STUDY PROTOCOL

Prepared by the TAAG Investigators in collaboration with NHLBI

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Table of Contents

1. EXECUTIVE SUMMARY

1.1. Background

Regular physical activity provides multiple health benefits (U.S. Department of Health and Human Services, 1996) including reduced risk of cardiovascular disease, hypertension, hyperlipidemia and Type 2 diabetes. Physical activity increases lean body mass and contributes to the control of body weight. Thus it aids in the prevention of obesity, a major public health problem in Americans of all ages including adolescents. In addition, physical activity promotes bone mass, reduces sleep disorders and improves psychological well-being. Although most of these benefits have been documented in adult populations, recent research suggests that habitual physical activity may also benefit children, including reducing the risk of cardiovascular disease (Rowland, 2001), obesity (Hager, 1995), hypertension (Hagberg, 1983) and hyperlipidemia (Tolfrey, 2000).

Despite these benefits, participation in physical activity has declined dramatically among U.S. youth (Centers for Disease Control, 1997). The transition from childhood to adolescence is associated with a 34% decline in physical activity in girls (Kimm, 2000). Data from the 1999 Youth Behavioral Risk Factor Survey indicated that female students (57%) were less likely than male students (72%) to report vigorous physical activity (Centers for Disease Control, 2000). Female students (69.6%) were also less likely than male students (82%) to exercise more than 20 minutes during PE classes (Centers for Disease Control, 2000). The prevalence of overweight among U.S. adolescents has also increased (Flegal, 2000, Troiano, 1998). In addition, most physical activity interventions have targeted children and have been based in schools (Stone, 1998). There is a need to improve interventions for middle school girls and to extend interventions beyond the school into the community.

The Trial of Activity for Adolescent Girls (TAAG) presents an opportunity to test the benefits and effectiveness of school- and community-based physical activity programs in middle school girls.

1.2. Specific aims

TAAG is a randomized, multi-center field trial of 36 middle schools with the goal of reducing the decline in physical activity in adolescent girls. Its primary aim is to determine if an intervention that links schools to community organizations reduces the age-related decline in moderate to vigorous physical activity (MVPA) in middle school girls. The intervention is hypothesized to reduce by one-half the decline in physical activity between 6th and 8th grade, resulting in a 10 percentage-point difference in minutes of intensity weighted moderate to vigorous physical activity in girls in intervention schools compared to those in control schools. Secondary aims include those at the individual, environmental (school and community), and maintenance (one year after the intervention) levels.

1.3. Study design

The study design is a two-arm group randomized trial. Evaluations for the primary outcome and most other response variables involve two cross-sectional samples, one drawn from 6th grade girls in spring 2003 and a second drawn from 8th grade girls in the spring of 2005. This sampling design is based upon the aim of intervening on the entire population of girls. Another cross-sectional sample of 8th-grade girls is measured in the spring of 2006. Variables hypothesized to be mediators of the effects of the intervention on physical activity are assessed using a closed-cohort design in which final measurements are made in the 8th grade during 2005 on the same girls measured in the cross-sectional sample of 6th grade. Environmental variables are assessed using cross-sectional samples in the spring of 2003, 2005 and 2006.

1.4. Eligibility

Public middle schools (i.e., schools housing 6th – 8th graders but not 9th graders), in which a majority of children enrolled currently reside in the community, are eligible to participate in TAAG. The size of middle school classes, transiency rates and characteristics of physical education are considered in setting the eligibility criteria. All girls in the 36 randomized middle schools are eligible, however, there are specific eligibility criteria for participation in measurements. A minority representation of least 25% for the entire study is the goal.

1.5. Recruitment of schools and girls

Strategies for obtaining parental consent, participant assent and interest of school administrators include use of direct mail to parents, small, up-front “tokens of appreciation” gifts to teachers, and non-binding memoranda of understanding (MOUs) with each school agreeing to participate in TAAG. All participating schools are given a gift (e.g., of a $500 value) at the end of each school year. Schools are assessed for eligibility using data collected from formative assessment and public documents, and then recruited by TAAG to participate in the study through letters, telephone calls, and in-person visits by TAAG senior staff, investigators, and PIs. Actual recruitment of a school is formalized by signing of the Memorandum of Understanding. Girls are recruited to participate in measurement activities through a variety of strategies each site develops, which includes in-class presentations by TAAG staff, teacher encouragement, and letters sent home to parents. Girls receive incentives after they assent to participate in the study and complete measurements. The incentive value is relatively small (e.g., movie passes) and is unrelated to physical activity.

1.6. Formative assessment

TAAG formative assessment provides information used to recruit schools and communities, and to select, design, implement and evaluate the intervention. It consists of two phases: Phase 1 provides information to develop the overall intervention strategy and materials; Phase 2 provides information to refine the development of intervention materials and messages, and to determine specific barriers for girls wearing accelerometer monitors (used to measure primary outcome) during structured physical

activity programs. Recommendations from each of the two phases are used to design the intervention and assure implementation of the outcome measures.

1.7. Intervention

The TAAG intervention is grounded in the social-ecological model, which targets intrapersonal variables but emphasizes interpersonal, organizational, policy, and other environmental factors that influence human behavior. It emphasizes structured and unstructured (or unsupervised) physical activities in and out of school. The intervention consists of four major components: physical education; health education with activity challenges; partnerships among TAAG investigators, schools, and community agencies for physical activity, called Programs for Physical Activity; and promotional activities.

