Protocol

I. Research Project Title:
ACTION PAC: Adolescents Committed to Improvement of Nutrition & Physical Activity

NCT number: NCT02502383

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II. Investigator's Name, Degree, Title, and Department: Alberta Kong, MD, MPH, Associate Professor, Department of Pediatrics

III. Hypothesis or Study Goals (questions hoped to be answered by study):

Specifically, our goals are to 1) prevent the development of overweight and obesity among students with BMI <85th percentile, 2) reduce BMI z score by 0.16 (change documented in a high intensity obesity intervention that produced clinical improvements in insulin resistance)[10] in students with BMI ≥85th percentile, 3) reduce insulin resistance (as measured by the homeostasis model assessment) in students with BMI ≥85th percentile, and 4) obtain participants' feedback on their experience with school-based BMI screening and weight management to guide future dissemination efforts and studies. To achieve these goals, we aim to:

1) Evaluate motivational interviewing (MI) as a method to prevent overweight/obesity in students with BMI <85th percentile.
   a. Hypothesis 1a -- Intervention schools (where parents are sent annual BMI results and students receive MI-based discussion of BMI results, healthful eating and physical activity) will have a lower incidence of overweight/obesity among their students compared with comparison schools (where parents are sent annual BMI results but students do not receive MI-based discussion) after two years.
   b. Hypothesis 1b -- Intervention schools will evidence greater mean improvements in physical activity and dietary intake (e.g., decreased consumption of sugar-sweetened beverages, decreased fat intake, and increased consumption of fruits, vegetables and whole grains) compared with comparison schools after two years.
2) Evaluate the SBHC weight management program (ACTION) that utilizes MI for treatment of overweight/obesity for intervention school students with BMI ≥85th percentile.
   a. Hypothesis 2 -- Compared with comparison school students with BMI ≥85th percentile, students receiving ACTION will have greater reduction in BMI z score and insulin resistance after two years.
3) Evaluate student and parent feedback at the end of the intervention trial about their experience with school-based BMI screening and weight management to inform future dissemination efforts and studies.

IV. Background:

i) Describe relationship of proposed study to previous investigations in the field, summarize those previous studies, including previous human, laboratory, and animal studies (describe existing knowledge).

High prevalence of obesity and metabolic syndrome: Since 1980, the prevalence of childhood obesity in the U.S. has tripled to 17%, affecting 12.5 million school-age children and adolescents.[11, 12] Associated with this epidemic is the rising prevalence of metabolic (or insulin resistance) syndrome among adolescents, typically described as a clustering of five cardiometabolic risk factors that includes central adiposity, elevated blood pressure, hypertriglyceridemia, low HDL-cholesterol, and impaired glucose metabolism.[1-3] Longitudinal studies show that children and adolescents with at least three of these metabolic derangements are more likely to suffer cardiovascular disease 25 years later[4] and to develop type 2 diabetes.[5, 6] Recent data reveal that the prevalence of metabolic syndrome in all U.S. teens varies from 2.0% to 9.4%; however, in obese teens, prevalence escalates from 12.4% to 44.2%.[13] Therefore, as recommended by the American Heart Association, to prevent the development of metabolic syndrome, overweight and obese adolescents need lifestyle modification to assist with weight loss, and normal weight youth should be encouraged to adopt healthier lifestyle habits to maintain their weight.[14]

Racial and ethnic disparities of obesity and metabolic syndrome: There are large disparities in overweight (defined in children and adolescents as BMI 85th-94th percentile) and obesity (BMI ≥95th percentile)[15] between demographic groups. Adolescents from several minority groups have the greatest increases in adiposity compared to their counterparts.[16] Nationally, Hispanic adolescents experience significantly higher BMI rates than non-Hispanic Whites.[12] In New Mexico, American Indian youth have the highest rate of obesity (17.8%), double that of White youth (8.7%); African American (13.5%) and Hispanic (12.8%) youth also have high rates --

about one-third higher than White youth.[17] More concerning is that obese youth gain more body fat over time, especially more central fat as indicated by waist circumference.[18] This increase is concerning because it is a component of the metabolic syndrome and a direct predictor of cardiovascular disease and type 2 diabetes. In a study of Hispanic youth in Los Angeles, 90% of overweight Hispanic children with a family history for type 2 diabetes had at least one feature of metabolic syndrome with 30% already meeting clinical criteria for metabolic syndrome.[19]

High economic costs of obesity and metabolic syndrome: The economic costs of childhood obesity compound the consequences of the epidemic. Annual prescription drug, emergency room and outpatient costs amount to $14 billion and inpatient costs total $238 million.[20, 21] Even greater cost is incurred when obese children become obese adults. An estimated $147 billion is expended to treat obese adults annually.[22] A study that investigated health care utilization and costs associated with metabolic syndrome in three health plans in Seattle found that average annual total costs for patients with metabolic syndrome compared to those without metabolic syndrome differed by a factor of 1.6 ($5,732 vs. $3,581).[23]

Prediabetes and type 2 diabetes in adolescents: In a recent National Health and Nutrition Exanimation Survey, nearly one in four adolescents, ages 12-19 years, had prediabetes or type 2 diabetes as defined by a fasting plasma glucose >99 mg/dL.[24] This is a sharp increase from 9% in 1999-2000 to 23% in 2007-2008. As type 2 diabetes progresses more rapidly in children and adolescents than in adults and is harder to treat (≥50% treatment failure rate),[25] it is imperative to prevent adolescents from developing the disease. People with prediabetes can prevent developing type 2 diabetes with modest weight loss and exercise.[26] Therefore, obesity treatment through lifestyle modification is possible for reducing long-term negative outcomes, and is an approach that is urgently needed for adolescents.

Limited healthcare access for adolescents: Adolescents averaged 1.9 clinical visits/year, lower than any other pediatric age-group.[8, 9] School-based health centers (SBHCs) offer a unique and important method to expand healthcare access for all adolescents, including those who do not have adequate health insurance. SBHCs provide preventive and primary health care services to all students on school campuses, with a particular focus on assisting uninsured and underserved youth. This healthcare model has demonstrated utility in intervening with public health needs such as immunization and chronic disease managment.[27] While there is clear promise, the role of SBHCs in preventing/treating childhood obesity has not yet been well investigated.

