80.00%	640	360	232

90.00%	860	480	308

Because the results of our pilot study currently underway have led us to consider including children with higher baseline BMI in the GROW trial than we had originally planned, we also estimated our primary model on Salud participants who were between the 50th and 99th percentile of baseline BMI to determine the effects of including these children with a higher BMI. While, as expected, the variance increased when we moved to the model that added children between the 95th and 99th percentiles, the difference between groups (control and intervention) also increased such that the standardized effect size changed very little and, thus, there was virtually no effect on power (i.e., the desired sample size, under various conditions, never changed by more than 2 people). If, then, we decide to extend our criteria in the GROW trial to include children who are in the 95th to 99th percentile of BMI at baseline, our analyses will continue to be sufficiently powered.

Currently, the design for the GROW trial includes 600 children, and, though we would expect to be adequately powered at a smaller number of subjects, we plan to recruit 600 subjects to allow for potential attrition. We note, however, that if recruitment of that higher number of subjects becomes problematic (and we have observed in our current pilot study the difficulties inherent in recruitment for a similar prevention trial), we will stop subject recruitment at a smaller number of subjects, though ideally not less than 480 (see Table 1), such that we are adequately powered.

11.6. Analysis for Possible Effect Modifiers

The variables that are listed in the previous section as moderators (e.g., race/ethnicity, genetic risk score, etc.) will be entered appropriately into the analytic model as interaction terms in order to test the effect of the moderator on the outcome (child BMI trajectory). Relevant three-way interactions (e.g., child gender by age by group) will also be tested.

11.7. Analysis for Possible Effect Mediators

The variables that are listed in the previous section as mediators/covariates will be entered into the analytic model as time-varying covariates and their effects on the outcome will be assessed accordingly, controlling for all else in the model.

11.8. Secondary Hypotheses and analysis

Secondary Analyses: We list below two sets of secondary analyses. The first is specific to our primary analysis (see Aim 1, Hypothesis 1); the second is specific to the secondary aims and related hypotheses (see Aims 2-6) and contained under section 11.9 (below).

Secondary Analyses in relation to the Primary Hypothesis and Analysis

1) Timing of adiposity rebound: We anticipate that we will be able to characterize and capture the timing of adiposity rebound for many of the children enrolled in

the study. At time of enrollment, each child is at least 3 years of age and is less than 6 years of age (and we will know, including fractions, how old they are at enrollment by collecting their date of birth); measurement occasion 6 will occur at least 3 years after enrollment. Using these conditions, those who enroll on their third birthday will be at least 6 years old at measurement occasion 6 (and everyone else will be older); in this scenario it is reasonable to assume that most subjects who enroll at age 3 will have reached adiposity rebound by measurement occasion 6, although we will miss some children who have earlier/later rebound timing. Also, virtually all children who enroll at age 4 should experience adiposity rebound during the study, but a few might be earlier than 4 or later than 7-plus. Finally, the majority of those who enroll at age 5 should experience adiposity rebound during the study, but a minority will have rebounded prior to age 5. Note that the mean age at adiposity rebound is a simple function of the coefficients from the main model: $-\beta 2/(2*\beta 3)$ will be the nadir for the control group (and a similar calculation captures the intervention group: $-\beta 4/(2*\beta 5)$).

2) The effect of parental change in BMI over the study period on child's growth trajectory: In this study, this effect will be modeled by including baseline BMI of the parent as a predictor, and also including other measures of parent BMI as time-varying covariates (i.e., the value of the covariate depends on the measurement occasion).
3) We will test the difference between mean BMI for both groups at the end of the trial (36 months) to determine whether they are significantly different from one another, thus adding additional information to our analyses.
4) We will test whether the trajectories of both normal and overweight children in the treatment group accelerate at a slower rate than those in the control group over time, such that those in the treatment group will be less likely to evidence trajectories of obesity compared to those in the control group. Each child will be categorized as having, or not having, an acceptable BMI trajectory. This binary variable will be the outcome variable for this secondary analysis. We will test this first, in an unadjusted analysis (a 2 by 2 table where one variable is the outcome variable and the other is group [control or treatment]), and then in an adjusted analysis using logistic regression. Predictors in the logistic regression will include demographics (e.g., gender) and various baseline variables, including the baseline BMI weight category (i.e., normal or overweight).
5) In a series of secondary analyses, we will examine the random-effects in more detail:
    1. Using our original fitted model, we will impose an independent covariance matrix (which assumes no correlation between random effects), reducing the resulting number of random effects from 7 to 5. The results of this change to the model will inform us about the next two steps (see below).
    2. We will add the two age-squared terms (for intervention and control) as random effects, continuing to use the independence structure, and bringing the number of random effects back to 7.
    3. Keeping the two age-squared terms as random effects, we will return to an unstructured covariance matrix, bringing the number of random-effects to 13.

4. At each step in the above process, we will evaluate the results of continuing to add additional random effects terms, including noting model convergence problems. While we believe the model with 13 random effects will have reduced power and thus do not propose this model for our primary analysis, we believe that fitting this model in a secondary analysis, via the systematic steps outlined above, will allow us to examine the consequences of including a large number of random effects and determine the viability of this alternate model.

6) It is possible that in addition to different ICC's per condition, variability may occur across sessions within condition, such that a range of ICCs exists. If that range is determined to be sufficiently wide, we will consider adding cluster-adjusted standard errors for both the fixed and random-effects. Note that this type of standard error is a generalization of the traditional sandwich estimator; StataCorp has provided a FAQ on this generalization with citations: http://www.stata.com/support/faqs/stat/robust_ref.html.

11.9. Additional Analyses

Secondary Analyses in relation to the Secondary Aims and Hypotheses
In addition to the above analyses, we will conduct analyses necessary to support our secondary aims of the trial, as outlined below.

Aim 2: Evaluate the effect of the intervention on children's activity levels and dietary behaviors
Hypothesis 2: Either or both activity level and adherence to age-specific USDA nutrition recommendations will mediate the relationship between the intervention and child BMI trajectories. Specifically, relative to children in the control condition, children in the intervention condition will
2.1 Have lower sedentary activity levels (as measured by actigraphy data) after the intensive phase of the intervention (T2) and these lower levels will be associated with slower BMI growth rates and/or
2.2 Have better adherence to age-specific USDA nutrition recommendations, (e.g., age-appropriate total calories increased, fruits and vegetables, decreased sugar sweetened beverages [measured via diet recall data]), after the intensive phase (T2) and this better adherence will be associated with slower BMI growth rates. .

Analysis:
(2.1) A multiple regression model in which child BMI is regressed on group, controlling for baseline sedentary activity level and including other relevant covariates (e.g., child gender) and including T2 sedentary activity level as a mediator, will be fit..
(2.2) Each child will be categorized as evincing, or not evincing, adherence to age-specific USDA recommendations (as defined in the hypothesis). This binary variable will be the mediator variable for this secondary analysis. We will fit a multiple regression model in which child BMI is regressed on group, controlling for baseline adherence and including other relevant covariates (e.g., child gender), and including the T2 binary adherence variable as a mediator of child BMI.

Aim 3: Evaluate the effect of parents' physical activity levels and dietary behaviors on children's levels of the same.

Hypothesis 3: Parents' activity level and/or adherence to age-specific USDA nutrition recommendations will mediate the relationship between child levels of the same, the intervention, and child BMI trajectories. Specifically, parents who have significantly lower sedentary activity levels (compared to baseline) after treatment and/or who have better adherence to USDA nutrition recommendations (age-appropriate total calories increased fruits and vegetables, decreased sugar sweetened beverages [measured via diet recall data]) will be more likely than parents who have higher sedentary activity levels or who do not adhere to USDA nutrition recommendations to have children who will show

3.1: Decreased sedentary activity levels post-treatment and

3.2: Better adherence to USDA nutrition recommendations (as measured in 2.2, above).

Analysis:

Two binary predictors will be created denoting whether parents have significantly lower sedentary activity compared to baseline (yes/no) and whether they have appropriate versus inappropriate dietary adherence (yes/no). These dichotomous variables will be entered as mediators into models as follows:

(3.1) A multiple regression model will be fit in which child BMI l is regressed on group, controlling for baseline child sedentary level and other relevant covariates [e.g., gender]).and including the child T2 activity level and the parent activity variable as a mediator. Similarly, the model will be re-fit to analyze the effect of the parent adherence variable.

(3.2) A multiple regression model will be fit in which child BMI l is regressed on group, controlling for baseline child dietary adherence and other relevant covariates [e.g., gender]) and including the child T2 adherence variable and the parent activity variable as a mediator. Similarly, the model will be re-fit to analyze the effect of the parent adherence variable.

Aim 4: Explore the potential for developing new social networks and their effect on child nutrition and physical activity.

Hypothesis 4: Parents in the treatment group will develop new social networks and the strength of those social networks will be positively associated with reduced sedentary activity levels and improved dietary behaviors (measured as indicated above) among both parents and children. Specifically, the type (e.g., network of discussion partners where ties are weighted by how close they feel to each other) and total number of social networks will mediate the effect of the intervention on child and parent nutrition and physical activity level.

Analysis:

A social network analysis will be conducted to determine the strength and cohesion of parents' reported networks. The survey will be administered at all time points to determine the number of networks. The cohesion measure will be administered at T1, 4 weeks after T1, and again at T2. The effect of these networks on parental and child

sedentary activity levels and dietary behavior will be estimated. Social network analysis will be conducted using the software packages UCINET and In-Flow. UCINET will be used for entering and analyzing network data and, along with In-flow, for generating network measures and graphical displays. This data set will thus contain both network and attribute variables at the individual level of analysis. Applying standard statistical techniques (e.g., regression, logistic regression, etc.) these independent variables will be modeled with selected dependent variables. The analysis will examine the change in these social networks over time and their impact on the main outcomes of interest including: growth trajectories (children's BMI); body composition (child and adult), parenting practices (child feeding); physical activity (child and adult), and total energy intake. The social network hypothesis suggests that members of a given network group will share health behavior characteristics more than members of other groups.

Aim 5: Evaluate the moderating relationship between genetic risk factors and child BMI trajectories over the course of the study.
Hypothesis 5: Higher levels of child genetic susceptibility to obesity (i.e., a higher genetic risk score (Kathiresan, Voight et al. 2009)) will be significantly associated with heavier-for-age BMI at baseline, and this susceptibility will moderate children's growth in BMI over time.