1.8. Outcome measures

School levels of moderate-to-vigorous physical activity are the primary outcome variable measured in MET-weighted minutes of MVPA in cross-sectional samples of 6th and 8th grade girls taken from each school approximately 18 months apart. The Computer Science Applications (CSA) accelerometer monitors, worn by each girl in the sample for one week, supply a record of the magnitude of her movements throughout the week and are supplemented by a retrospective questionnaire she completes concerning her daily activities for that week. The level of cardiorespiratory fitness (a secondary outcome variable) in cross-sectional samples of girls in each school is measured by means of a cycle ergometer in the 6th grade and again in the 8th grade. Height, weight and skinfold measurements provide values for calculating body-mass index and percent body fat in cross-sectional samples of girls in each of the two grades. Self-reported data are collected on secondary measures, mediators, descriptive variables, and environmental outcome variables. Other measures include classroom observations of physical activity.

1.9. Process evaluation

Process evaluation assesses various aspects of the intervention, particularly whether the intervention was delivered and received as intended. Fidelity of intervention delivery, the intervention dose, reach, context, and potential effects of contamination and secular trends are evaluated.

1.10. Environmental outcomes

Environmental outcomes are defined as change in physical activity-related organizational, policy, physical or social environments that are targeted by the intervention. Physical education class structure, school physical activity programs and school-community physical activity partnerships are evaluated.

1.11. Quality assurance

The goal of quality assurance is to ensure that data collected by TAAG investigators are accurate and of high quality. This goal is accomplished by training and certifying intervention staff, measurement staff, process evaluation staff, and data coordinators; monitoring the timeliness of data transfer, and the quality and consistency of

measurements. Prior to baseline data collection, Field Center staff are trained and certified. Central training is repeated and re-certification occurs prior to collecting 8th grade measurements in January 2005, and again in January 2006 for repeated 8th grade measurements. Other quality control measures include monitoring of data coordinators, quality assessment of outcome measures, and site visits.

1.12. Data analyses and management

The primary analysis, a test of intervention effect on MVPA, is performed in two stages. First, the 36 pairs of school MET-weighted MVPA mean values are calculated adjusting for ethnicity, grade (6th or 8th), and school, by means of a regression model, which allows for interactions of these three factors. In the second stage, the 72 adjusted school means (weighted by their variances) are regressed on study condition (intervention/control), adjusting for 6th grade school MET-weighted MVPA mean and stratifying on Field Center. Other analyses involve longitudinal comparisons of 6th and 8th grade school means of selected mediator and modifier variables for girls with these measurements in both grades.

An Internet-based data management system is developed and maintained by the Coordinating Center. The data management system provides all the required capabilities of data entry, validation, transfer, retrieval, inventory and database updating, closure, security, and archiving. It also enables each Field Center to generate reports that allow study coordinators to monitor site performance, identify and resolve data collection and processing problems, and provide feedback on efficacy of corrective actions. The data management system tracks students as they move from grade to grade.

1.13. Human subjects and informed consent procedures

Before implementing the study, the protocol, informed consent and assent forms, recruitment materials, and any other information for girls and their parents are reviewed by Institutional Review Boards at each institution of the Principal Investigator and by the Coordinating Center. The Board also approves any amendments to the protocol, other than administrative ones. Sample informed consent forms for parent and assent forms for the girls and Memoranda of Understanding with the schools and community agencies are in the protocol appendix, section 20.

1.14. Adverse outcomes and safety monitoring

Potential intervention-related risks include musculoskeletal injuries and electrolyte imbalance or dehydration as a result of physical activity in hot, humid weather. Others that are very unlikely include reduction in growth due to negative energy balance, sudden death or psychological problems such as disorders of eating, which may be the result of increased attention to physical activity, fitness, and weight. Adverse events are monitored at baseline and follow-up using forms, logs and school records. Serious adverse events, defined as “any event that is life-threatening, requires an inpatient hospitalization, results in significant disability, congenital anomaly, or death, requires intervention to prevent impairment or damage, or is an otherwise important medical event,” are reported to the Principal Investigators and their Institutional Review Boards,

the Coordinating Center, the NHLBI, and the Data and Safety Monitoring Board (DSMB).

1.15. Study administration

TAAG is a collaborative study supported by Cooperative Agreements from the NHLBI. The Steering Committee is the main governing body of the project. It comprises the Principal Investigators from the six Field Centers, the Principal Investigator from the Coordinating Center, and the NHLBI Project Scientist. Each has one vote on the Steering Committee; all decisions are determined by consensus or majority vote. Subcommittees include the Executive Subcommittee; Design and Analysis; Recruitment, Retention and Tracking; Intervention; Measurement; Formative and Process Evaluation; Project Coordinators; and Publications, Presentations and Ancillary Studies. A DSMB appointed by the NHLBI monitors the study.

2. BACKGROUND AND CONCEPTUAL MODEL

2.1. Physical activity and health in adolescence

Physical activity (PA) during youth has been associated with multiple favorable health outcomes. Physical activity may positively affect adolescents in many arenas, including increasing aerobic fitness, bone mass and HDL cholesterol (McKenzie, 1996); and reductions in CVD-related risks such as obesity (Bar-or, 1994), low HDL-cholesterol (Armstrong, 1994; Craig, 1996a), elevated blood pressure (Craig, 1996a), and components of the metabolic syndrome (Kahle, 1996). In addition, physical activity can improve mental health variables such as depression, anxiety, and self-esteem (Calfas, 1994; Mutrie, 1998). Although the results are not entirely consistent (Riddoch, 1998) and tracking of physical activity from youth to adulthood is often found to be limited (Riddoch, 1998), many of the health effects may prove important for quality of life during youth itself.