Providers in SBHCs have the unique ability to access almost the entire adolescent population during a key developmental stage, when youth are beginning to develop autonomy, and are just beginning to make and enact independent health decisions (e.g., what foods to eat, whether/how to exercise). In contrast to their clinical colleagues in the community, SBHC providers have more time to devote to complicated lifestyles and behavioral issues that are often found among adolescents, and which directly influence obesity. This is an exceptionally good fit, as healthy dietary habits are among the top three health topics that adolescents want to discuss with their providers.[28] Particularly within low-income and minority communities, SBHCs may **truly** offer the **only** point of intervention for overweight and obese adolescents.

Need for obesity interventions in high schools: The 2012 Institute of Medicine Report has recommended "making schools a national focal point" in the battle against obesity.[29] The majority of the school-based obesity intervention research has focused on children in middle and elementary schools.[30-32] However, high school offers an important time to facilitate and foster active living and healthy eating behaviors for adolescents, who are eager to learn skills that directly address their autonomy and independent decision making (such as their choices about health, foods and exercise). This is critically important, as this is the last stage before adolescents enter young adulthood, a time when they are especially vulnerable to weight gain due to leaving home for college, cohabitation, pregnancy, and child rearing.[7] Accessing youth before they become young adults provides a critical time to prevent dramatic increases in the prevalence of overweight and obesity (e.g., from 34% in 12-19 year olds[12] to 62% in 20-39 year olds[33]). Efficacious obesity prevention programs are needed to prepare adolescents for the transition into adulthood.

ii) Identify specific knowledge gaps which research is intended to fill (rationale for performing the research).

Discussion of school-based BMI screening results: While the Institute of Medicine (IOM) has recommended body mass index (BMI) screening in schools to address pediatric obesity[34] and the US Preventive Task Force

has recently concluded that there is sufficient evidence to support BMI screening in clinical practice,[35] the CDC has maintained that there is insufficient evidence to recommend for or against such programs in the schools.[36] Despite the unclear evidence of school-based BMI screening for obesity prevention, twenty states (40%) have already adopted school-based BMI or body composition screening.[37] Only nine of these states require parental notification and none report directly discussing results with students. Provider discussions about BMI, healthier eating, and physical activity habits is an important missing piece. Not only does it model active collaboration with healthcare providers, it is also consistent with important psychosocial goals for this developmental stage, which include gaining independence from parents and making autonomous decisions. With the use of SBHCs, it is possible to discuss with adolescent students their BMI, diet and physical activity as is recommended in clinical practice.

Motivational interviewing (MI) to change adolescent eating and physical activity behavior: While investigations of MI as a prevention/intervention approach for youth at risk for overweight/obesity are still emergent, these studies have strongly indicated the fit and acceptability of MI approaches with minority youth, and among pediatric clinicians.[38-40] In contrast with the adolescent research, there has been a much broader spectrum of studies with adults, which unequivocally demonstrate that MI contributes to significant changes in physical activity.[41-44] Specifically, 80% of studies examining MI to increase physical activity demonstrate significant effects.[45] Additionally, naturalistic studies have shown that primary-care physicians are more successful in facilitating activity increases and weight loss among their patients when they are more adherent to MI principles.[46] Furthermore, researchers have explicitly stated that MI would be useful for exercise intervention and prevention efforts with difficult-to-treat conditions like pediatric obesity.[47, 48] However, these recommendations still need empirical evaluation. This study would directly address the paucity of data needed to clarify the efficacy and effectiveness of MI-based interventions to prevent and intervene with adolescent overweight/obesity, with a critical sample of high-risk and high-need adolescents. This evaluation has direct public health implications.

Referral system to treat students identified with overweight and obesity: One argument against school-based BMI screening is that there is not an effective referral system in place to link students identified as overweight/obese from the school system to community health resources for treatment.[49] Yet, with SBHCs, it is possible to not only conduct school-based BMI screening, but also to directly treat identified youth.[50] To ensure the efficacy of this mechanism, it is necessary to evaluate the impact of schools with SBHCs as a venue to prevent and treat overweight and obesity for adolescents with limited access to health care. If successful, use of SBHCs may help to decrease the disparity of obesity and metabolic syndrome in adolescent minority populations.

Use of Adolescents Committed to Improvement of Nutrition and Physical Activity (ACTION) weight management program: The NHLBI-funded pilot study for this proposal, ACTION (PI: Kong), demonstrated empirical support. More specifically, this program included three primary components: 1) clinical encounters with the SBHC clinician every two to three weeks for a total of eight visits over one academic year, 2) use of MI[51, 52] to support adoption of healthier behaviors, and 3) use of obesity risk reduction strategies from a clinician toolkit co-created with overweight/obese adolescents and their parents. This innovative toolkit includes a DVD (given to the overweight/obese adolescent at the first clinical visit) which was developed with our community adolescent-parent partners and contains: 1) adolescents discussing their motivation for change, 2) strategies targeting energy balance and nutritional quality, and 3) physical aerobic dance (e.g., hip hop, salsa, kick boxing) and strength training exercises created by celebrity fitness trainer Giselle Roque de Escobar (TV fitness host of ESPN International's "Mente y Cuerpo" 2001-2003 and selected top 10 best workout DVD by Fitness Magazine 2006). Print intervention materials in the clinician toolkit include weight loss guidelines, an overview of MI strategies for clinicians, newsletter for caregivers to create a healthier home environment, clinic displays to stimulate discussions about healthier food options, and adolescent session tools (e.g., goal setting, internet resources, and activity/food journal). A Community Based Participatory Research approach was used to ensure that the intervention was culturally- and developmentally-appropriate. In this NIH-funded R21, we also partnered with School Health Advisory Councils (SHACs), comprised of parents, students, community members, and school staff, to demonstrate the acceptability and feasibility of this intervention.[53] Our goal in this pilot R21 was to create an intervention that could be easily implemented across settings with limited resources. Our ACTION weight management program was supported as an innovative solution to this issue, as it is of low-intensity (10-25 hours)[54] and highly feasible and acceptable to our previous school partners. We have not been able find any published randomized controlled trials evaluating the efficacy of SBHC overweight/obesity

treatment with adolescents. Thus, the proposed study would provide a unique opportunity to evaluate the broader reach and efficacy of this intervention, by evaluating outcomes across a large number of schools with high-risk and high-need youth.

V. Experimental Design and Methods:

i) Provide concise description of experimental design and procedures to be used to accomplish study goals. Include precise descriptions of all tests and measurements, and their expected duration. Include optional testing and blinding/un-blinding procedures if applicable.