Analysis:
"Heavier-for-age-BMI at baseline", the outcome, will be regressed on genetic risk score and the interaction between risk score and time, controlling for other covariates as deemed important (e.g., child gender, etc.).

Aim 6: Assess the degree to which implementation of the GROW program encourages additional lifestyle programming for preschool children and their parents in the Metro Community Centers.
Hypothesis 6: The two Metro Community centers participating in the GROW trial will implement a higher number of activity or nutrition programs for families (as defined by the centers) with young children at the end of the study compared to the number they implemented at baseline, and they will also implement a higher number after the study compared to the number implemented by non-participating Metro Community Centers.

Analysis:
A simple count of the number of activity and nutrition programs will be taken at baseline within both Community Centers (i.e., East and Coleman) and then again at the end of the study to determine whether the number at study end within each center exceeds that at baseline. Similarly, counts will be taken of these types of programs at non-participating Metro Community Centers at baseline and study end and these numbers will be compared to counts at both East and Coleman to determine if both participating centers have higher numbers than the non-participating centers at baseline and at study end.

12. DATA MANAGEMENT & QUALITY CONTROL

12.1. Common Database

The COPTR Data Center was designed after extensive discussions with representatives from all of the sites to provide a secure, easy, and effective set of tools for submitting Common Measures to a central repository for the consortium. Each of the four Field Sites has a site-specific data system for conducting the daily tracking and data collection.. The COPTR Data Center does not dictate how those disparate site systems are designed or used. Instead, the Data Center provides a set of web-based tools for sites to upload completed Common Measures to the central repository at the RCU.

Field Sites collect a subset of the Common Measures following the protocols and manual of procedures (MOPs) for those common measures. The common measure subsets for each Field Site differ slightly but the MOPs and protocols defining the measurement/collection procedures are identical. The recruitment data elements identified for submission to the RCU are identical at each Field Site. Each Field Site submits the current collection of common measures quarterly and the recruitment and retention data monthly to the RCU to be included in the central data store of the Consortium. Variables collected at only one Field Site are not transferred to the RCU.

One or more representatives from each Field Site have been designated as members of the Data Capture Working Group. These representatives contributed to the design of the Data Center tools and continue to contribute to improved functionality of the Data Center site. These representatives also serve as the primary contacts at a Field Site when the RCU notices irregularities with the submitted data.

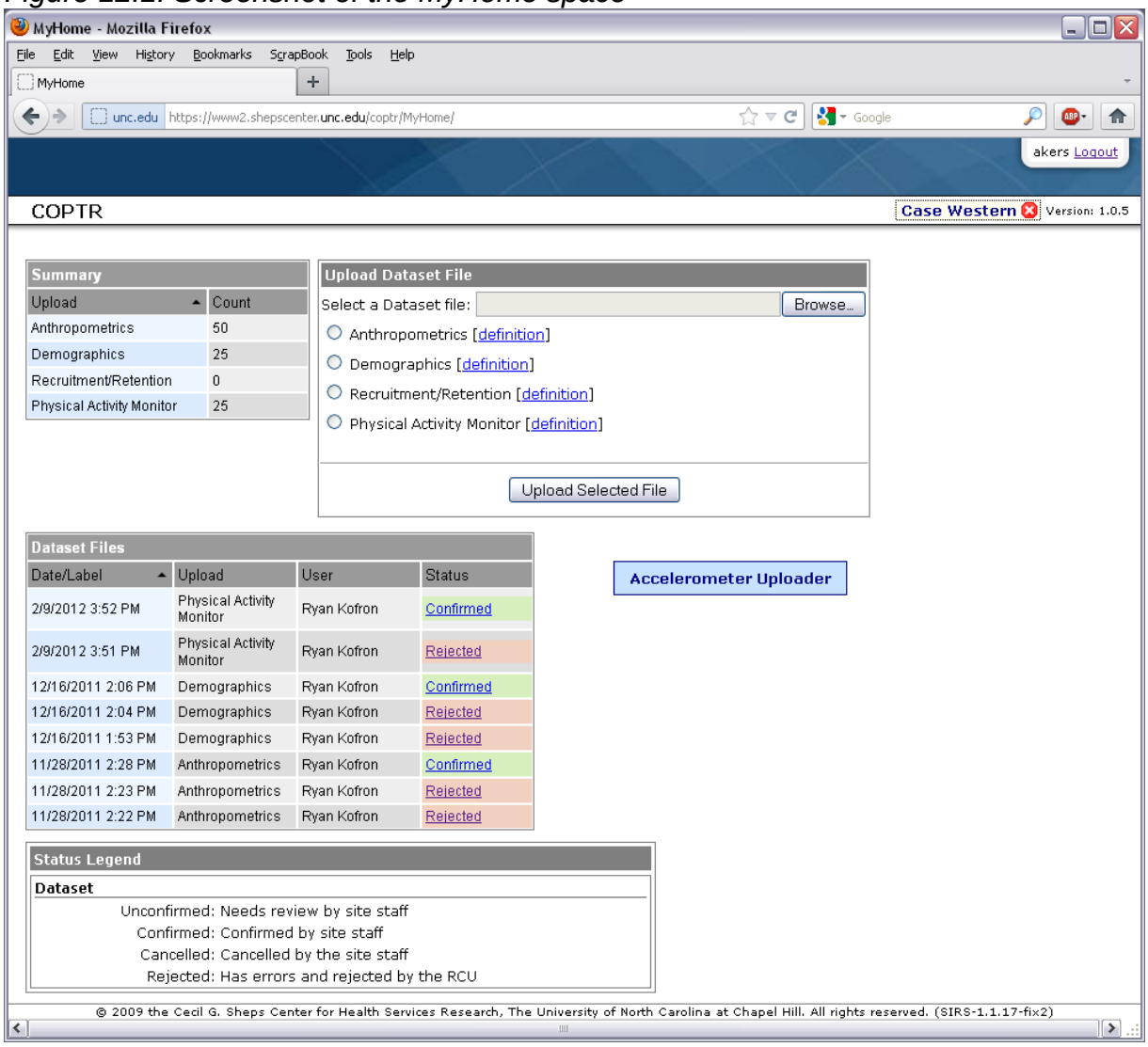
The RCU data transfer system utilizes a restricted access website to provide encrypted transfer of data files containing common measures (measurements collected at more than one Field Site) to a central data repository at the RCU. Each Field Site will have one or more project staff authorized to have access to the Data Center website. An individual at a site must receive authorization from the site's PI prior to getting an assigned Data Center userid and password. Field Site staff login to the Data Center via the following URL: http://www.shepscenter.unc.edu/coptr

After successful authentication, the user will land on the "MyHome" page of the affiliated Field Site. Access is restricted according to Field Site affiliation and defined roles. An authorized staff for a Field Site only has permission to work within that site's defined workspace. Some RCU staff are authorized to work across all Field Sites' workspace. Figure 12.1 is a screenshot of the Case Western MyHome space.

On this MyHome page, a Field Site user (e.g. Case Western user) will see two sections that give real-time information on successful uploads and attempts. The top left box provides a Summary of the data records by type that have been uploaded to the Data Center and Confirmed by any of the site's authorized users. The Dataset Files box just below the Summary box provides more detailed information on each upload attempt. Authorized site users always have access to these status displays. Furthermore, authorized RCU users can see the status displays of all four Field Sites, providing an opportunity for RCU staff to monitor upload processes and provide assistance when

errors are displayed. In addition to the MyHome displays, the Data Center system has extensive error logging available to RCU staff to troubleshoot any problems encountered. Last, to the right of the Summary box are the tools for uploading data sets.

Figure 12.1: Screenshot of the MyHome space



Data Capture and Data Audits

Uploading Data to the RCU: The COPTR Data Capture Working Group decided to use file upload facilities versus web data entry forms for submitting site data to the Data Center. To upload a data set, the user will Browse his/her local file space for the desired CSV file, select the corresponding type by clicking on the appropriate radio button (e.g. Anthropometrics, Demographics, etc.), then click “Upload Selected File”. The upload process evaluates the incoming data file, looking for the required unique identifiers, the correct site ID, and comparing the field names, data types, and data values according to the predefined “definition”. (The “definition” files are available to read via the “definition” links.) If any required data check fails, the RCU rejects the incoming file and reports the

reasons to the user. The user can then correct those issues and upload the file again. If all required data checks pass, the incoming file is held with “Unconfirmed” status and the user is presented a report on the number of new records and number of modified records found in this incoming file. This report provides the user an opportunity to confirm that those numbers are as s/he expects. If the numbers are as expected, the user can “Confirm” the upload and the process is complete. Otherwise, the user can “Cancel” the upload then investigate the issues offline and attempt the upload again at another time.