In spite of physical activity's potential salutary effects, population surveys from the United States consistently demonstrate that youth activity levels fail to meet recommended guidelines for physical activity participation (Pate, 1994; Stone, 1998). Data from the 1997 Youth Risk Behavior Survey show that approximately 25% of males and 50% of females failed to meet the guidelines for participation in sustained vigorous physical activity (Centers for Disease Control and Prevention, 1998). In 1999, only 27% percent of students in grades 9 through 12 engaged in moderate physical activity for at least 30 minutes on five days of the previous seven (U.S. Department of Health and Human Services, 2000a). Black and Hispanic girls were at even greater risk for inactivity than were white girls. Only 17% of Latinas and 18% of African-American girls in high school were active at this level, compared to 26% of white girls (U.S. Department of Health and Human Services, 2000a). These figures were all below boys' levels for the same age and ethnicity groups. Although the proportions of girls engaged in recommended levels of vigorous physical activity are more favorable, the discrepancies remained the same. The 1999 National Youth Risk Behavior Survey showed that among Latinas and African American and white girls, 49%, 50% and 60% respectively engaged in vigorous physical activity three or more days per week for 20 or more minutes per occasion. There was an even greater gender discrepancy in favor of boys, especially pronounced in the Latino and African American groups.

A comprehensive literature review from a decade ago shows that aerobic power relative to body mass remains stable among males as they age from six to 16, but declines at about 2% per year for girls (Sallis, 1993). Over the lifespan, the greatest decline in physical activity occurs between the ages of 13 and 18 (Sallis, 2000a; Caspersen, 2000). This drop is especially apparent in vigorous physical activity and in non-organized sports. The vast majority of studies investigating the physical activity levels in girls between 10 and 15 years old indicate a decline in the range of 4% to 24% per year based on both objective measures and self report and using both longitudinal and cross-sectional designs. Recently Kimm et al. (Kimm, 2000) published a quantitative estimate of activity decline of 9.6% from 11.5 to 12.5 years and 12.8% from 12.5 to 13.5

years in a longitudinal sample of 685 girls. Also Trost, et al. (Trost, 2000), using 7-day CSA data found a 14% difference comparing 11 and 12 year olds and a 19.6% difference comparing 12 and 13 year olds.

The importance of reversing the declines in activity among adolescents is clearly recognized in the Healthy People 2010 Objectives. The objectives include a number of goals for youth activity and goals for policy change that support youth activity. The Healthy People 2010 (U.S. Department of Health and Human Services, 2000a) objectives are for adolescents to engage in vigorous physical activity three or more days per week for 20 minutes or more per occasion, and for adolescents to engage in moderate intensity physical activity for 30 minutes or more on a daily basis. These objectives are targeted to youth in grades 9 through 12, presumably because national surveillance data are not available for younger adolescents. However, examination of objective data indicate that younger adolescents rarely engage in bouts of vigorous activity that are recommended (Armstrong, 1998), though the vast majority of youth appear to already meet the guideline of 30 minutes of moderate intensity activity daily (Pate, 1994). Thus, recommendations for adolescents should integrate vigorous as well as moderate activity categories.

Healthy People 2010 objectives go beyond simply encouraging activity in youth. To accomplish this objective, the report advocates increasing the proportion of schools that require daily physical education classes, increasing the proportion of students who participate in daily school physical education and increasing the amount of time spent being physically active in physical education classes. In addition, goals were set to increase accessibility of school facilities for physical activity during periods schools are not formally in session and to decrease the number of hours youth spend watching television. Thus, Healthy People 2010 emphasizes both healthy levels of activity-related behavior and healthy environments that will make such behavior more likely.

2.2. Barriers to physical activity in adolescent girls

National survey data consistently show a higher prevalence of physically active men than women, with some evidence that this adult-gender gap starts in adolescence and grows wider into adulthood (U.S. Department of Health and Human Services, 1996). Although physical activity is important for both boys and girls, girls are at higher risk for inactivity than boys (MMWR, 1996). Understanding the differences in physical activity behavior between gender groups requires an understanding of factors that predict those behaviors (Baranowski, 1998). It is known that girls feel less competent to participate in physical activities, believe they have less behavioral control over their participation, and perceive more barriers to participation in physical activity than do boys (Allison, 1999; Craig, 1996b). Girls have different preferences than boys in the types of physical activities they select. The Youth Behavioral Risk Factor Surveys I & II (Ross, 1985; Ross 1987) found competitive activities dominate boys' choices, whereas individual activities dominated girls' choices. To increase physical activity, youth must believe that benefits outweigh barriers. Unfortunately, adolescent girls are less likely than pre-adolescent girls to believe that the benefits of exercise outweigh the barriers (Garcia, 1994).

2.3. Theoretical background of the TAAG intervention

In conceptualizing an intervention to improve physical activity in adolescent girls, TAAG uses a socio-ecological approach. This approach emphasizes etiological explanations and behavioral theories that focus on considering the behavior solely from individual-level perspectives and predisposing factors (i.e., individuals' motivation, knowledge, attitudes or values surrounding a behavior). An ecological approach also includes theories that address interpersonal, organizational, policy, and other setting and environmental factors that comprise the context wherein behaviors occur.