Research Design: A cluster randomized control trial will be used to test hypotheses. The NM Department of Health, Office of School and Adolescent Health provided a list of recommendations for schools with functioning SBHCs serving a large Hispanic student population. PI Kong successfully approached these schools about collaborating on the proposed research; they agreed (see Letters of Support). To limit the possibility of confounding effects, our collaborating high schools all share the following four characteristics: 1) Enrollment/ethnicity: At least >700 enrolled students, with at least 40% Hispanic youth, 2) Environmental resources: at least one outdoor field, one gymnasium, and physical activity opportunities, 3) Food service resources: at least one cafeteria, competitive foods (foods brought into schools from outside vendors), and vending machines, and 4) a functioning SBHC. To further control for plausible alternative explanations of outcomes between groups, pretest differences will be compared between groups. The pretests will allow exploration of the possible size and direction of bias that may exist. Thus, the joint use of a pretest and a comparison group will allow examination of possible threats to validity (see Analyses). Assessments will be conducted at pretest (baseline) and annually for two more years (see Table 1). The assessment time waves will allow us to follow 9th grade students annually until their 11th grade year and 10th grade students until their 12th grade year.

Data Collection Measurements: All measures will be collected in both intervention and comparison schools. Protocols with standardized procedures and quality control procedures will be followed by research staff to ensure accuracy, precision, and completeness of data collection. Training for data collection team members will be given by Sarah Sanders, RN, MS (for physical activity related measures) and by Dr. Yakes (for anthropometrics and nutrition related measures). Each year, before measurements begin, these investigators will retrain and certify the data collection team in all measures. Demographic, physical, dietary intake and physical activity data will
be collected at baseline (pretest), at one year (intermediate), and at 2 years (follow-up) in both intervention and comparison schools. These time intervals will allow us to assess pretest to posttest changes on hypothesized outcomes, and intermediate effects of the intervention. Students will be reimbursed $20 per measurement wave (total possible=$60); compensation is consistent with other clinical trials in NM.

- Demographic information to be collected on participants and their parents include age, sex, socioeconomic status, education, and race/ethnicity, using our previously developed Health History Survey. Our Health History Survey also includes questions on family history of type 2 diabetes (first and second degree relatives), chronic medical conditions, and current medications.

A follow-up health history will be administered at intermediate (year one) and follow-up (year two) measurement periods. Participants will update contact and health information. Participants will be exluded at intermediate and follow-up measurement periods if they are pregnant or have been diagnosed with an eating disorder.

- Anthropometric measurements include height, weight, waist circumference and triceps skinfold. Height and weight will be measured twice using the method described by Gordon and colleagues and the National Health and Nutrition Examination Survey (January 2007).[66] Participants will be weighed to the nearest 0.1 kg on a portable strain-gauge digital scale (Secca Model 770) and height will be measured to the nearest 0.1 cm using avertical measuring rod (Seca Model 213). A third measurement will be done if the first two measurements differ by greater than 0.1 kg (weight) or 0.5 cm (height). If three measurements are taken, the closest two measurements will be used for analysis. BMI will be calculated as kilograms per meters squared. We will use the CDC program, NUTSTAT,[67] that calculates a precise BMI percentile and Z-score based on the participants' height (cm), weight (kg), sex, and age (in months). Participants' waists will be measured twice with a steel tape using the method described by Callaway and the National Health and Nutrition Examination Survey (January

2007).[68] Measurements will be recorded to the nearest 0.1 cm. Triceps skinfold will be measured with the participant in the standing position using a Lange Skinfold caliper (Beta Technology, Santa Cruz, CA). The measurement will be obtained at the upper arm mid-point on the posterior surface of the right upper arm using the technique as described by Harrison and the National Health and Nutrition Examination Survey (January 2007).[69] Three triceps skinfold measurements will be performed and recorded to the nearest 1.0 mm. The average of the three measurements will be used for calculations in determination of percent body fat.

- Blood pressure will be measured on the right arm in the seated position with an aneroid sphygmomanometer. Technique and cuff sizes will be adapted from the National Health and Nutrition Examination Survey (May 2009). Computation of blood pressure percentiles for sex, age and height will follow statistical procedures specified in the Fourth Task Force Report on High Blood Pressure in Children and Adolescents.
- Biomarkers include insulin, glucose, hemoglobin A1c, and lipids will be obtained in overweight/obese adolescents. Samples will be drawn after an ten hour overnight fast. Serum samples will be allowed to clot. All samples will be centrifuged on-site and transported in an ice chest with freezer packs to Tricore Laboratory for processing. Insulin resistance will be calculated using the homeostatic model assessment insulin resistance index [HOMA-IR = (Product of fasting insulin mU/L and fasting glucose mmol/L)/22.5] which has been shown to have reliable sensitivity and specificity in assessing insulin resistance.[63, 71] HOMA-IR increases with increasing insulin resistance.
- Dietary intake will be assessed by the Block Food Screener 2007 a validated food frequency questionnaire. This self-administered tool estimates an individual's usual intake over a period of 1 week. NutritionQuest (Berkeley, CA) will create the data base from the completed surveys for analysis.
- Physical activity will be assessed using the 3-Day Physical Activity Recall (3DPAR) and accelerometry. The 3DPAR has established instrument validity in adolescents based on concurrent observation with motion sensors.[73, 74] Objective assessments of physical activity will be obtained using the ActiGraph GT3X accelerometer (Shalimar, FL). The Actigraph has documented evidence of validity and inter-instrument reliability in children and adolescents.[75, 76] Consistent with previous studies, monitors will be attached to adjustable elastic belts and worn over the right hip during waking hours for 7 consecutive days. Accelerometer counts will be uploaded to a customized EXCEL macro written by Dr. Trost for determination of daily time spent in sedentary, light, moderate, vigorous, and moderate-to-vigorous physical activity. The age-specific count thresholds corresponding to these intensity levels will be derived from the MET prediction equation developed by Freedson and co-workers as published by Trost and colleagues[77] and replicate the intensity categories used in population-representative objective monitoring studies (e.g., NHANES).[78, 79]
- We will assess change using readiness to change (casaa.unm.edu), sedentary behavior (Robinson, 1999), eating attitudes (Garner et al, 1982) and health related quality of life (Varni) by evaluating adolescents' status on these measures at assessment waves.
- A questionnaire will be administered to elicit feedback from participants regarding their experiences with the study.