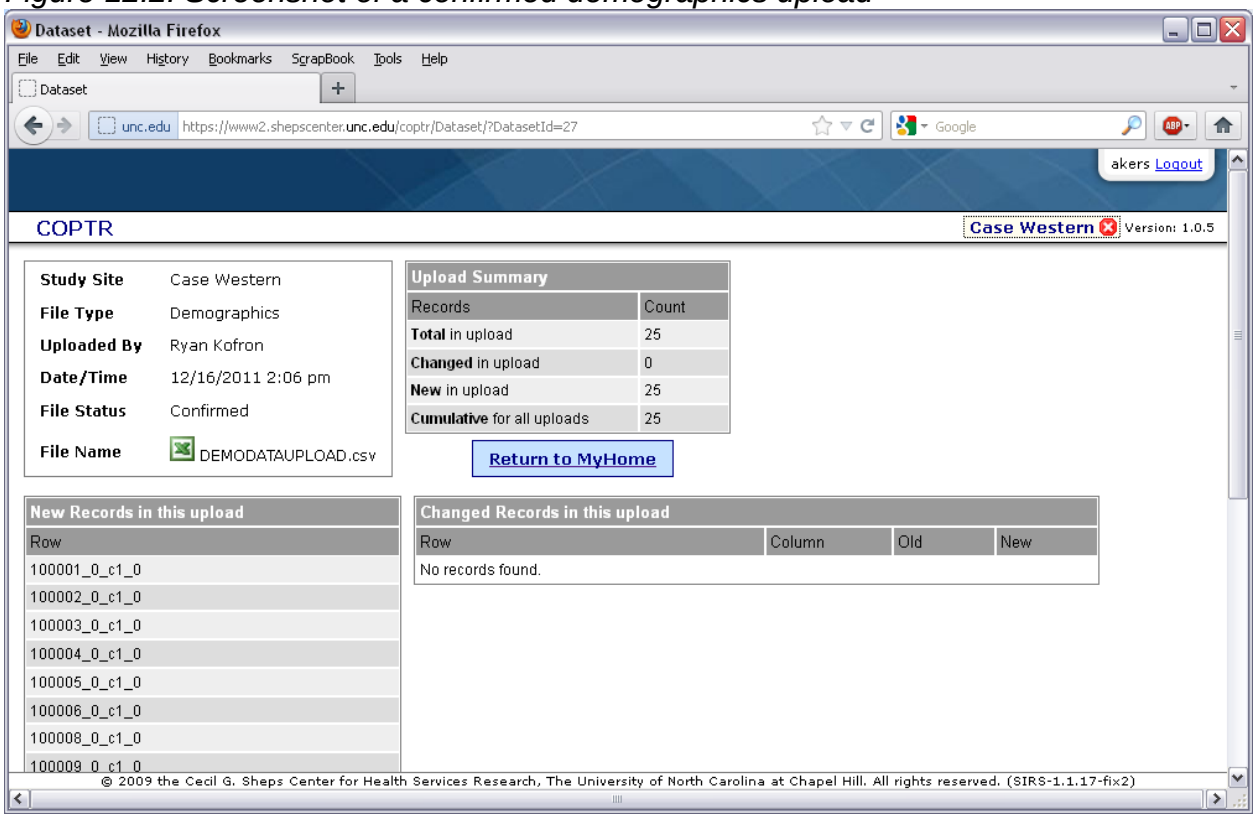
The next section on the screenshot in Figure 12.1 shows a running log of the dataset upload activities for the site. The log shows the date and time of each upload attempt, the type of upload, the user performing the upload, and the status of that upload attempt. Clicking on a “Confirmed” link in the Status column loads more detailed information about the confirmed upload. Figure 12.2 shows the details of a confirmed Demographics upload from Case Western. The more detailed information includes the local File Name of the uploaded file, the Upload Summary, and the unique identifiers of the New Records that were included in that file. In addition, if there were records uploaded that were intended to update or correct data that had previously been uploaded to the RCU Data Center, details of those changes would be listed in the right hand table labeled “Changed Records in this upload”. Changes to data fields in existing records are made by matching the unique record key of an existing record with that of an incoming record then accepting the new incoming record as the most up-to-date. (The older record is kept for reference. It is not overwritten.)

The Data Center is designed with three objectives in mind:

1) Promote the submission of the highest quality data to the RCU for future use of the Common Measures;
2) Provide an upload facility that is efficient and easy to use from the individual site’s perspective;
3) Give the users enough information and flexibility to track progress and correct problems with Common Measures submissions.

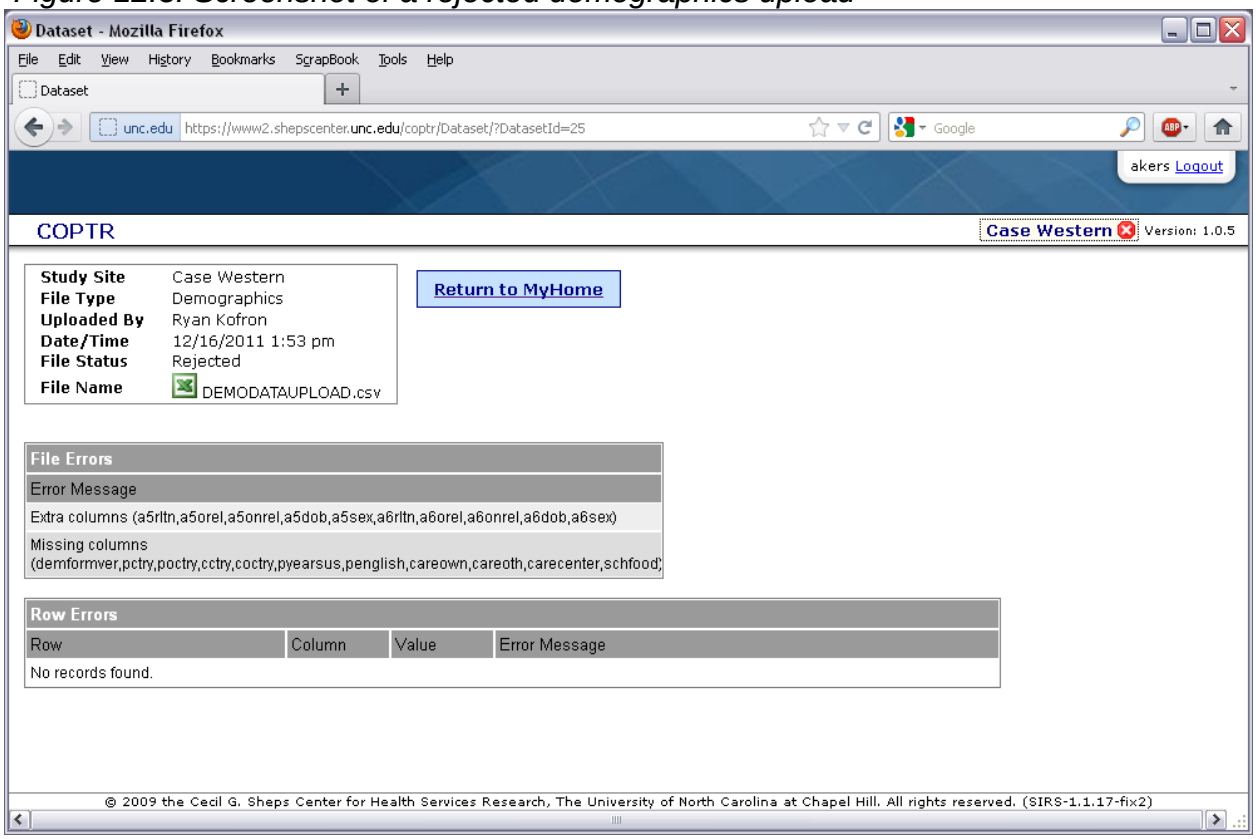
To that end, all data uploads with the exception of the accelerometer GT3X or AGD uploads, follow the same general model: organize your data to fit the approved definition, upload a CSV file via the website, confirm the upload or correct the errors and try again. Figures 1-3 illustrate the information provided and assistance with identifying and correcting problems prior to the RCU accepting data.

Figure 12.2: Screenshot of a confirmed demographics upload



Clicking on a “Rejected” link in the Status column will load more detailed information about a file with data that did not match the required criteria for acceptance in the Data Center. Figure 12.3 below shows the details of a rejected Demographics upload. Again, the local File Name is displayed along with Date/Time and Uploaded By user. The File Errors box in this example indicates that an upload was attempted that contained extra fields that the RCU was not expecting (first message). Also, the second message indicates there are fields or columns missing in the upload that are required as Demographics Common Measures. If there had been any data type mismatches or data values out of range, error messages would be presented in the “Row Errors” box.

Figure 12.3: Screenshot of a rejected demographics upload

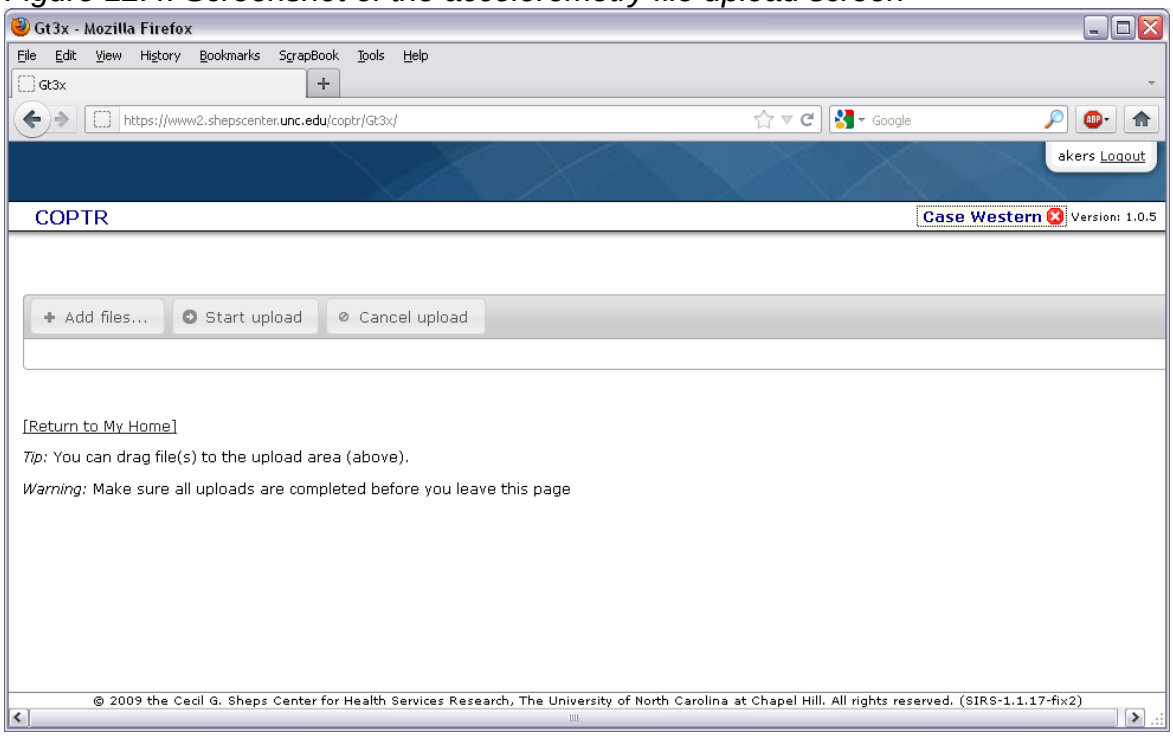


Authoritative ID File – Study Arm: The RCU Data Center requires one of the data uploads to be the authoritative source for Index Child IDs. Having an authoritative "master" list of Index Child IDs allows the RCU to prevent orphan records from being introduced in any of the other data uploads. The consortium has designated the Study Arm upload to be this source. As such, a Study Arm record for an Index Child must be uploaded to the RCU before any other Common Measure records are accepted into the Data Center. The Index Child IDs in other data uploads (e.g. Anthropometric, Demographic, etc.) are verified against the RCU's Study Arm records prior to accepting the data records. Data records that do not have a matching Index Child ID in the RCU's Study Arm data are rejected to prevent orphan records from being introduced into the Data Center.