This social ecological model, as presented in Figure 7.1, page 34, allows us to be explicit about the multilevel nature of our approach with an emphasis on influencing environmental factors. Although Social Learning Theory (Social Cognitive Theory) (Bandura, 1986) and other more cognitively based models include the environment in the construct of reciprocal determinism, many applications of Social Cognitive Theory are limited to individuals' cognitions and perceptions of environmental influences. Our objective was to address directly the social and physical contexts for physical activity in order to optimize sustained population change. In addition to affecting individual behavior change, we are attempting to change the environment so that the larger environment prompts and reinforces behavior change by the individual.

Ecological models acknowledge the role of interpersonal variables but place their emphasis instead on the pervasive influences of "behavior settings" – clusters of socio- and physical-environmental factors that cue or reinforce behaviors. For example, McLeroy et al. (McLeroy, 1988) and Stokols (Stokols, 1992) have described a social ecological model for health promotion in terms of four major sources of influence on behavior in addition to intrapersonal factors. Interpersonal factors are person-to-person influences, such as the role friends, family members, or social groups may have on behavior. Organizational factors are those aspects of an institutional or organizational setting that may have an influence on behavior, such as availability of school-based sport clubs or intramural programs. Community factors are aspects of the environment within individuals' lives that may influence their behavior. Community factors are exemplified by availability of recreational programming for girls during the middle school years and the availability of safe walking areas. Finally, policy factors are those rules or laws that affect human behavior and are significant in the promotion of physical activity in young people. Policies that alter the content (e.g., number of MVPA minutes per class) and structure (e.g. co-ed vs. gender-segregated classes) of middle school physical education (PE) are examples of policies that affect youth physical activity.

In their version of the social ecological model, Cohen and her colleagues (Cohen, 2000) describe a "structural approach" to understanding how health behavior occurs and how it is changed. Specifically, this model's structures comprise product availability, physical structures, social structures, and communication. Product availability refers to how available and accessible heath-and illness-promoting products are in the environment. Physical structures refer to the actual physical make-up of these products or of the home or community environment that increase or decrease the likelihood of specific behaviors (e.g., poorly lit and otherwise dangerous playgrounds versus well lit and

maintained jogging paths and safe bicycling paths). Social structures refer to policies and formal and informal norms that make some behaviors more likely and others less likely (e.g., specific physical education curricula that optimizes the amount of MVPA during physical education classes, as well as gender-integrated versus gender-segregated PE classes which may make activity among girls less or more likely). Finally, health communication and social marketing can promote specific messages in different behavior settings, that not only directly increase physical activity by cueing behavior, but also positively influence individual level predisposing factors such as perceived benefits to being active.

The social ecological model of health behavior is to a great degree based in Operant Psychology (behavior modification) and Social Cognitive Theory (Bandura, 1986). Operant psychology (Skinner, 1953) presents an important building block of the social ecological model. Whereas social ecology emphasizes the behavior of large numbers of individuals in various "behavior settings" (i.e., in certain places and at certain times), behavior modification describes the direct mechanism by which individual behaviors are changed. Specifically, behaviors are strengthened through the process of reinforcement. Behavior that is followed by a pleasant consequence (positive reinforcement) or the escape from an aversive situation (negative reinforcement) is likely to be "strengthened" (i.e., more likely to occur again in the future). Prompts, modeling and other antecedents to the behavior may also make it more likely to occur, at least initially. Behavior that is followed by an aversive consequence (punishment) or one that is impeded by various social or environmental barriers (threat of punishment) will be less likely to occur again in the future.

The operant basis for behavior change has been demonstrated to be central in the promotion of physical activity. In a meta-analytic review of 127 intervention studies, Dishman and Buckworth (Dishman, 1996) studied the contributions of behavior modification, cognitive behavior change, health education, and curriculum on effect sizes for physical activities. They concluded that behavior modification had an average of a .9 effect size, more than four times greater than that for physical education curricula and nine times that of the other two approaches.

Social Cognitive Theory (Bandura, 1986) provides a second element of social ecological theory's foundation. Social Cognitive Theory describes relationships between self-regulatory behavior and the supportive functions of the physical and social environments for adopting and maintaining health-promoting behaviors (Saunders, 1997). Research has identified Social Cognitive Theory-related physical activity mediators such as self-efficacy, perceived barriers, outcome expectancies, enjoyment, social norms, time spent outdoors, involvement in community-based agencies that promote physical activity, access to equipment and facilities, parental encouragement, and parental activity as factors associated with youth activity behavior (McLeroy, 1988). Self-efficacy refers specifically to the confidence an individual may have in her or his ability to perform a certain behavior or skill. Regardless of overall skill level, high levels of self-efficacy may lead to a greater likelihood of engaging in a specific behavior. Positive outcome expectations comprise the expectation of positive reinforcement

consequent to behavior and that “punishment” is unlikely. Social Cognitive Theory has long played a key role in the development of health behavior change efforts, especially those emphasizing nutritional health promotion (Lytle, 1995; Contento, 1995), tobacco use prevention, and heart health (Edmundson, 1996). Closely related to health communication models (e.g., McGuire’s communication/persuasion model) (McGuire, 1989) it is also a mainstay of health promotion programs that provide prompts and cues for behavior change via electronic, print and interpersonal media.