Post-intervention interviews: There is considerable controversy about the psychosocial impact of school-based BMI screening on overweight and obese adolescents. Our experience and formative results from overweight and obese teens in previous studies have been very positive. To contribute to the literature on this topic and improve future dissemination of the proposed intervention, we will conduct a qualitative evaluation of participants' experience with school-based BMI screening and weight management among teens and parents in our intervention. We will conduct 12-20 semi-structured interviews with student participants (3-5 interviews with overweight/obese males, 3-5 interviews with non-overweight/non-obese males, 3-5 interviews with overweight/obese females, and 3-5 interviews with non-overweight/non-obese females). Additionally, 12-20 interviews with parent participants as above will be conducted (3-5 parents of overweight/obese males, 3-5 parents of non-overweight/non-obese males, 3-5 parents of overweight/obese females, and 3-5 parents of non-overweight/non-obese females). The "rule of thumb" most frequently used to determine when a sufficient sample size for interviews has been reached is to conduct interviews until the same perceptions, themes, issues and concerns are emerging from the study participants, called saturation. In our experience saturation occurs between 3-5 interviews of homogeneous informants (i.e., teens of same sex and weight status).[80, 81] Interviews will be semi-structured and last approximately 45 to 60 minutes. Stem questions will focus on student views pertaining to BMI screening and weight management using SBHCs, the processes associated with the proposed

intervention- specifically eliciting perspectives about potential barriers (e.g., social, scheduling) to participation. Parent interviews will triangulate similar issues and also explore barriers/facilitators to supporting interventional goals in the home environment. These interviews will concentrate on process evaluation components aimed at elucidating the contextual factors most influential in participation. SBHC clinicians will provide names of student and parent participants willing to be interviewed; selection will be based on ensuring an equal representation of the two counties where the schools are located. Co-I Feldstein Ewing will train research staff to conduct interviews; she has over 9 years of experience in qualitative research that has been used to develop or modify intervention approaches for youth and underserved communities.[82]
Interview questions have been finalized and are titled "parent qualitative questions" and "youth qualitative questions."

Intervention schools

- Rationale for the selected intervention- Based on the preliminary positive data for MI with minority youth,[38, 40] the acceptability of an MI approach by health care providers,[39, 64] and the promising foundational outcomes from the PI's R21 (ACTION), this study will utilize MI[52, 83] for both the prevention component (discussing BMI results) as well as the treatment component of this study (ACTION weight management program).
- Training in and monitoring of MI- All interventionists will be SBHC clinicians from the intervention schools. The goal of MI is to bolster and support youth's internal motivation, autonomy, and self-efficacy to enact positive behavioral choices, which have been observable up to twelve months post-intervention.[65, 84, 85] In line with the approaches of MI,[51, 52] all interventionists will be taught to utilize MI with adolescents to support and promote the selection of healthier food options and to consistently engage in physical activity for maintenance or achievement of a healthy weight. Consistent with her role across five prior NIH-funded R01s and R03s, Co-I Feldstein Ewing will oversee the training and supervision of MI providers to ensure intervention integrity and fidelity. To that end, all interventionists will be trained using the following five steps. Interventionists will (1) begin their training with an in-person MI training (2 days), which will include interactive training (didactic and role playing) on the use of MI, (2) be required to read the study manuals, (3) pass a knowledge test to evaluate their grasp of the concepts within and behind MI (e.g., with a pass rate of at least 80% on the fidelity checklist and 100% adherence to essential therapeutic elements), (4) watch a MI intervention session with a pilot participant and discuss the details of the session, and (5) conduct two pilot sessions, during which Co-I Feldstein Ewing will evaluate interventionists' proficiency in MI, with an eye to the following MI integrity components (e.g., MI spirit, MI consistent behaviors including use of reflections, demonstration of accurate empathy, minimal to no closed questions, minimal to no advice without permission).[86] As delineated in the adolescent assent and parent consents, all visits with the adolescent patient will be audio taped to facilitate the continuous monitoring of fidelity of the intervention. All interventionists will participate in once per week teleconference-based supervision, during which randomly selected tapes will be reviewed by Dr. Feldstein Ewing, who will provide feedback and coaching to the providers. This approach also facilitates continuing performance review, minimization of drift, and a venue to discuss potential problems that might arise in conducting MI-based interventions. We utilize this thorough, multi-level training approach because providers who receive coaching after the initial training are more likely to fully retained clinical trial proficiency levels with MI when compared to those who receive only workshop training.[87]
- Prevention intervention (discussing BMI results/healthful eating/physical activity)- All youth in intervention schools will participate as follows: 1) SBHC providers will use BMI obtained by the data collection team to discuss BMI results directly with adolescent participants. This visit will be a standard part of each 9th or 10th grade student's start-of-school year health visit; 2) all providers in the intervention schools will use MI-based approaches throughout this discussion to support and enhance adolescent's healthy eating and physical activity behaviors; 3) consonant with prior data indicating that youth have questions around how to select healthier foods[28] and AAP recommendations,[15] all youth will be invited to actively engage in a discussion around how adolescents can maintain or achieve a healthy weight; 4) finally, all parents of intervention school students, regardless of BMI, will be sent a letter describing their children's BMI results and AAP recommendations. Annual BMI results, healthful eating and physical activity for healthy weight will be discussed each year. For students with BMI ≥ 85th percentile (defined as overweight or obese),[11] this will be the first interaction with SBCH providers. At the end of the discussion (steps 2-3), SBHC providers will schedule the student's first meeting for the weight management intervention after summer.

- Treatment intervention (ACTION weight management program)- Participants with BMI ≥85th percentile (overweight/obese) at baseline will receive ACTION. Consistent with our approach in our NIH-funded pilot study,[53] prior to their first session of ACTION, adolescents will be scheduled by the data collection team in the SBHC for fasting blood sampling to evaluate for impaired fasting glucose, insulin resistance and dyslipidemia. SBHC providers will review these results at the youth's first session of ACTION. Session 1 will begin with SBHC clinicians providing youth with an educational DVD on nutrition and physical activity. At this time, using MI-based approaches (e.g., emphasis on autonomy, support of self-efficacy) clinicians will review pertinent physical exam and laboratory findings with the adolescent, assess the adolescent's dietary and physical activity behavior, provide feedback about how their diet and activity compare to national recommendations, and elicit the participant's over-all response to this information.[52] Next, providers will invite adolescents to discuss barriers to healthier eating and physical activity, as well as general and personal strategies that might be helpful in overcoming these obstacles. For youth who are not yet ready to engage in discussions about change,[88] providers will openly and supportively explore ambivalence about dietary and physical activity change, with an eye to supporting autonomy and self-efficacy around behavior change. For youth who are interested in exploring a change behavior, as indicated by their change talk;[89] providers will help youth identify and develop 1-2 strategies for enacting positive behavior changes for the upcoming weeks (in the interim between ACTION sessions). These plans might include topics such as how and when to conduct physical activity, and how and where to purchase healthy foods. Because of the broad-based consensus that long-term interventions are needed for long-term behavioral change across pediatric nutrition[90] and physical activity,[91] and based on our R21 outcomes, we propose doubling our prior ACTION intervention (8 sessions/1 year) to yield a total of 16 sessions (e.g., 8 sessions per academic year for two years). This type of approach is uniquely possible due to the close proximity that SBHCs have to participating youth.