Accelerometer Data: Accelerometer data on an individual consists of two distinct parts: a Physical Activity Monitor (PAM) record, and recorded data from the ActiGraph device (GT3X or AGD format). The RCU requires sites to upload the PAM record of the pair prior to uploading the matching GT3X or AGD file. The steps for uploading PAM records follows the same steps described above for other data uploads. However, the steps for uploading GT3X or AGD files are different because of the difficulties introduced in handling these large files. (We are anticipating the average size of these files to be around 200MB.) After successfully uploading and confirming PAM records, the user clicks the "Accelerometer Uploader" button shown in Figure 12.1. The user is then presented with a screen similar to Figure 12.4 below. The user can then queue up one

or more GT3X/AGD files for upload either by clicking “Add files…” or by dragging files from local file space into the upload area. Clicking “Start upload” will begin uploading the queued files in the order they are shown. Each GT3X/AGD file is verified against the uploaded PAM records to ensure a PAM record exists for a GT3X/AGD file before allowing the upload to proceed. This verification allows the RCU to accurately link a PAM record to an incoming GT3X/AGD file. The user must make sure all queued uploads are completed before leaving this web page.

Figure 12.4: Screenshot of the accelerometry file upload screen



Uploaded GT3X and AGD files are not automatically analyzed at the RCU. The files are simply stored in a file system for later use. Each site is responsible for analyzing GT3X and AGD files for completeness prior to uploading to the RCU Data Center.

12.2. Site-specific Data Capture

At all major data collection time points, data are entered directly into a REDCap database. REDCap is a secure, web-based data management system that allows direct entry of participant data (e.g., measurements, responses to survey questions, etc.) into an electronic format. This direct entry system facilitates the process of downloading and transferring data to the research coordinating unit (RCU). Other REDCap features include built-in data validity checks as well as automated export procedures for downloads to Excel and common statistical packages (SPSS, SAS, Stata and R).

12.2.1. Data collection and recording

All data are collected on-site at the two regional centers used for the intervention sessions with the exception of some measures for the control group which may be administered at the libraries (i.e., executive functioning). The data are collected by staff

trained in the areas of eligibility screening, measurements, and survey collection. The following stations are included in the data collection session: height, weight, waist circumference, triceps skinfold, accelerometer use, genetics (optional), and survey. Once a participant is deemed eligible, he or she will fill out the informed consent, be assigned an ID number, and complete the various stations. Additional data, such as diet recall and process measures, are collected outside of the major data collection time points.

Data collectors will input all data directly into a computerized database using REDCap (v. 4.9.4). Each station will contain its own laptop (Dell Latitude E6420) connected to the internet through either a password protected wireless internet connection or a mobile hotspot (Verizon Samsung 4G LTE). Once entered and saved, all data are immediately stored on a secure server at Vanderbilt and is only accessible to those with an assigned username and password. In case the internet should fail, paper copies of all measurement tools will be utilized. REDCap allows for data validity checks during the data collection process through range checks and branching logic. Additionally, it allows research staff to run reports on various aspects of the data collected. All tools within the REDCap database will contain a 'Comments' section to allow for notes to be made for any issues during data collection or processing for a particular participant; these will be monitored regularly.

Some data requires an extra processing step before being uploaded into REDCap. For example, diet recall data are entered into NDS-R (version 2012) and then output into an excel file with specific variables that is then uploaded into the REDCap database. Similarly, the gt3x+ files from the accelerometers are separately processed using the ActiLife software, consolidated into variables in excel files, and then uploaded to REDCap. Any information stored in an excel file will be housed on a secure server at Vanderbilt with access limited to those working on the study.

Data unassociated with certain time points, such as process measures, may be collected on paper and transferred into a database. These measures will be entered into a Microsoft Access database and continually updated.

12.2.2. Transfer of data from Vanderbilt to the Coordinating Center

The participant data are downloaded from REDCap onto computers at the Vanderbilt site, and then, data that is common to two or more sites is transferred electronically to the RCU, where it can ultimately be loaded into a consolidated database. Before data files can be transferred to the RCU, they must be in a specified format. To prepare data for transfer, variables that are unique to Vanderbilt must be removed, and variables that are common to two or more of the other sites are generated and left blank.

12.2.3. Database closure

During active data collection, a copy of the REDCap data will be periodically downloaded into an excel file. These files will be housed in a read-only format on a secure server. After data collection is complete, the REDCap database will be moved into inactive status, where all data are still visible but no new entry can be made.

12.2.4. Data security and confidentiality

All data collected on paper will be housed in a locked file cabinet at the offices of the research staff. Access to the files is restricted to study staff. Files will be labeled by the unique participant IDs assigned to each parent-child pair. On REDCap, all files are protected by the need for a user name and password. Through REDCap's user rights function, the data analyst can limit and grant access for specific tools to study staff as needed. Any computerized data will be kept on a secure server at Vanderbilt with limited access and/or in a read-only file. Any material that must be thrown away that involves participant information will be shredded through the document management procedures available at Vanderbilt through Cintas. Upon hiring, all study staff must complete CITI training through Vanderbilt's IRB. They must complete the following Behavioral and Social modules: Introduction, History and Ethical Principles, Regulations and the Social and Behavioral Sciences, Informed Consent, Privacy and Confidentiality, Research with Children, and Studies with Minors (parts 1-3). In order to pass, all employees must score an 80% or better on each end of module quiz.

12.2.5. Data quality assurance

Many of the features of the web-based REDCap data management system, such as range checks and branching logic, are designed to ensure the quality and completeness of the study data. In addition, all data are manually entered directly into the database on-site, which eliminates data entry errors and greatly reduces the occurrence of skipped data. After every data collection session, the data analyst will review the data entered for both flagged issues noted in data collection and blank answers. These will be corrected as necessary before analysis. Anthropometric measurement error will be reduced through quality checks, which involve replicating, within a small margin of error, 10% of all measurements by another data collector.

13. SITE-SPECIFIC TIMELINE

Table 13.1: GROW timeline

Main Trial		
COHORT 1	**Start**	**Duration**
Recruitment	May 2012	6 months
Baseline data collection	September 2012	2 months
Intervention	September 2012	36 months
Follow-up data collection	3, 9, 12, 24, and 36 months	2 months
COHORT 2	**Start**	**Duration**
Recruitment	December 2012	6 months
Baseline data collection	June 2013	2 months
Intervention	June 2013	36 months
Follow-up data collection	3, 9, 12, 24, and 36 months	2 months
COHORT 3	**Start**	**Duration**
Recruitment	September 2014	6 months
Baseline data collection	March 2014	2 months
Intervention	March 2014	36 months
Follow-up data collection	3, 9, 12, 24, and 36 months	2 months

14. LITERATURE CITED

Agras, W. S., L. D. Hammer, et al. (2004). "Risk factors for childhood overweight: a prospective study from birth to 9.5 years." The Journal of pediatrics **145**(1): 20-25.

American Dietetic Association (2006). "Position of the American Dietetic Association: individual-, family-, school-, and community-based interventions for pediatric overweight." J Am Diet Assoc **106**(6): 925-945.

An, D., R. J. Little, et al. (2010). "A multiple imputation approach to disclosure limitation for high-age individuals in longitudinal studies." Statistics in medicine **29**(17): 1769-1778.

Appel, L. J., J. M. Clark, et al. (2011). "Comparative effectiveness of weight-loss interventions in clinical practice." The New England journal of medicine **365**(21): 1959-1968.

Bahr, D. B., R. C. Browning, et al. (2009). "Exploiting social networks to mitigate the obesity epidemic." Obesity (Silver Spring) **17**(4): 723-728.

Baker, D. W. (2006). "The meaning and the measure of health literacy." J Gen Intern Med **21**(8): 878-883.

Bandura, A. (1986). Social Foundations of Thought and Action: A Social Cognitive Theory. Englewood Cliffs, NJ, Prentice-Hall.

Barkeling, B., S. Ekman, et al. (1992). "Eating behaviour in obese and normal weight 11-year-old children." Int J Obes Relat Metab Disord **16**(5): 355-360.

Barker, D. J., C. Osmond, et al. (2005). "Trajectories of growth among children who have coronary events as adults." N Engl J Med **353**(17): 1802-1809.

Barness, L. A., J. M. Opitz, et al. (2007). "Obesity: genetic, molecular, and environmental aspects." Am J Med Genet A **143A**(24): 3016-3034.

Berenson, G. S., S. R. Srinivasan, et al. (1998). "Association between multiple cardiovascular risk factors and atherosclerosis in children and young adults." New England Journal of Medicine **338**(23): 1650-1656.

Berkey, C. S. and G. A. Colditz (2007). "Adiposity in adolescents: Change in actual BMI works better than change in BMI z score for longitudinal studies." Ann Epidemiol **17**(1): 44-50.

Birch, L., Ventura, AK (2009). "Preventing childhood obesity: what works?" International Journal of Obesity **33**: 74-81.

Brantley, P. J., V. H. Myers, et al. (2005). "Environmental and lifestyle influences on obesity." J La State Med Soc **157 Spec No 1**: S19-27.

Bray, G. A., J. P. DeLany, et al. (2001). "Evaluation of body fat in fatter and leaner 10-y-old African American and white children: the Baton Rouge Children's Study." American Journal of Clinical Nutrition **73**(4): 687-702.

Browning, L. M., S. D. Hsieh, et al. (2010). "A systematic review of waist-to-height ratio as a screening tool for the prediction of cardiovascular disease and diabetes: 0.5 could be a suitable global boundary value." Nutr Res Rev **23**(2): 247-269.

Caprio, S., L. D. Hyman, et al. (1995). "Central Adiposity and Its Metabolic Correlates in Obese Adolescent Girls." American Journal of Physiology-Endocrinology and Metabolism **269**(1): E118-E126.