A body of knowledge termed “interorganizational relations theory” extends the social-ecological model and will guide the linkage of schools and community organizations through TAAG. Interorganizational relations is a branch of organizational theory that focuses on how organizations work together. With the increasing complexity of health and social issues, economic and political factors, and other environmental demands like increased competition, organizations began to link efforts and form networks of organizations to create more comprehensive and effective responses. Examples of interorganizational linkages range from grass roots coalitions of leaders from rural Black churches (Sutherland, 1997) to multi-hospital systems that reduce competition and provide flexibility in the face of accelerated changes in technology (Zuckerman, 1995).

Major benefits of collaboration include access to new information, ideas, materials and other resources; potential to minimize duplication of services and to use existing resources more efficiently; potential to maximize power and influence by combining forces; ability to address issues beyond a single organization's domain; and shared responsibility across organizations for complex or controversial issues (Alter, 1993; Butterfoss, 1993). Many coalitions and collaborative partnerships form in public health for these very reasons. In a study of local Project ASSIST coalitions in North Carolina, Kegler and colleagues (Kegler 1998a; Kegler 1998b) found that benefits to member organizations included opportunities to build new relationships; access to new information, ideas, and materials; increased coordination, visibility for the organization, a vehicle for engaging in meaningful community involvement, and help in meeting organizational goals.

Other factors important in the formation of Interorganizational Relations include recognition of interdependence and the need for coordination, acknowledgment that an organizational goal is more likely to be attained through collaboration, resources such as time, staff, and expertise for maintaining a coordinated process, mandates from a powerful outside force such as a funding agency or regulating body, clear and mutually shared goals, awareness of potential partners and geographic proximity, similar organizational interests and values, a positive attitude toward cooperation and norms for collaboration, and successful previous experience in working together (Gray, 1989; D'Aunno, 1987; Alter, 1993).

Parallel to Interorganizational Relations, TAAG also draws on direct action community organizing to institute change at the community level. Community organizing approaches have been successfully applied in interventions aimed at reducing adolescents’ use of tobacco (Forster, 1998; Blaine, 1997) and alcohol (Perry, 2000b). A

direct action community organizing approach uses five stages to engage and mobilize a community to action. Those stages are 1) Assessment -- a thorough evaluation of the strengths and resources of a community with regard to environmental factors that influence adolescent physical activity including the use of one-on-one interviews to find individuals and agencies with a shared interest in the topic ; 2) Action Team Creation -- the formation of action teams of 10-20 committed community partners identified through the assessment phase; 3) Creation of an action plan -- identification of potential policy, initiatives and activities that would help create a community environment that facilitates youth activity; 4) Mobilization and Action -- mobilizing the community to act on the initiatives in the action plan, including education and increasing awareness of the issue in the community and 5) Implementation -- where the Action Team, in concert with wider community participation and support initiate change (Perry, 2000a).

In TAAG, elements of this model are being used to create the school and community links that provide out of school programming. The TAAG school-community partnerships relies on finding individuals and agencies in the community who are committed to providing more opportunities for adolescents to be physically active and to working with schools to promote programs and reduce barriers to participation.

The TAAG Programs for Physical Activity (PPA) draws heavily from organizational change theory. Stages of coalition development (Florin, 1993) are instrumental in developing the partnership process. The first stage of initializing mobilization occurs using one-on-one interviews (a technique from Direct Action Community Organizing) to identify a diverse group of potential stakeholders in the community. As was done in the ASSIST project, an organizational structure is established once partners are identified. This second stage in the development of the coalition or partnership includes agreement on governance and responsibilities of members of the partnership. The third stage of coalition development is operationalized in the TAAG PPA through partners meetings where orientation and information-sharing occur and the potential for community and school-wide activities developed in partnership is explored. Action planning (Stage 4 of coalition building) includes agreeing on ways to use start-up funds and administering mini-grants to increase activity opportunities in the school and community. Implementing activities is a collaborative effort requiring partners of the coalition to work together to overcome barriers to offering programs and girls participation in programs (including funding for programs, finding appropriate instructors and programs girls want to attend, and transportation issues). Finally, the steps of refining and institutionalizing are built into the PPA structure with feedback on programs being offered, girls' and other stakeholders' reaction to programming solicited and considered, and evaluating future needs addressed at partnership meetings.

2.4. School settings

Two settings predominate in research on physical activity among youth: structured and unstructured programs in schools and in the community. Schools are important physical, social and normative environments in which students observe, imitate, learn and practice health behaviors. As such, schools have a great opportunity to positively influence levels of physical activity, but have failed to take advantage of this opportunity

(U.S. Department of Health and Human Services, 2000a). Most secondary schools (88.5%-89.1%) allow students to be exempted or excused from PE courses for reasons unrelated to illness or injury. Even though many children actually do have PE within the school day, it may be inadequate to build motor skills and fitness because large amounts of class time are spent being inactive (Simons-Morton, 1994; McKenzie, 1995). Baseline data from the CATCH study showed that in third grade PE classes, students were involved in moderate to vigorous physical activity (MVPA) (any activity that is at least as vigorous as walking) for only about 10 minutes of a 30 minute PE class, and involved in vigorous activity for only 5.5 minutes of a 30 minute class (McKenzie, 1995).