Another advantage of SBHCs is their on site location (school) which adds convenience for students and caregivers. Students are already at school and the caregivers do not have to leave work to bring their adolescent child to the clinic. However, because caregivers usually do not accompany the adolescent to the SBHC clinic visit, family and parental involvement is limited. Our formative findings in our NIH-funded pilot indicated that parents and adolescents both wanted some involvement of parents throughout the intervention. To increase caregiver involvement in ACTION, telephone contact will be made with the caregiver after each clinic visit to update them about their child's progress. In addition, a caregiver newsletter containing obesity risk reduction strategies will also be given at the beginning of the intervention. The purpose of the newsletter is to help caregivers create a more health-promoting home environment, so as to effectively support their adolescent child in improving nutrition and physical activity. This approach was pilot tested in the R21 study.

To improve convenience and access, we will also use telemedicine, through a secure, web-based, pass-coded network as a way to carry out motivational interviews for intervention participants. This mode of contact will be used in situations where it is not possible for the student and provider to attend the clinic for their in-person scheduled visit. To ensure privacy, telemedicine will be done in school-based health center exam rooms behind a closed door in the same way that in-person visits will be conducted.

Comparison schools

- Parent notification of results only- Annual BMI results collected by the data collection team will be sent to parents/caregivers with AAP obesity prevention recommendations. Students in the comparison schools will not receive discussions about their BMI results, healthful eating and physical activity. Consistent with standard of care,[92] students with BMI in the overweight or obese category will be scheduled by the data collection team for fasting blood insulin, glucose, hemoglobin A1c and lipid tests in the SBHC. The BMI and laboratory blood results of overweight/obese students will be sent to their parents/caregivers with a recommendation to follow-up with their school's SBHC or their primary care provider. Annual BMI results (and laboratory blood results if the student is overweight/obese) will be mailed to parents at the same points in time for both the intervention and comparison schools.

ii) Describe methods by which data will be managed - stored and destroyed.

Only research team members have access to study information. Students will be given unique identifiers so that names will not be used on data collection instruments or during data entry. Students names with their unique

identifiers will be kept in only one place in their study charts so that the team can ensure that they have the correct participant before starting data collection. Links will be kept until all data entry and analysis are completed. Data will be stored in locked file cabinets in the PI's research space in the UNM Prevention Research Center. Electronic data will be stored on a password protected computer. REDCap, a secure, web-based application from the UNM CTSC, will be used to for building and managing databases. REDCap access will be restricted to PI and research team. For intervention overweight and obese students attending the SBHC weight management program, visits will be kept separately from their SBHC medical records in a locked file cabinet used specifically for the project. All audio recordings will be securely destroyed within 3 years of study completion. Destroying data will follow HIPAA regulations, 6 years after HRPO acknowledged of study closure.

iii) Describe methods by which data will be analyzed and interpreted. Include the following, if applicable:

•Process measures and analysis: The purpose of process evaluation is to accurately describe the implementation of measures and the intervention, to assess the quality and consistency of measurement and intervention implementation (fidelity), and to document the extent of participant exposure to the intervention (reach and dose).[93] Process evaluation data will be collected continuously from the intervention schools as follows: 1) MI training and monitoring will include training attendance log and evaluation forms from interventionists at MI training sessions; and weekly teleconference supervision for intervention providers. 2) BMI result/healthful eating/physical activity discussions with students will include tracking attendance of students. 3) Referral of overweight/obese students to the SBHC weight management program will include tracking the number of overweight/obese students referred by the number eligible for referral. 4) The ACTION program will include student attendance; length of clinic visit; content of visit; receipt of materials (as reported by students) and use of toolkit handouts (as reported by providers); parent phone contact by providers; and parent receipt of newsletter and toolkit handouts. We will conduct mid-year monitoring on these process measures to ensure intervention fidelity and adjust accordingly if participant exposure is lower than expected. If we determine that any component is not occurring as planned, we will immediately address these inconsistencies with the appropriate personnel.

•06.16.14 A Doctor of Nursing Practice project will evaluate Session 1 MI-based intervention discussions: assess adolescent satisfaction with Session 1 MI-based discussions and explore perceived primary care provider (interventionist) comfort with Session1 MI-based discussions using the MI Participant Satisfaction Survey and MI Provider Self Assessment Survey evaluation forms as part of process and program evaluation. However, all of the sessions will be evaluated by the ACTION PAC team.

Sample size and power analysis: Given that incidence of overweight/obesity after 2 years (percent of students who were not overweight or obese at baseline but who become overweight or obese) is the primary outcome for the prevention intervention (discussing BMI results/healthful eating/physical activity with students using MI) (**Hypothesis 1a**), calculations are based on the ability to detect a 7.4% incidence difference between the intervention and comparison schools as previously reported from a policy-based school intervention to prevent overweight and obesity.[94] Recruitment of 120 students per school with ~36% who will be overweight or obese and ~64% who will not be overweight or obese (estimated from our previous experience) will give us a total sample of 960 students. Student retention rates in the proposed schools from 9^{th} – 11^{th} grades and from 10^{th} – 12^{th} grades range from 52% to 92% (mean of 72%). In our previous R21, 5% dropped out of the study and 8% left school. Taking into account the schools' retention rates and also our small dropout rate from our previous NIH-funded R21, we are using 35% as the potential attrition rate to calculate a sufficient sample size for testing: 1) BMI result/healthful eating/physical activity discussion with MI component, and also for 2) the weight management component. ~77 students per school are anticipated to be <85^{th} percentile (120 students × 64% who are <85^{th} percentile). If there is 35% attrition, ~50 students per school (400 total) will be available to calculate incidence of overweight/obesity. Based on analysis of our NIH-funded R21 study at two high schools, we used a value of 0.01 for the intraclass correlation (ICC). Therefore, with two-tailed alpha of 0.05 and power level of 0.80, differences of 6% to 10% will be detectable if incidence from the comparison schools range from 7% to 15%, respectively.