Caprio, S., L. D. Hyman, et al. (1996). "Fat distribution and cardiovascular risk factors in obese adolescent girls: Importance of the intraabdominal fat depot." American Journal of Clinical Nutrition **64**(1): 12-17.
Carnell, S. and J. Wardle (2008). "Appetite and adiposity in children: evidence for a behavioral susceptibility theory of obesity." Am J Clin Nutr **88**(1): 22-29.
Carpenter, J. R., M. G. Kenward, et al. (2007). "Sensitivity analysis after multiple imputation under missing at random: a weighting approach." Statistical Methods in Medical Research **16**(3): 259-275.
Center for Disease Control and Prevention (2007). National Health and Nutrition Examination Survey (NHANES): Anthropometry Procedures Manual.
Choi, L., K. Y. Chen, et al. (2010). "Distributed lag and spline modeling for predicting energy expenditure from accelerometry in youth." J Appl Physiol **108**(2): 314-327.
Chrispeels JH, W. J., Rivero E (2000). Evaluation summary of the Impact of the Parent Institue for Quality Education on Parent's Engagement with their Children's Schooling. Santa Barbara, University of California.
Christakis, N. A. and J. H. Fowler (2007). "The spread of obesity in a large social network over 32 years." N Engl J Med **357**(4): 370-379.
Cliff, D. P., J. J. Reilly, et al. (2009). "Methodological considerations in using accelerometers to assess habitual physical activity in children aged 0-5 years." J Sci Med Sport **12**(5): 557-567.
Coady, S. A., C. E. Jaquish, et al. (2002). "Genetic variability of adult body mass index: a longitudinal assessment in framingham families." Obes Res **10**(7): 675-681.
Cole, T. J. (2004). "Children grow and horses race: is the adiposity rebound a critical period for later obesity?" BMC pediatrics **4**: 6.
Cole, T. J., M. S. Faith, et al. (2005). "What is the best measure of adiposity change in growing children: BMI, BMI %, BMI z-score or BMI centile? (vol 59, pg 419, 2005)." Eur J Clin Nutr **59**(6): 807-807.
Collins, L. M., S. A. Murphy, et al. (2004). "A conceptual framework for adaptive preventive interventions." Prevention science : the official journal of the Society for Prevention Research **5**(3): 185-196.
Conway, J. M., L. A. Ingwersen, et al. (2004). "Accuracy of dietary recall using the USDA five-step multiple-pass method in men: an observational validation study." J Am Diet Assoc **104**(4): 595-603.
Crockett, S. J., R. M. Mullis, et al. (1988). "Parent nutrition education: a conceptual model." J Sch Health **58**(2): 53-57.
Daniels, S. R., P. R. Khoury, et al. (1997). "The utility of body mass index as a measure of body fatness in children and adolescents: Differences by race and gender." Pediatrics **99**(6): 804-807.
de la Haye, K., Robins, G., Mohr, P., Wilson, C. (2010). "Obesity-related behaviors in adolescent friendship networks." Social Networks **32**(3): 161-167.
De Vries, S. I., H. W. Van Hirtum, et al. (2009). "Validity and reproducibility of motion sensors in youth: a systematic update." Med Sci Sports Exerc **41**(4): 818-827.
Dezenberg, C. V., T. R. Nagy, et al. (1999). "Predicting body composition from anthropometry in pre-adolescent children." Int J Obes (Lond) **23**(3): 253-259.
Dwyer, J. T., E. J. Stone, et al. (1998). "Predictors of overweight and overfatness in a multiethnic pediatric population. Child and Adolescent Trial for Cardiovascular

Health Collaborative Research Group." The American journal of clinical nutrition **67**(4): 602-610.
Economos, C. D., R. R. Hyatt, et al. (2007). "A community intervention reduces BMI z-score in children: Shape Up Somerville first year results." Obesity (Silver Spring) **15**(5): 1325-1336.
Epstein, L. H., M. D. Myers, et al. (1998). "Treatment of pediatric obesity." Pediatrics **101**(3 Pt 2): 554-570.
Epstein, L. H., A. Valoski, et al. (1994). "Ten-year outcomes of behavioral family-based treatment for childhood obesity." Health Psychol **13**(5): 373-383.
Epstein, L. H., R. R. Wing, et al. (1987). "Long-term effects of family-based treatment of childhood obesity." J Consult Clin Psychol **55**(1): 91-95.
Estabrooks, P. A., R. E. Lee, et al. (2003). "Resources for physical activity participation: does availability and accessibility differ by neighborhood socioeconomic status?" Ann Behav Med **25**(2): 100-104.
Freedman, D. S., W. H. Dietz, et al. (1999). "The relation of overweight to cardiovascular risk factors among children and adolescents: the Bogalusa Heart Study." Pediatrics **103**(6 Pt 1): 1175-1182.
Freedman, D. S., S. R. Srinivasan, et al. (1987). "Relation of Body-Fat Distribution to Hyperinsulinemia in Children and Adolescents - the Bogalusa-Heart-Study." American Journal of Clinical Nutrition **46**(3): 403-410.
Freedman, D. S., S. R. Srinivasan, et al. (1989). "Relation of Body-Fat Patterning to Lipid and Lipoprotein Concentrations in Children and Adolescents - the Bogalusa Heart-Study." American Journal of Clinical Nutrition **50**(5): 930-939.
Freedson, P., D. Pober, et al. (2005). "Calibration of accelerometer output for children." Med Sci Sports Exerc **37**(11 Suppl): S523-530.
Garcia, A. W., Langenthal, C.R., Angulo-Barroso, R.M., Gross, M.M. (2004). "A comparison of accelerometers for predicting energy expenditure and vertical ground reaction force in school-age children." Meas Phys Educ Exerc Sci. **8**(3): 119-144.
Gelman, A., Hill, J (2007). Data Analysis Using Regression and Multilevel/Hierarchical Models.
Gesell, S. B., Bess, K., Barkin, S.L. (2012). "Understanding the new social networks that form within the context of an obesity prevention intervention." Journal of Obesity.
Gesell, S. B., Tesdahl, E., Ruchman, E (2012). "The Distribution of Physical Activity in an Afterschool Friendship Network." Pediatrics.
Giles-Corti, B. and R. J. Donovan (2002). "Socioeconomic status differences in recreational physical activity levels and real and perceived access to a supportive physical environment." Preventive medicine **35**(6): 601-611.
Glass, T. A., McAtee, Matthew J (2006). "Behavioral science at the crossroads in public health: Extending horizons, envisioning the future." Soc Sci Med **62**: 1650-1671.
Goran, M. I. (1998). "Measurement issues related to studies of childhood obesity: Assessment of body composition, body fat distribution, physical activity, and food intake." Pediatrics **101**(3): 505-518.
Goran, M. I., P. Driscoll, et al. (1996). "Cross-calibration of body-composition techniques against dual-energy X-ray absorptiometry in young children." American Journal of Clinical Nutrition **63**(3): 299-305.

Goran, M. I., B. A. Gower, et al. (1998). "Prediction of intra-abdominal and subcutaneous abdominal adipose tissue in healthy pre-pubertal children." Int J Obes (Lond) **22**(6): 549-558.
Gordon-Larsen, P., P. Griffiths, et al. (2004). "Barriers to Physical Activity: Qualitative Data on Caregiver-Daughter Perceptions and Practices." Am J Prev Med **27**(3): 218–223.
Gordon-Larsen, P., M. C. Nelson, et al. (2006). "Inequality in the built environment underlies key health disparities in physical activity and obesity." Pediatrics **117**(2): 417-424.
Hands, B. P., Parker, H., & Larkin, D. (2006). "Physical activity measurement methods for young children: a comparative study." Measurement in Physical Education and Exercise Science **10**(3): 203-214.
Harrell, F. E. (2001). Regression Modeling Strategies. New York, Springer.
Hedeker, D. and R. D. Gibbons (1997). "Application of random-effects pattern-mixture models for missing data in longitudinal studies." Psychological methods **2**(1): 64-78.
Hesketh, K. D. and K. J. Campbell (2010). "Interventions to prevent obesity in 0-5 year olds: an updated systematic review of the literature." Obesity (Silver Spring) **18 Suppl 1**: S27-35.
Huang, T. T., Drewnowski, Adam., Kumanyika, Shiriki K., Glass, Thomas A. (2009). "A Systems-Oriented Multilevel Framework for Addressing Obesity in the 21st Century." Prev Chronic Dis **6**(3).
Institute of Medicine (2011). Early Childhood Obesity Prevention Policies. Obesity Prevention Policies for Young Children, Institute of Medicine.
Institute of Medicine (2012). Measuring Progress in Obesity Prevention - Workshop Report. Accelerating Progress in Obesity Prevention Institute of Medicine.
Institute of Medicine Committee on Health Literacy (2004). Health Literacy: A Prescription to End Confusion. Washington DC, The National Academies Press.
Institute of Medicine. Committee on Progress in Preventing Childhood Obesity (September 2006). Progress in Preventing Childhood Obesity: How do we measure up. C. o. P. i. P. C. Obesity, The National Academies Press.
Jansen, A., N. Theunissen, et al. (2003). "Overweight children overeat after exposure to food cues." Eat Behav **4**(2): 197-209.
Jenkins, S. P., R. V. Burkhauser, et al. (2011). "Measuring inequality using censored data: a multiple-imputation approach to estimation and inference." Journal of the Royal Statistical Society Series a-Statistics in Society **174**: 63-81.
Kahn, H. S., G. Imperatore, et al. (2005). "A population-based comparison of BMI percentiles and waist-to-height ratio for identifying cardiovascular risk in youth." Journal of Pediatrics **146**(4): 482-488.
Kamath, C. C., K. S. Vickers, et al. (2008). "Clinical review: behavioral interventions to prevent childhood obesity: a systematic review and metaanalyses of randomized trials." J Clin Endocrinol Metab **93**(12): 4606-4615.
Kathiresan, S., B. F. Voight, et al. (2009). "Genome-wide association of early-onset myocardial infarction with single nucleotide polymorphisms and copy number variants." Nat Genet **41**(3): 334-341.