2.5. School based physical activity interventions

The effectiveness of youth physical activity interventions is shown by results of a meta-analysis that showed a higher effect size for youth programs, as compared to those for adults and older adults (Dishman, 1996). A comprehensive review identified 22 published or ongoing studies of school-based interventions (Stone, 1998). Most of these programs altered school physical education, but even the best PE programs only provide about 20% of the recommended amount of physical activity. Seven additional studies were classified as "community-based" because they targeted families or the interventions were conducted in community settings such as in a housing project. Many of the studies documented increased physical activity both during PE classes and outside of school. The literature reflects limited experience working with community agencies to promote youth physical activity. A further limitation is that only two of the studies were conducted in middle schools, including the M-SPAN study. Stone, et al. (Stone, 1998) concluded that the highest priority for further intervention research is "for girls, middle schools, and community settings for all youth." In spite of federal priorities, however, studies to date have evaluated few of the school (or community) physical activity guidelines (Centers for Disease Control, 1997). Five environmentally - oriented programs with fairly extensive evaluation in public schools include CATCH, SPARK, Planet Health, MSPAN and Pathways.

Child and Adolescent Trial for Cardiovascular Health (CATCH). CATCH, sponsored by NHLBI, studied multi-center interventions, including classroom curriculum, school environment, and family-based activities directed towards physical activity, nutrition and non-smoking behaviors of elementary school children (Stone, 1994; Elder, 1994). Results showed that school environments could be altered and diet and physical activity levels could be changed in and out of school (Leupker, 1996). Recently published results indicate continuing intervention effects detectable in the 8th grade: vigorous physical activity (+8 to 9 minutes difference) and total fat intake (-1.7% difference in percent calories from total fat) reported by intervention compared to control students across all four sites (Nader, 1999). MVPA during lessons in intervention schools increased from 37.4% at baseline to 51.9%, thereby meeting the then-established Healthy People guideline of 50%. Intervention children also reported 12 more minutes of daily vigorous physical activity than did control children, and ran 18.6 yards more on a nine minute run test of fitness (McKenzie, 1996). CATCH

demonstrated the feasibility of multi-level interventions that target both students and the school environment.

Sports, Play and Active Recreation for Kids (SPARK). SPARK was funded by NHLBI to develop and evaluate a comprehensive health-related PE program for elementary school students. This program was successful in improving PE classes taught by classroom teachers and PE specialists (Sallis, 1997a). Results showed increased physical activity at school, enhanced physical fitness, better sports skills, and improved academic achievement. Students spent more time being physically active in specialist-led (40 minutes) and teacher-led (33 minutes) physical education classes than in control classes (18 minutes). After two years, girls in the specialist-led condition were superior to girls in the control condition on tests of strength and endurance. There were, however, no effects on physical activity outside of the school, implying a need for broader community interventions (Sallis, 1997a).

Planet Health. Planet Health (Gortmaker, 1999) was a middle school-based health behavior change intervention designed to reduce the onset of obesity among girls and boys in 6-8th grades in four Massachusetts communities. Students participated in a school-based interdisciplinary intervention over two school years. Sessions were integrated with existing PE and other curricula, and emphasized healthy nutrition, activity options, and the reduction of sedentary behavior. The prevalence of obesity among girls (but not boys), as measured by a composite of body mass index (BMI) and triceps skinfold, was significantly more favorable in the intervention compared to the control schools at post-test. This change was accompanied by reductions in television viewing time, an increase in fruit and vegetable consumption, and smaller increases in overall energy intake. This study emphasized an individual-level intervention with some success.

Middle School Physical Activity and Nutrition (M-SPAN). **M-SPAN** examined whether environmental changes at school improve physical activity and dietary habits of ethnically diverse students. The sample included 24 public middle schools (grades 6-8) from nine districts in San Diego County. Twelve of the 24 schools participated in a two-year environmental intervention to improve physical activity and nutrition. The physical activity intervention consisted of PE curricular enhancement, staff development, and follow-up services. Prior to beginning staff development, student focus groups were conducted at each school to learn what new physical activity programs might be popular with students. The PE intervention produced an 18% overall increase in observed moderate to vigorous physical activity (MVPA) during PE classes ($p<.01$), without changing the frequency or duration of classes (McKenzie, 2000b). The effect on boys was significant and the effect on girls showed a trend (Sallis, 2000c). These results are promising but show that even more emphasis is needed on promoting girls' MVPA in PE and that approaches that exclusively target the school environment may be inadequate.

Pathways. Pathways was a randomized school trial to reduce obesity among American Indian school children using culturally appropriate methods. Physical activity and nutrition programs were introduced in 21 schools, with 20 other schools comprising the

control group. The intervention, which included both instruction via an educational curriculum, as well as environmental change (PE classes, food service) was carried out from 3rd through 5th grades. The intervention significantly lowered the percent of fat contained in school-provided meals, but did not affect the primary outcome variable of percent body fat. The intervention also resulted in significantly higher levels of obesity related knowledge, self-reported physical activity, and food choices ($p < .05$ for all) (Stevens, 2001). Activity as measured by the Tritrac accelerometer was 10% higher in the intervention compared to the control group ($p=.08$) (Going, 2001). BMI and mean body fat, the primary outcomes of the trial, were virtually identical in intervention and control children at the end of the study (Lohman, 2001). It may be that the intervention, which focused on the school setting and did not target community, was not broad enough in its scope.