Due to higher than anticipated attrition at the high schools from baseline to 1^{st} annual measurements, we will increase our current total sample enrollment (n=960) by 5%, to give a new total sample of 1008 participants.

For (**Hypothesis 1b**) pre-post measurements of our secondary outcomes (physical activity and dietary intake of sweetened beverages, fat, whole grains, and fruits and vegetables which are continuous variables), we will analyze students with BMI <85th percentile and students with BMI ≥85th percentile separately. For students with BMI <85th percentile, assuming 35% attrition (400 total), ICC of 0.01, two-tailed alpha of 0.05 and power level of 0.80, we will be able to detect an effect size of 0.41, which falls between a small to medium effect size as defined by Cohen.[95] For students with BMI ≥85th percentile, assuming 35% attrition (224 total), ICC of 0.01, two-tailed alpha of 0.05 and power level of 0.80, we will be able to detect an effect size of 0.51, which is a medium effect size as defined by Cohen.

For (**Hypothesis 2**) the treatment intervention primary outcomes, ~43 students per school are anticipated to be overweight or obese (120 students × 36% who are ≥85th percentile). If there is 35% attrition, ~28 students will have BMI ≥ 85th percentile (overweight or obese) per school (224 total) and be available to calculate difference in BMI z score and insulin resistance (HOMA-IR) after two years. Therefore, we will have 84% power for detecting a difference of 0.16 in two-year BMI z score change between the intervention group and the comparison group. BMI z score change of 0.16 [10] was the change documented in a high intensity (>75 hours of contact) obesity intervention that was cited in the most recent Cochrane review[96] and an evidence report prepared for the US Department of Health and Human Services[54] as one of the best outcomes of intensive lifestyle interventions in children and adolescents. Using data from this study, we will have 80% power to detect a 27% change between the intervention and comparison groups for HOMA-IR.

Analysis Plan: As a preliminary step, we will examine the skewness and kurtosis of all variables to assure no problematic deviations from normality. In the event of such deviations, we will use appropriate transformations or use non-parametric methods. Analyses will be conducted using SAS Version 9.3, STATA Version 12 and Mplus Version 5.[97] All programs include capabilities to test models with categorical outcomes, missing data, and to account for a design that uses a multilevel or clustered framework.

- Pretest equivalence: To explore the possible size and direction of bias that may exist, the pretest equivalence of conditions across demographics, BMI percentile, and other outcome variables of interest will be assessed via t-tests on continuous items and χ^2 tests of categorical items from the pretest. Wilcoxon rank sum tests or appropriate transformations will be used for non-normal data. We will use the Bonferroni approach[98] to correct for alpha inflation with an experiment-wise alpha of 0.05. For variables where there are significant differences, the baseline values will be included as covariates in the analysis of intervention effects.
- Analysis of intervention effects: Analyses will be conducted in a multilevel framework to account for clustering within schools.[65] Mixed effects linear regression (SAS Proc Mixed) will be utilized for continuous outcomes (e.g., minutes of moderate or vigorous physical activity, BMI z score) and the generalized estimating equation approach (SAS Proc Genmod) will be used for binary dependent variables (e.g., hypertriglyceridemia, prediabetes defined by glucose and hemoglobin A1c) to study intervention impact on physical, behavioral and biochemical outcomes after 2 years. The following main outcomes of interest will be assessed: **(Hypothesis 1a)** Incidence of overweight and obesity after 2 years among students who were not overweight or obese at baseline; (**Hypothesis 1b)** sweetened beverage consumption, fat intake, fruits and vegetable intake, whole grain consumption, and time in moderate and vigorous physical activity after 2 years; **(Hypothesis 2)** BMI z score and HOMA-IR (insulin resistance index score) after 2 years among those students who were overweight or obese at baseline. Additional outcomes that will be assessed in the cohort of students who are overweight or obese at baseline include waist circumference, percent body fat, blood pressure percentiles, and biochemistries (glucose, insulin, hemoglobin A1c, and lipids) after 2 years. Hypotheses will be tested at a 0.05 significance level, two sided. Descriptive statistics (e.g., means ± SD, percentages) will be used to evaluate process data. Bivariate relationships of participants' BMI z score change to student attendance will be assessed in the intervention group and a multivariate analysis will be subsequently used to control for other demographic variables. An intention to treat analysis plan will be used. To that end, adolescents who complete a fraction of the sessions will still be accounted for in the analyses. Data imputation methods will be used for missing data. Additionally, we will assess number of sessions completed to determine how attendance is associated with outcomes. The study will assess BMI trends in NM using data from the Youth Risk Resiliency Survey (the NM version of the CDC's Youth Risk Behavior Survey) to evaluate secular trends. The study will use the school's demographic data on race/ethnicity, age, and free/reduced lunch meals to assess the representativeness of the recruited population. If the recruited population does not appear to be representative, we will use weighted data

analysis procedures to estimate outcomes for the school population.

Baseline values will be included as covariates in the mixed effects linear regression models for continuous dependent variables and the generalized estimating equation models for binary dependent values including the incidence of overweight or obesity or the presence or absence of specific components of the metabolic syndrome.[99] For students who repeat grades, we will include "repeated grade" as a covariate. Intervention (coded 0=control and 1=intervention) will be entered as a fixed effect into the multilevel models predicting outcomes. One equation will be estimated for each of the outcomes of interest. This approach is conceptually identical to an analysis of variance or covariance (ANOVA or ANCOVA) but has two distinct advantages. First, it allows for the analysis of clustered data, and second, it avoids list-wise deletion of subjects with missing assessments. The model relaxes the restrictive assumption that the data are missing completely at random and provides unbiased estimates under the less restrictive assumption of missing at random. This approach to missing data, i.e., the use of techniques that include full information maximum likelihood estimation of missing values, will be used.[100, 101]

• Analysis of semi-structured Interviews (**Aim 3**): Parent and student interviews conducted following the intervention will be analyzed using standard qualitative assessment methods. Dr. Feldstein Ewing will lead this analytic process. The interviews will each be transcribed and distributed to the research team. Each member will review transcripts independently, identifying themes related to the stem questions as well as other emergent areas of interest. The analysis will proceed in an iterative fashion, with the team reviewing sets of 3 to 4 transcripts in each category (parent and student). Following the independent reading, the team will meet to list the full range of themes, identify anomalous or unanticipated findings, and revise the interview guides accordingly. This process will continue until the team has reached consensus. At that stage, the thematic list will be converted into a template for coding purposes. Interviews will be coded in NVivo 9 (Melbourne, Australia), a qualitative data analysis software package, at which point queries to refine analytic and interpretive understandings will be conducted.