Kelly, L. A., J. J. Reilly, et al. (2004). "Comparison of two accelerometers for assessment of physical activity in preschool children." Pediatr Exerc Sci **16**(4): 324-333.
Kropski, J. A., P. H. Keckley, et al. (2008). "School-based obesity prevention programs: an evidence-based review." Obesity (Silver Spring) **16**(5): 1009-1018.
Kuczmarski, R. J., C. L. Ogden, et al. (2000). "CDC growth charts: United States." Adv Data(314): 1-27.
Kuczmarski, R. J., C. L. Ogden, et al. (2002). "2000 CDC Growth Charts for the United States: methods and development." Vital and health statistics. Series 11, Data from the national health survey(246): 1-190.
Leunissen, R. W., G. F. Kerkhof, et al. (2009). "Timing and tempo of first-year rapid growth in relation to cardiovascular and metabolic risk profile in early adulthood." JAMA **301**(21): 2234-2242.
Levine, A. S., C. M. Kotz, et al. (2003). "Sugars and fats: the neurobiology of preference." J Nutr **133**(3): 831S-834S.
Little, R. J. A. (1993). "Pattern-Mixture Models for Multivariate Incomplete Data." Journal of the American Statistical Association **88**(421): 125-134.
Little, R. J. A. and D. B. Rubin (2002). Statistical analysis with missing data. Hoboken, N.J., Wiley.
Macfarlane, A., V. Cleland, et al. (2009). "Longitudinal examination of the family food environment and weight status among children." International Journal of Pediatric Obesity **4**(4): 343-352.
Mcgill, H. C., C. A. Mcmahan, et al. (1995). "Relation of Glycohemoglobin and Adiposity to Atherosclerosis in Youth." Arteriosclerosis Thrombosis and Vascular Biology **15**(4): 431-440.
McMurray, R. G., Bangdiwala, S. I., Catellier, D. J., Harrell, J. S. (2010). "The relationship between insulin sensitivity and surrogates for adiposity in youth." Int J Child Adolesc Health **3**(1): 93-98.
Miller, P. E., D. C. Mitchell, et al. (2011). "Development and evaluation of a method for calculating the Healthy Eating Index-2005 using the Nutrition Data System for Research." Public Health Nutr **14**(2): 306-313.
Montgomery, C., J. J. Reilly, et al. (2004). "Relation between physical activity and energy expenditure in a representative sample of young children." Am J Clin Nutr **80**(3): 591-596.
Moshfegh, A. J., Borrud, L., Perloff, B., LaComb, R. (1999). "Improved Method for the 24-hour Dietary Recall for Use in National Surveys." FASEB Journal **13**(4): A603.
Must, A., P. F. Jacques, et al. (1992). "Long-term morbidity and mortality of overweight adolescents. A follow-up of the Harvard Growth Study of 1922 to 1935." N Engl J Med **327**(19): 1350-1355.
Nader, P. R., M. O'Brien, et al. (2006). "Identifying risk for obesity in early childhood." Pediatrics **118**(3): e594-601.
Neuman, S. B., Celano, Donna (2011). Every Child Ready to Read, Association for Library Service to Children (ALSC) and the Public Library Association (PLA).
Nich, C. and K. Carroll (1997). "Now you see it, now you don't: A comparison of traditional versus random-effects regression models in the analysis of longitudinal follow-up data from a clinical trial." Journal of Consulting and Clinical Psychology **65**(2): 252-261.

Ogden, C. L., K. M. Flegal, et al. (2002). "Prevalence and trends in overweight among US children and adolescents, 1999-2000." JAMA **288**(14): 1728-1732.
Ogden, C. L., C. D. Fryar, et al. (2004). "Mean body weight, height, and body mass index, United States 1960-2002." Adv Data(347): 1-17.
Olshansky, S. J., D. J. Passaro, et al. (2005). "A potential decline in life expectancy in the United States in the 21st century." N Engl J Med **352**(11): 1138-1145.
Oman, R. F., S. K. Vesely, et al. (2009). "Methodological considerations in a community-based longitudinal study." Am J Health Behav **33**(1): 58-68.
Pate, R. R., M. J. Almeida, et al. (2006). "Validation and calibration of an accelerometer in preschool children." Obesity (Silver Spring) **14**(11): 2000-2006.
Perusse, L., A. Tremblay, et al. (1989). "Genetic and environmental influences on level of habitual physical activity and exercise participation." Am J Epidemiol **129**(5): 1012-1022.
Pietrobelli, A., M. S. Faith, et al. (1998). "Body mass index as a measure of adiposity among children and adolescents: a validation study." J Pediatr **132**(2): 204-210.
Pinhas-Hamiel, O., L. M. Dolan, et al. (1996). "Increased incidence of non-insulin-dependent diabetes mellitus among adolescents." J Pediatr **128**(5 Pt 1): 608-615.
Posner, B. M., C. Smigelski, et al. (1992). "Validation of two-dimensional models for estimation of portion size in nutrition research." J Am Diet Assoc **92**(6): 738-741.
Pryor, L. E., R. E. Tremblay, et al. (2011). "Developmental trajectories of body mass index in early childhood and their risk factors: an 8-year longitudinal study." Archives of pediatrics & adolescent medicine **165**(10): 906-912.
Rabe-Hesketh, S. & Skrondal, A. (2012), Multilevel and Longitudinal Modeling Using Stata, Vol. 1: Continuous Responses. College Station, TX: Stata Press.
Raudenbush, S. W. and L. Xiao-Feng (2001). "Effects of study duration, frequency of observation, and sample size on power in studies of group differences in polynomial change." Psychological methods **6**(4): 387-401.
Reilly, J. J. (2010). "Low levels of objectively measured physical activity in preschoolers in child care." Med Sci Sports Exerc **42**(3): 502-507.
Reilly, J. J., L. A. Kelly, et al. (2006). "Validation of Actigraph accelerometer estimates of total energy expenditure in young children." Int J Pediatr Obes **1**(3): 161-167.
Roberts, C., & Roberts, S.A. (2005). Design and analysis of clinical trials with clustering effects due to treatment. *Clinical Trials*, 2, 152-162.
Robinson, T. N. (1999). "Behavioural treatment of childhood and adolescent obesity." Int J Obes Relat Metab Disord **23 Suppl 2**: S52-57.
Rolland-Cachera, M. F., M. Deheeger, et al. (1984). "Adiposity rebound in children: a simple indicator for predicting obesity." The American journal of clinical nutrition **39**(1): 129-135.
Rolland-Cachera, M. F., M. Deheeger, et al. (2006). "Early adiposity rebound: causes and consequences for obesity in children and adults." Int J Obes (Lond) **30 Suppl 4**: S11-17.
Rootman, I. (2004). "Health promotion and literacy: implications for nursing." Can J Nurs Res **36**(1): 13-21.
Rothman, R. L., D. A. DeWalt, et al. (2004). "Influence of patient literacy on the effectiveness of a primary care-based diabetes disease management program." JAMA **292**(14): 1711-1716.

Rothman, R. L., R. Housam, et al. (2006). "Patient understanding of food labels: the role of literacy and numeracy." Am J Prev Med **31**(5): 391-398.
Rothman RL, Y. H., Mulvaney S, Co JP, Homer CJ, Lannon C (2009). "Addressing Health Literacy in Pediatric Quality." Pediatrics **In Press**.
Sallis, J. F., M. F. Hovell, et al. (1990). "Distance between homes and exercise facilities related to frequency of exercise among San Diego residents." Public Health Rep **105**(2): 179-185.
Savva, S. C., M. Tornaritis, et al. (2000). "Waist circumference and waist-to-height ratio are better predictors of cardiovascular disease risk factors in children than body mass index." Int J Obes Relat Metab Disord **24**(11): 1453-1458.
Schmitz, K. H., M. Treuth, et al. (2005). "Predicting energy expenditure from accelerometry counts in adolescent girls." Med Sci Sports Exerc **37**(1): 155-161.
Scott, C. R., J. M. Smith, et al. (1997). "Characteristics of youth-onset noninsulin-dependent diabetes mellitus and insulin-dependent diabetes mellitus at diagnosis." Pediatrics **100**(1): 84-91.
Silventoinen, K., B. Rokholm, et al. (2010). "The genetic and environmental influences on childhood obesity: a systematic review of twin and adoption studies." Int J Obes (Lond) **34**(1): 29-40.
Sirard, J. R., Trost, S.G., Pfeiffer, K.A., Dowda, M., Pate, R.R. (2005). "Calibration and evaluation of an objective measure of physical activity in preschool children." J Phys Act Health **3**: 324-336.
Slaughter, M. H., T. G. Lohman, et al. (1988). "Skinfold equations for estimation of body fatness in children and youth." Hum Biol **60**(5): 709-723.
Small, D. M., M. Jones-Gotman, et al. (2003). "Feeding-induced dopamine release in dorsal striatum correlates with meal pleasantness ratings in healthy human volunteers." Neuroimage **19**(4): 1709-1715.
Smith, K. P., Christakis, Nicholas A (2008). "Social Networks and Health." Annual Reviews **34**: 405-429.
Snijders, T. A. B., Berkhof, J (2008). Handbook of Multilevel Analysis In J. de Leeuw & E. Meijer (Eds).
Spybrook, J., Raudenbush, S.W., Congdon, R., and Martinez, A (2011). Optimal Design for Longitudinal and Multilevel Research: Documentation for the "Optimal Design" Software.
Strauss, R. S. and J. Knight (1999). "Influence of the home environment on the development of obesity in children." Pediatrics **103**(6): e85.
Suminski, R. R., W. S. Poston, et al. (1999). "Early identification of Mexican American children who are at risk for becoming obese." Int J Obes Relat Metab Disord **23**(8): 823-829.
Summerbell, C. D., E. Waters, et al. (2005). "Interventions for preventing obesity in children." Cochrane Database Syst Revs(3).
Tansey, C. M., A. L. Matte, et al. (2007). "Review of retention strategies in longitudinal studies and application to follow-up of ICU survivors." Intensive Care Med **33**(12): 2051-2057.
Teixeira, P. J., L. B. Sardinha, et al. (2001). "Total and regional fat and serum cardiovascular disease risk factors in lean and obese children and adolescents." Obes Res **9**(8): 432-442.