2.6. Community settings

Although school programs remain an attractive setting in which to promote physical activity among adolescents, there are barriers to their effectiveness in preventing the decline of overall physical activity. Most youth physical activity is performed outside of the classroom setting -- before or after school or on weekends (Simons-Morton, 1990). Traditional PE programs emphasize team sports skills, which favor the athletically gifted, and do little to teach lifestyle oriented physical activity skills that can carry into adulthood (Kohl, 1998). Physical activity interventions in schools that taught lifestyle physical activity skills and have promoted more physical activity in PE class as well as out-of-class have met with incomplete success. Most have been able to demonstrate an increase in the amount of time spent being physically active during PE class, but they have not had an impact on overall daily physical activity (Kelder, 1993; Leupker, 1996; Simons-Morton, 1986; Sallis, 1997a; Stone, 1998). The CATCH investigators recently reported sustained improvements three years after the intervention, although by 8th grade, less than nine minutes per day were spent in vigorous physical activity (Nader, 1999). It is now recognized that, while schools can be an efficient path for providing lifestyle-oriented physical activity instruction, school programs to increase overall physical activity may not be effective without partnership and support from families, communities, and authoritative bodies (Centers for Disease Control and Prevention, 1997). Adolescents in middle school are at the stage in which they are influenced by both their classmates in school, peers and others in the community, and by their families, representing a time in which integrated multi-component interventions are appropriate. Thus, TAAG links schools and communities to provide a comprehensive approach to increase physical activity.

2.7. Mediators and Determinants of Physical Activity in Youth.

Identifying the social ecological and other factors that influence physical activity behavior in youth is an important prerequisite for designing effective interventions for this population (Baranowski, 1997, Baranowski, 1998). As a result**,** a great deal of research has focused on identifying the psychosocial and environmental determinants of physical activity in youth. Collectively, this body of research has identified physical activity self-efficacy, perceived barriers, outcome expectancies, enjoyment, social norms, time spent outdoors, involvement in community-based agencies that promote

physical activity, access to equipment and facilities, parental encouragement, and parental activity as factors associated with youth activity behavior (Sallis, 2000c). Although these findings have helped researchers focus intervention strategies on specific targets, very few studies in this area have utilized longitudinal study designs, making it impossible to infer temporal sequencing and causal relationships between the hypothesized determinants and physical activity behavior. Moreover, few intervention studies have documented that intervention strategies result in positive changes in the determinants of physical activity and that these changes account for changes in physical activity behavior. Finally, studies rarely examine the permanency of environmental changes that may cue physical activity not only within a given cohort but for future groups of individuals as they pass through their school years or spend extensive time in other behavior settings.

TAAG presents the opportunity to determine whether these ostensible mediators of change indeed are influenced by a comprehensive intervention, and lead to behavior change. TAAG's emphasis on the physical and social environments that set the stage for physical activity leads us to emphasize the maintenance of environmental and behavior change.

3. SPECIFIC AIMS

The Trial of Activity for Adolescent Girls (TAAG) is a group randomized, multi-center trial of 36 middle schools with the goal of decreasing the decline in physical activity of adolescent girls. To accomplish this goal, TAAG is implementing a two-year coordinated school- and community-linked intervention to evaluate its effects on moderate to vigorous physical activity of middle school girls.

3.1. Primary specific aim

The primary aim of TAAG is to determine if an intervention that links schools to community organizations reduces the age-related decrease in moderate to vigorous physical activity (MVPA) in middle school girls. We hypothesize that the intervention will reduce by half the decline in physical activity between 6th and 8th grade in girls, resulting in a 10 percentage point difference in minutes of intensity weighted moderate to vigorous physical activity in girls in schools assigned to the intervention compared to the control condition.

3.2. Secondary specific aims

Individual level:

To determine if 8th grade girls in intervention schools, compared with girls in control schools, have differences in:

1. cardiorespiratory fitness
2. percent body fat
3. hypothesized intervention mediators
4. proportion of time during physical education class spent in moderate to vigorous physical activity
5. total physical activity and physical activity performed on weekdays, weekends, in-school, and out-of-school

Environmental level (School/Community):

5. To determine if intervention schools, as compared with control schools, provide physical education classes that more frequently employ strategies that enhance girls' physical activity.
6. To determine if, at intervention school sites, there is a greater density of after-school physical activity programs offered to girls than in control schools.
7. To determine if intervention schools develop a greater density of school-community physical activity-related partnerships compared with control schools.
8. To determine if hypothesized school-level mediators differ in intervention schools compared to control schools.

Maintenance of change:

9. To determine if the effects observed after the 2-year intervention are maintained in 8th grade girls one year later.
10. To determine if the TAAG intervention is maintained 1 year after the end of the active intervention period.

4. STUDY DESIGN

4.1. Overview

To meet the study objectives, a school and community linked intervention has been designed to promote physical activity in middle-school girls. This intervention is evaluated via a group-randomized trial involving 36 schools. Eighteen schools are randomly allocated to implement the intervention, and 18 serve as control schools. Baseline measures are collected January to March of 2003 from a cross-sectional sample of 6th grade girls in the participating middle schools. Follow-up measures are collected in the spring semester of 2005 from a cross-sectional sample of 8th grade girls in those same schools. The intervention is implemented soon after completion of the baseline measurements and randomization in the spring of 2003. The primary endpoint for evaluating the intervention is the mean difference in intensity-weighted minutes of moderate-to-vigorous physical activity (i.e. MET-minutes) between intervention and control schools in the cross-sectional sample of girls in the 8th grade in 2005 controlling for 6th grade activity levels.