06.16.14 As part of process and program evaluation, a Doctor of Nursing Practice program evaluation project will include data analysis of Session 1 MI-based intervention discussions to assess adolescent satisfaction with the MI-based discussions and explore perceived provider comfort with MI using the MI Participant Satisfaction Survey and the MI Provider Self Assessment Survey evaluation forms. However, all of the sessions will be evaluated by the ACTION PAC team.

iv) Specific description of any experimental drug, device, or procedure. Any substance or instrument to be used in or on humans which has not received FDA approval for the proposed use requires an IND, IDE, or approval of the Radioactive Drug Research Committee.

v) Specific description of any use of biological samples. This is to include their origin, links to identifying information, storage, access, and future use.

Biomarkers include insulin, glucose, hemoglobin A1c, and lipids will be obtained in overweight/obese adolescents. Samples will be drawn by venipuncture. Serum samples will be allowed to clot. All samples will be centrifuged on-site and transported in an ice chest with freezer packs to Tricore Laboratory (1001 Woodward Place NE Albuquerque, NM 87102) or Tricore in Las Cruces for processing. We will not put names on tubes with blodd; instead, the tubes will receive a unique indentification number that will be used to indentify the blood. No blood will be stored for future use.

VI. Human Subjects:

i) Describe characteristics (inclusion criteria) of subject population, including precautions to be taken with vulnerable populations (e.g. children, prisoners, mentally ill/disabled person). Answer for each subject group, if different.

Inclusion criteria are as follows: 1) enrolled in 9th or 10th grade at the participating school, and 2)

informed written assent and informed written parent/guardian consent to participate in the full study for two years.
Research nurses or phlebotomist and clinical providers who are familiar with working with children and adolescents are used to collect data in this study. Data collection will be done in a private setting. Parental consent and adolescent assent is required prior to participation.

ii) Provide approximate number of subjects (both control and intervention groups).

A total of 960 high school students in the 9th and 10th grades (ages 14-17 years) will be recruited from 8 high schools to participate (480 in the intervention group and 480 in the comparison group); students will be followed until they are in the 11th and 12th grades, respectively. Enrollment will end when samples are met.
Due to higher than anticipated attrition at the high schools from baseline to 1st annual measurements, we will increase our current total sample enrollment (n=960) by 5%, to give a new total sample of 1008 participants.

iii) What characteristics (exclusion criteria) would exclude subjects, who are otherwise eligible, from this study? (Answer for each subject group, if different.)

Exclusion criteria are as follows: 1) blood pressure in the range of stage 2 hypertension in which an immediate medical assessment for pharmacotherapy is required, 2) diabetes, 3) use of oral or injectable corticosteroids or antipsychotics, 4) inability to perform moderate to vigorous physical activity, 5) not ambulatory, 6) medications for the control of diabetes, hypertension, and hyperlipidemia (or high cholesterol), 7) a score of 20 or more on the EAT-26 screening measure, and 8) developmental disorders that affect weight or the ability to understand the study procedures or counseling.
Students who meet withdrawal criteria (e.g., pregnancy) will be offered care in the SBHC.

iv) Please see HRRC Recruitment Guidelines **Section 11.2** for more information about acceptable recruitment methods. Describe recruitment (source, initial contact method, etc.)

Written informed parent consent and student assent will be required for study participation. UNM staff will present the project to students who will have completed the 8th grade by the summer before 9th grade registration and 9th and 10th graders either through an assembly or a required class (e.g., English) or at registration, or other school sponsored events and distribute project information packets with parental consent/student assent forms to adolescents, who will take them home for private discussions with their parents. When packets are distributed to students, we will ask interested students to voluntarily provide their parent's/guardian's name and contact phone number for a reminder call regarding information packet. Study staff will perform a follow up call to parents/guardians of students who have not returned packets within 1-2 weeks. Students and parents will be given appreciation gifts, no more than ten dollars in value, for their time in allowing us to present to them during their lunch and meeting group times (e.g. student activity groups and parent association groups). Examples of gifts include but not limited to Frisbees, T-shirts, tote bags, resistance bands, and pens. We will recruit adult ACTION PAC champions, who are either parents or employed by the schools and are familiar with the study, to help with recruitment and buy in by presenting information about the study to students and staff at the schools. They will be reimbursed for their time with a stipend in the amount of no more than $500.00 per year. We will post ACTION PAC fliers with information about the study at the schools, and send out automated school telephone ACTION PAC

messages to remind parents about the study and to return the project information packets.
Study contact phone numbers will be provided for questions. We will provide recruitment materials to district and school administration, which they will label and mail to prospective study candidates in the 8th and 9th grade. Study staff will not be a part of mailing process as district/school administrators cannot provide name and addresses of prospective study candidates who have not signed a consent form. Signed forms will be returned to the school's SBHC. SBHC medical assistant will monitor the return rates of consent/assent forms and ensure that they are completed. UNM research staff will collect consent/assent forms and phone all students and parents to confirm that they have agreed to participate in the study and to ensure they understand the expectations. At the beginning of each assessment wave, research staff will verbally ask participating students to summarize their understanding of what is expected of them and ensure that they voluntarily agree to participate. Parental consent forms will be developed and distributed in English and Spanish versions. This process has been used successfully in our previous studies. Students who do not wish to participate still have access to all standard SBHC services.

v) Describe Informed Consent procedures, including parental/guardian permission and minor assent for studies involving minors. Address any additional measures to be taken with any vulnerable populations. If you are requesting a waiver of informed consent, indicate request and justifications.

Study packets (in both English and Spanish) for enrollment will be sent home with students after a class or assembly presentation. Students will be instructed to review the forms with their parents/guardians in the privacy of their home and to call the study phone number provided in the study packet for questions. Students will be instructed to return completed forms in a sealed envelope (provided by the study team to protect students' privacy) to the SBHC. The SBHC medical assistant will check that consents/assents are completed. UNM research staff will collect the consent/assent forms and call all interested participants and their parents/guardians to ensure that they understand their involvement and expectations of the study. Assent will be reviewed with the student again prior to each measurement wave to ensure they want to continue to participate. This process has been used successfully in our previous studies.