Tooze, J. A., D. Midthune, et al. (2006). "A new statistical method for estimating the usual intake of episodically consumed foods with application to their distribution." J Am Diet Assoc **106**(10): 1575-1587.
Trost, S. G., R. Way, et al. (2006). "Predictive validity of three ActiGraph energy expenditure equations for children." Med Sci Sports Exerc **38**(2): 380-387.
U.S. Department of Health and Human Services (2004). Strategic plan for NIH obesity research: a report of the NIH Obesity Research Task Force, National Institutes of Health. Rockville, MD.
Valente, T. W., K. Fujimoto, et al. (2009). "Adolescent affiliations and adiposity: a social network analysis of friendships and obesity." J Adolesc Health **45**(2): 202-204.
Velott, D. L., S. A. Baker, et al. (2008). "Participant recruitment to a randomized trial of a community-based behavioral intervention for pre- and interconceptional women findings from the Central Pennsylvania Women's Health Study." Womens Health Issues **18**(3): 217-224.
Wardle, J., S. Carnell, et al. (2008). "Evidence for a strong genetic influence on childhood adiposity despite the force of the obesogenic environment." Am J Clin Nutr **87**(2): 398-404.
Webber, L., C. Hill, et al. (2008). "Eating behaviour and weight in children." Int J Obes (Lond).
Whitaker, R. C., M. S. Pepe, et al. (1998). "Early adiposity rebound and the risk of adult obesity." Pediatrics **101**(3): E5.
White, I. R., P. Royston, et al. (2011). "Multiple imputation using chained equations: Issues and guidance for practice." Statistics in medicine **30**(4): 377-399.
Willer, C. J., E. K. Speliotes, et al. (2009). "Six new loci associated with body mass index highlight a neuronal influence on body weight regulation." Nat Genet **41**(1): 25-34.
Williams, S. M. and A. Goulding (2009). "Patterns of growth associated with the timing of adiposity rebound." Obesity (Silver Spring) **17**(2): 335-341.
Wilson, D. K., K. A. Kirtland, et al. (2004). "Socioeconomic status and perceptions of access and safety for physical activity." Ann Behav Med **28**(1): 20-28.
Wilson, T. A., A. L. Adolph, et al. (2009). "Nutrient adequacy and diet quality in non-overweight and overweight Hispanic children of low socioeconomic status: the Viva la Familia Study." J Am Diet Assoc **109**(6): 1012-1021.
Witkos, M., M. Uttaburanont, et al. (2008). "Costs of and reasons for obesity." J Cardiometab Syndr **3**(3): 173-176.
Zizza, C., A. M. Siega-Riz, et al. (2001). "Significant Increase in Young Adults' Snacking between 1977–1978 and 1994–1996 Represents a Cause for Concern." Preventive Medicine **32**(4): 303-310

APPENDIX 1. INFORMED CONSENT DOCUMENTS

Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Shari Barkin, MD, MSHS Revision Date: 07-11-11
Study Title: Formative Phase of Growing Right Onto Wellness (GROW): Changing Early Childhood Body Mass Index (BMI) Trajectories
Institution/Hospital: Vanderbilt University Medical

Name of participant: _____ Age: _____

This tells you about this research project and your participation in it. Please read this form with care and ask any questions you may have about this study and the information below. We are happy to answer your questions. Also, you will be given a copy of this consent form.

We would like you to join a project called "Growing Right Onto Wellness (GROW)", which is being run by the Monroe Carell, Jr. Children's Hospital at Vanderbilt.

PURPOSE OF THE STUDY

We are testing a parenting program for families with young children. The purpose of the study is to improve child well-being. We invite you and your child to participate in the study. The study will last for 6 months.

HOW WE SELECTED YOU

We have identified you as an interested parent with a child between 3-5 years, who lives near the East Park Community Center.

WHAT WE WILL ASK YOU TO DO AND HOW LONG IT WILL TAKE

If you choose to be part of this study, you will be asked to participate in a 6-month parenting program at the East Park Community Center on 700 Woodland Street in Nashville.

The program will teach parenting skills by teaching you how to improve your child's nutrition and physical activity, establishing early healthy habits. This program is designed to increase the quality time you spend with your child, help you understand your child's world, and teach you skills to guide your child through a healthy and happy childhood. The program will meet weekly for 90 minutes introducing you and your family to skills such as preparing a healthy meal on a budget and finding time to be active with your child. Groups of 6-10 families will meet together weekly for 12 weeks and then biweekly for 12 weeks for a total of 18 sessions.

For all sessions we will provide a nutritious snack. Staff from the East Park Community Center will provide child supervision for siblings not enrolled in the study and transportation if needed. There is no cost for your family to use these services. The study team will work with you to arrange a shuttle van that transports you and your child(ren) to and from the East Park Community Center, if needed. We will have several pick up areas such as a local school or bus stop.

To help us evaluate the program, we will ask you to participate in 2 data collection sessions, one at the beginning of the program and one at the end. These data collection sessions will take about 60-90 minutes each, and include:

Date of IRB Approval:

Date of IRB Expiration:

Date of IRB Approval: 7-14-2011
Date of IRB Expiration: 4-28-2012

- filling out a survey (about how you parent; what you eat; how physically active you are; your child's doctor; reading to your child)
- wearing a small device on your waist (like a watch) for 7 days to measure how much you and your child use your muscles
- filling out a diet recall log
- measuring you and your child for height and weight and waist size
- measuring you and your child for body composition. *The triceps skinfold* is a measure used to assess subcutaneous adipose tissue (the fat under the skin) and estimate your overall percentage of body fat. This measurement may create a small pinch.

Providing a sample of genetic material by spitting into a cup is an optional part of this study and is described in a separate consent form.

RISKS OF PARTICIPATION

There are minimal research related risks associated with this study. All suggested exercises will be mild and are unlikely to cause injury. All suggested dietary changes are evidence based and healthy. If any physical injury or illness should occur as a direct result of participation in this study, Vanderbilt maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses.

The total amount of time we expect you to spend in program sessions and filling out data forms for the study is about 22 hours over 6 months in the nutrition and physical activity program. This time commitment may be an inconvenience to you.

Principal Investigator: Shari Barkin, MD, MSHS Revision Date: 07-11-11
Study Title: Formative Phase of Growing Right Onto Wellness (GROW): Changing Early Childhood Body Mass Index (BMI) Trajectories
Institution/Hospital: Vanderbilt University Medical

COMPENSATION

As described above, there will be two times that we will ask for you and your child to wear activity monitors. As a token of appreciation for your time and the inconvenience of data collection during the week, you will receive a gift valued at $20 for each time we collect data. You will also get a small gift valued at $10 each time you wear the activity monitor for a week and return it (example: children's book, cooking utensil).That will total a gift value of $60 over 6 months. In order to give you these small gifts, we will have to ask you for your (or your child's) social security number and mailing address. Vanderbilt is required to keep track of everyone who receives any money or gift from the institution. After you have completed data collection at two points in time, you will receive a free membership to the East Community Center for one year.

BENEFITS OF PARTICIPATION

There may be no direct benefits to you for participation. You will learn about things that you can do as a parent to improve your child's well-being. You will be introduced to other families with children. You will spend time with your child.

CONFIDENTIALITY

This study is confidential. Your information will be protected by the study team working on this project. It will be combined with the information from other families and never reported individually. We will use the information you give us for research purposes only. Your information may be shared with Vanderbilt or the government, such as the Vanderbilt University Institutional Review Board, Federal Government Office for Human Research Protections, the Tennessee Department of Health, if you or someone else is in danger or if we are required to do so by law.

WITHDRAWING FROM THE STUDY

Your participation in the study is completely voluntary. You may refuse to participate, or you may stop participating at any time and for any reason, without any penalty. If you would like to withdraw from the study, please tell the person who gave you this form or call Juan Escarfuller (615) 414-5713. If you choose to withdraw, we will not use any data collected from you prior to your withdrawal.

Date of IRB Approval:

Date of IRB Expiration:

Date of IRB Approval: 7-14-2011
Date of IRB Expiration: 4-28-2012

Principal Investigator: Shari Barkin, MD, MSHS Revision Date: 07-11-11
Study Title: Formative Phase of Growing Right Onto Wellness (GROW): Changing Early Childhood Body Mass Index (BMI) Trajectories
Institution/Hospital: Vanderbilt University Medical

WHOM TO CONTACT

If you have any questions about the study, please contact the principal investigator, Dr. Shari Barkin at (615) 936-8066, or the coordinator, Juan Escarfuller at (615) 414-5713. For additional information about giving consent or your rights as a participant in this study, please feel free to contact the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

CONSENT TO PARTICIPATE

I have read this statement, and I understand what it says. I agree to participate in this study under the conditions outlined above. I also acknowledge that I have received a copy of this form.

I understand that I am agreeing to participate in a 6-month program.
☐ Yes ☐ No

I understand that both my child and I will be asked to wear a monitor for 1 week to measure how much our muscles move at 2 different times throughout the program, totaling 2 weeks of wearing the monitors.
☐ Yes ☐ No

Volunteer Signature _____ Date _____

Staff Signature _____ Date _____

Date of IRB Approval:

Date of IRB Expiration:

Date of IRB Approval: 7-14-2011
Date of IRB Expiration: 4-28-2012

Principal Investigator: Shari Barkin, MD, MSHS Revision Date: 07-11-11
Study Title: Formative Phase of Growing Right Onto Wellness (GROW): Changing Early Childhood Body Mass Index (BMI) Trajectories
Institution/Hospital: Vanderbilt University Medical

Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You and your child are being asked to give a saliva sample for genetic research. What we learn about you and your child from these saliva samples will not be put in your or his/her health record. Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results. Your sample(s) will only be used for research at Vanderbilt University and will not be sold.

A single saliva sample will be taken from you and from your child using Oragene saliva kits. You and your child will each be asked to spit into a small container that shows the amount of saliva needed (2-3 ccs, which is about half a teaspoon). This will take less than 5 minutes of your time.

One risk of giving saliva samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job. To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Shari Barkin and her research team will have access to your name.

Your samples will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The samples will be destroyed when it is no longer needed.

Your samples will be used for research only and will not be sold or used to make products that could be sold for money.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent pediatric obesity and other health problems.

Giving a saliva sample for research is your free choice and you may be in the GROW study even if you do not want your or your child's saliva sample used or stored for gene research.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers

Date of IRB Approval:

Date of IRB Expiration:

Date of IRB Approval: 7-14-2011
Date of IRB Expiration: 4-28-2012

Principal Investigator: Shari Barkin, MD, MSHS Revision Date: 07-11-11
Study Title: Formative Phase of Growing Right Onto Wellness (GROW): Changing Early Childhood Body Mass Index (BMI) Trajectories
Institution/Hospital: Vanderbilt University Medical

with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

At any time, you may ask to have your saliva samples destroyed. You should contact Dr. Shari Barkin or Juan Escarfuller to have your sample destroyed and no longer used for research. Their contact information is below.