Language about the possible selection to participate in post-intervention interviews will be included in the consent/assent forms as an option that participants can opt in or out of. SBHC clinicians will provide names of student and parent participants willing to be interviewed.

vi) Describe potential risks, including physical, psychological, social, economic, or legal, as well as those that might arise due to a breach of confidentiality.
(1) Identify their seriousness and likelihood.

Potential risks include the possibility of experiencing psychological stress or embarrassment from participating in the assessments and being audio taped. Fasting 10 hours prior to blood sampling may cause hunger. Venipuncture risks may include temporary pain and discomfort at the site of the needle stick, and occasional bruising, sweating, or lightheadedness, and in rare cases faintness or infections. Participants may also experience psychological stress from finding that they have risk factors for heart disease and diabetes or that they have an abnormal laboratory finding. Increasing physical activity may cause muscle soreness. Muscle strain and sprain due to increased physical activity. A general risk from participating in research may include the potential loss of privacy and inconvenience of time. Participants involved with the post-intervention interviews may feel psychological stress or embarrassment from being interviewed. All study procedures and evaluations are no different than what would be encountered during routine medical visits or daily living.

(2) Discuss alternative treatments where appropriate.

Students who do not wish participate still have access to all standard SBHC services or may go to their primary care provider.

(3) Identify circumstances for terminating the study.

The University of New Mexico may stop the study at any time if it is in the participant's best interest or the study's best interest.

vii) Describe procedures for protecting against or minimizing likelihood of identified risks. Include any procedures that will be used to maintain confidentiality as applicable.

To reduce the risk of psychological stress and embarrassment from the assessments during the annual measurement waves, students will be escorted in small groups of six from classes and will be seen privately in the SBHC exam and counseling rooms, away from other students. Pediatric research nurses experienced with phlebotomy in infants and children will be performing blood sampling. Breakfast (e.g. fruit, yogurt, and juice) will be given after the fasting blood draw to alleviate hunger.

For overweight and obese students in the weight management program, all visits will be scheduled on an individual basis consistent with health care visits delivered in the SBHC. All weight management visits will be conducted individually in private exam rooms. Appointment reminders for the study will be similar to reminders used for SBHC appointments and will look the same as other school-related notices to maintain student confidentiality.

Medical adverse events (e.g. bulimia) will be handled by the medical staff in the SBHC and will follow medical protocols (for treatment and referral) established by the SBHC program. Adverse events will also be documented by the research assistant and reported to the PI and UNM HRPO. Students who meet withdrawal criteria (e.g., pregnancy) will be offered care in the SBHC. Monitoring of muscle strains and sprains due to increased physical activity. Confidentiality will be handled as best as possible to the extent allowable by state law. Adolescent confidential issues (e.g., pregnancy) found during the course of the study will be handled according to SBHC clinic procedures which are consistent with state law. Students may refrain or discontinue their participation in the study at any time.

Only research team members have access to study information. Students will be given unique identifiers so that names will not be used on data collection instruments or during data entry. Students names with their unique identifiers will be kept in only one place in their study charts so that the team can ensure that they have the correct participant before starting data collection. Data will be stored in locked file cabinets in the PI's office. Electronic data will be stored on a password protected computer. For intervention overweight and obese students attending the SBHC weight management program, visits will be kept separately from their SBHC medical records in a locked file cabinet used specifically for the project. Participants may refrain or discontinue their participation at any time.

Post-intervention interviews will be conducted with individual participants to maintain confidentiality and to alleviate possible psychological stress or embarrassment to the participant. Parents/guardians and adolescents are interviewed separately. Participation is voluntary and participants may discontinue at any time. Interviews will be audio taped, transcribed with all personally identifiable information removed.

Data Safety Monitoring Plan: School-based health center clinicians and research staff will be trained in the detection and recording of potential adverse events and also unanticipated events by the PI. Adverse events to be monitored will include infection from phlebotomy, anorexia, bulimia, hospitalizations, development of hypertension, development of type 2 diabetes, development of psychosis, and monitoring of muscle sprains and strains. Adverse events will be monitored annually at

BMI screenings for all participants. For overweight and obese participants in the weight management intervention, adverse events will be monitored at each clinical visit which will be scheduled 8 times (about every month) during the 9 month school year. Adverse and unanticipated events will be communicated to the research coordinator within 48 hours and then recorded on a tracking log by school-based health center providers. The team's research assistant will collect the logs every 2 months during the school year for review by the PI. Reportable events will be reported to UNM HRPO as the event occurs by the PI within 48 hours. On a quarterly basis, data completeness, interim results, unanticipated events and adverse events will be reviewed by the PI (who is adolescent medicine board certified) and clinical research team members (a board certified pediatrician, a child psychologist, and a registered dietician). Protocol changes and amendments resulting from the quarterly review will be sent to the UNM HRPO for approval. A summary of unanticipated and adverse events will be written and provided to the UNM HRPO and NIH for review annually. Additionally, any new onset of medical problems (including infection from phlebotomy, anorexia, bulimia, hypertension, type 2 diabetes, psychosis and muscle sprains and strains) encountered will be handled following standard clinical management protocols from the school-based health centers. If assessment and treatment are beyond the scope of care in the school-based health centers, appropriate medical referrals will be made consistent with standing protocols in the school-based health centers.

viii) Describe the expected benefits, including any possible direct benefit (such as alleviating a condition or providing a better understanding of a participant's condition.

The risks of this proposed study are minimal and are no greater than what is experienced in routine medical visits. These risks are reasonable when compared to the expected benefits to the participants and others. The collaborative effort of partners involved will strengthen the capacity in schools with SBHCs to better address the childhood obesity epidemic. Benefits to adolescent subjects participating in this study are numerous and include: learning strategies to improve nutrition and physical activity, potential early diagnosis of co-morbid conditions related to obesity, and having accessible professional medical support to prevent metabolic syndrome, cardiovascular disease and type 2 diabetes. Benefits to parents of adolescent subjects include learning strategies to create a more health-promoting home environment. If study results are positive, the intervention has potential to be used in numerous schools and SBHCs in NM and the U.S. to help prevent overweight/obesity and prevent overweight/obese adolescents from developing chronic illnesses such as metabolic syndrome, cardiovascular disease and type 2 diabetes.