Shari L. Barkin, MD, MSHS
Professor of Pediatrics
Division Chief of General Pediatrics
Vanderbilt Children's Hospital
8246 Doctors' Office Tower
2200 Children's Way
Nashville, TN 37232-9225
Tel: 615-936-8066

Juan Escarfuller, MA, MADiv
Coordinator, Salud con la familia
Division of General Pediatrics
Monroe Carell Jr. Children's Hospital at Vanderbilt
AA-0216 Medical Center North
Nashville, TN 37232-2504
Tel: (615) 414-5713

We will not be able to destroy research data that has already been gathered using your samples. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Date of IRB Approval:

Date of IRB Expiration:

Date of IRB Approval: 7-14-2011
Date of IRB Expiration: 4-28-2012

Principal Investigator: Shari Barkin, MD, MSHS Revision Date: 07-11-11
Study Title: Formative Phase of Growing Right Onto Wellness (GROW): Changing Early Childhood Body Mass Index (BMI) Trajectories
Institution/Hospital: Vanderbilt University Medical

Please check Yes or No to the questions below.

My saliva sample may be used for gene research.
☐ Yes ☐ No

My saliva sample may be stored/shared for future gene research in pediatric obesity.
☐ Yes ☐ No

My saliva sample may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc).
☐ Yes ☐ No

Please check Yes or No to the questions below.

My child's saliva sample may be used for gene research.
☐ Yes ☐ No

My child's saliva sample may be stored/shared for future gene research in pediatric obesity.
☐ Yes ☐ No

My child's saliva sample may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc).
☐ Yes ☐ No

Volunteer Signature: _____ Date: _____

Staff Signature: _____ Date: _____

Date of IRB Approval:

Date of IRB Expiration:

Date of IRB Approval: 7-14-2011
Date of IRB Expiration: 4-28-2012

VANDERBILT UNIVERSITY
Institutional Review Board

APPENDIX 2. RECRUITMENT ELIGIBILITY (PRE-SCREEN) FORM

Confidential

Recruitment Eligibility Criteria

What is your full name? _____

Are you 18 years of age or older?
- ☐ Yes
- ☐ No

What is your date of birth? _____

What is your gender?
- ☐ Female
- ☐ Male

Do you speak English?
- ☐ Yes
- ☐ No

In which of these zip codes do you live?
- ☐ 37206
- ☐ 37207
- ☐ 37208
- ☐ 37228
- ☐ 37213
- ☐ 37210
- ☐ 37211
- ☐ 37217
- ☐ 37204
- ☐ 37220
- ☐ 37013

Do you have a child age 3 to 5 that will participate with you in the program?
- ☐ Yes
- ☐ No

What is this child's full name? _____

What is this child's date of birth? _____

What is this child's gender?
- ☐ Female
- ☐ Male

What is your relationship to this child?
- ☐ Mother
- ☐ Father
- ☐ Aunt
- ☐ Uncle
- ☐ Sister
- ☐ Brother
- ☐ Cousin
- ☐ Stepmother
- ☐ Stepfather
- ☐ Grandmother
- ☐ Grandfather
- ☐ Other relative
- ☐ Other non-relative

Other relative (please describe): _____

Other non-relative (please describe): _____

Do you spend the majority of the time with this child when the child is at home?
- ☐ Yes
- ☐ No

Are you committed to participating regularly in this program with this child for 12 weeks plus additional phone call coaching?
- ☐ Yes
- ☐ No

Has this child ever received a diagnosis of failure to thrive or an eating disorder?
- ☐ Yes
- ☐ No

Does your child have any current medical conditions that would interfere with increasing daily physical activities?
☐ Yes
☐ No

What medical condition(s)? _____

Is this/Are these currently controlled?
☐ Yes
☐ No

Are you able to participate in mild to moderate physical activity?
☐ Yes
☐ No

Has your doctor ever said you have heart trouble?
☐ Yes
☐ No

Do you frequently have pains in your heart or chest?
☐ Yes
☐ No

Do you often feel faint or have spells of severe dizziness?
☐ Yes
☐ No

Do you have high blood pressure?
☐ Yes
☐ No

Is it currently controlled?
☐ Yes
☐ No

Has your doctor ever told you that you have a bone or joint problem, such as arthritis, that has been aggravated by exercise or might be made worse by exercise?
☐ Yes
☐ No

Is there any reason you should not follow a physical activity program?
☐ Yes
☐ No

Are you over the age 65 and not accustomed to vigorous exercise?
☐ Yes
☐ No

Do you or anyone in your household participate in of these programs or services? TennCare CoverKids WIC Food Stamps (SNAP) Free and Reduced Price School Lunch and Breakfast Families First (TNAF)
☐ Yes
☐ No

Valid Participant?
☐ Yes
☐ No
☐ Don't Know

Recruitment Contact Information

What is your address? _____

Do you have access to a phone where you can be reached regularly for the next 6 months?
☐ Yes
☐ No

What is your primary phone number? _____

What type of number is this?
☐ Home
☐ Cell
☐ Work

What is a secondary phone number for you? _____

What type of number is this?
☐ Home
☐ Cell
☐ Work

What is the best day and time to call you? _____

Do you have the ability to text and receive texts (at no extra cost)?
- ☐ Yes
- ☐ No

Which phone number can receive texts?
- ☐ Primary Number
- ☐ Secondary Number
- ☐ Other Number

Other number (please enter): _____

Do you have access to the internet?
- ☐ Yes
- ☐ No

How often do you have access?
- ☐ Every day
- ☐ Almost every day
- ☐ Once a week
- ☐ Less than once a week

What is your email address? _____

Do you have a Facebook account?
- ☐ Yes
- ☐ No

We know contact info changes for many families, so we would like 3 alternate contact to help us stay in touch. Could we have the full name your first contact? _____

What is this person's relationship to you? _____

What is a phone number to reach this person? _____

What type of phone number is this?
- ☐ Home
- ☐ Cell
- ☐ Work

Could we have the full name your second contact? _____

What is this person's relationship to you? _____

What is a phone number to reach this person? _____

What type of phone number is this?
- ☐ Home
- ☐ Cell
- ☐ Work

Could we have the full name your third contact? _____

What is this person's relationship to you? _____

What is a phone number to reach this person? _____

What type of phone number is this?
- ☐ Home
- ☐ Cell
- ☐ Work

Recruitment Session Information

Which of these days would be your first choice for a session time? (Sessions would be approximately 90 minutes in length.)
- ☐ Tuesday
- ☐ Wednesday
- ☐ Thursday
- ☐ Friday
- ☐ Saturday

Tuesday Times:	☐ 10am-12pm ☐ 6pm-8pm
Wednesday Times:	☐ 10am-12pm ☐ 6pm-8pm
Thursday Times:	☐ 10am-12pm ☐ 6pm-8pm
Friday Times:	☐ 10am-12pm ☐ 6pm-8pm
Saturday Times:	☐ 8am-10am ☐ 10am-12pm ☐ 1:30pm-3:30pm
Which of these days would be your second choice for a session time?	☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday ☐ Saturday
Tuesday Times:	☐ 10am-12pm ☐ 6pm-8pm
Wednesday Times:	☐ 10am-12pm ☐ 6pm-8pm
Thursday Times:	☐ 10am-12pm ☐ 6pm-8pm
Friday Times:	☐ 10am-12pm ☐ 6pm-8pm
Saturday Times:	☐ 8am-10am ☐ 10am-12pm ☐ 1:30pm-3:30pm
Which of these days could you definitely not come to a session?	☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday ☐ Saturday
Tuesday Times:	☐ 10am-12pm ☐ 6pm-8pm
Wednesday Times:	☐ 10am-12pm ☐ 6pm-8pm
Thursday Times:	☐ 10am-12pm ☐ 6pm-8pm
Friday Times:	☐ 10am-12pm ☐ 6pm-8pm
Saturday Times:	☐ 8am-10am ☐ 10am-12pm ☐ 1:30pm-3:30pm
Would you need free transportation to and from the sessions for you and your family?	☐ Yes ☐ No
Do you have a car seat/booster seat?	☐ Yes ☐ No

Additionally, we will be offering supervised activities for both the child participating in the program and siblings of that child. Is this something that you would use?

☐ Yes
☐ No

For how many children? _____

What are their ages? _____

Recruitment Referrals

If you know of anyone that may be interested in our program, we would welcome their contact information to add to our registry.

Person #1 What is this person's full name? _____

What is this person's relationship to you? _____

What is a phone number to reach this person? _____

What type of phone number is this?

☐ Home
☐ Cell
☐ Work

Person #2 What is this person's full name? _____

What is this person's relationship to you? _____

What is a phone number to reach this person? _____

What type of phone number is this?

☐ Home
☐ Cell
☐ Work

Person #3 What is this person's full name? _____

What is this person's relationship to you? _____

What is a phone number to reach this person? _____

What type of phone number is this?

☐ Home
☐ Cell
☐ Work

Person #4 What is this person's full name? _____

What is this person's relationship to you? _____

What is a phone number to reach this person? _____

What type of phone number is this?

☐ Home
☐ Cell
☐ Work

Person #5 What is this person's full name? _____

What is this person's relationship to you? _____

What is a phone number to reach this person? _____

What type of phone number is this?

☐ Home
☐ Cell
☐ Work

CONTACT INFORMATION CHANGES (for later use) _____

APPENDIX 3. SAMPLE SESSION FIDELITY PLAN

Date:_____
Site: _____
Interventionist: _____

GROW Pilot Intervention Fidelity Plan
Group _____ Week 12
Eating Together

SESSION KEY MESSAGES: Eating Together	Covered	How Well	Comments
Eat a rainbow of fruits and vegetables at every meal.			
Control your plate and eat appropriate portion sizes.			
Eat together once a day.			

0=not covered 1=partially covered 2=fully covered How well: scale of 1-5

SESSION OUTLINE: Eating Together	Happened	How Well	Comments
Interventionist welcomes participants and recites group purpose.			
Interventionist facilitates goal check in.			
Interventionist reviews goals for today's session.			
Interventionist facilitates small group and whole group activities discussing and practicing the key messages.			
Interventionist facilitates goal setting.			
Interventionist facilitates skill building activity.			

0=did not happen 1=happened How well: scale of 1-5

Did this session take place at the scheduled location? YES NO
(if no, where did the session take place?)

Did this session take place at the scheduled time? YES NO
(if no, why not)

Did this session last for at least 90 minutes? YES NO
(if no, how early did it end)

Did this session exceed 90 minutes? YES NO
(if yes, how long was the session)

How many staff members were present for this session?

Interventionists:
Kids Club:
Kitchen help:

Did the staff have all of the necessary materials on site and ready for the session (as listed in interventionist guide)? YES NO
(if no, what was missing)

Did the interventionist use and explain the module booklet during the session? YES
NO

Did any of the participants leave the module booklets behind? (if yes, which ones) YES
NO