We enroll six schools per Field Center for a total of 36 schools. The Field Centers (and associated universities) are in the vicinities of Baltimore, Maryland and Washington, DC (University of Maryland); Columbia, South Carolina (University of South Carolina); Minneapolis, Minnesota (University of Minnesota); New Orleans, Louisiana (Tulane University); Tucson, Arizona (University of Arizona) and San Diego, California (San Diego State University).

The study design for the primary outcome and the secondary individual and environmental level outcomes involves two cross-sectional samples: one in the spring of 2003 and a second in the spring of 2005. For the primary outcome, the first sample consists of at least 1,728 girls and is drawn from 6th grade girls who meet eligibility criteria in spring semester of 2003. A second sample, of at least 3,456 girls, is drawn from 8th grade girls who meet eligibility criteria in 2005. Also, all girls who were measured in the 6th grade who were not randomly selected to be part of the 8th grade sample are measured in the 8th grade to facilitate certain types of analyses of variables which may be mediators of the effect of the intervention on physical activity.

The sustainability of the TAAG intervention is determined by assessment of a cross-sectional sample of girls in the 8th grade one year after the end of the intervention in spring of 2006. These results are compared to those in the cross-sectional sample of 8th grade girls examined in the previous year while the TAAG intervention was on-going. This comparison determines whether the effects of the intervention are maintained in the TAAG schools one year after the active intervention has ceased.

Minutes per day of MVPA (unweighted by METS), physical fitness, body composition, types and context of physical activity, physical activity in PE, self-reported physical activity related variables and environmental outcomes are assessed at baseline and at the end of the 2-year intervention. These time periods are designated in this document

as 6 (baseline) and 8A (spring of 2005). Minutes of MVPA and environmental outcome variables (described in section 10) are also measured at the time of the second assessment of 8th grade girls in the spring of 2006 (designated here as 8B). Additional measurements to be obtained at that time (8B) are determined based on the analyses of the effect of the intervention assessed in spring of 2005 (8A). Higher priority is given to the measurement of variables that were different among intervention versus control girls and schools at the end of the intervention period. In addition, financial considerations influence the number of variables that can be measured.

4.2. Justification of study design for primary and secondary outcomes

The study design for the primary analysis for TAAG includes two cross-sectional samples: one drawn from 6th graders at the beginning of the study and the second drawn from 8th graders following the 2-year implementation of the intervention. Numerous factors were considered in the selection of this design, however, the primary reason for this choice is consistency with the goals of TAAG, which focus on environmental level in addition to individual level interventions to produce change. In addition, use of a closed cohort design requires data to be imputed for girls lost to follow-up in order to meet the criteria of "intention to treat." The imputation is done under the assumption that the missing girls would have outcomes similar to girls who did not receive the intervention. It is likely that over 30% of the girls present at baseline would not have measurements at follow-up due to transiency rates. Imputation under these circumstances reduces the power of the cohort design below that available for the cross-sectional design. Another strength of the two-sample design is that it provides an assessment of the change in physical activity levels from 6th to 8th grade as a school-level variable.

4.3. Justification of study design for mediators and moderators

The impact of the intervention on hypothesized mediators and moderators is evaluated using the two cross-sectional samples as outline in section 4.2. Other types of evaluation of mediators and moderators call for linking variables measured at baseline to variables measured at endpoint within individual girls. For these analyses a closed cohort design is used. Some of the 8th grade girls measured in the cross-section are also in the 6th grade sample. They may not be present in numbers to provide a sufficiently powerful analysis of the mediators and moderators, and therefore, all girls who were in the baseline cohort and are still present in the school in 8th grade are re-measured and used in these analyses. Girls who have left the school are not to be tracked and re-measured, but their data are imputed. This approach was deemed to be a cost-effective way to increase the sample size for these analyses, since the expense of measuring girls that are in the school is low compared to the expense of tracking and measuring girls who have left the school.

4.4. Randomization

The unit of randomization is the school. Schools are stratified by Field Centers and, for Field Centers with multiple schools within a school district, by school districts. The Coordinating Center randomly assigns half of the schools to the intervention condition after baseline data collection. The randomization is constrained to insure that one half

of each Field Center's schools and approximately one half of the schools in each school district are assigned to the intervention.

4.5. Timeline

Key Activities	Start	Finish
Baseline – 6th grade measurements (6)	1/8/03	4/1/03
Randomization	4/2/03	4/3/03
Intervention activities	4/4/03	5/15/06
Endpoint – 8th grade measurements (8A)	1/1/05	5/15/05
Follow-up measurements (8B)	1/1/06	5/15/06
Field Center close-out	5/15/06	8/31/06
Data analysis and reporting	5/15/06	8/31/07

5. ELIGIBILITY, RECRUITMENT, AND RETENTION

5.1. School eligibility criteria

TAAG-eligible schools are those public middle schools (i.e. schools enrolling 6th – 8th graders but not 9th graders) in which a majority of children enrolled currently reside in the community served by the middle school. The rationale for this eligibility criterion is to exclude schools that predominately serve students outside of the local community.

Other school eligibility criteria for participation in TAAG are based on the need to create a sufficient intervention "dose" and the power needed to detect differential reduction (from 6th to 8th grades) in MVPA between the intervention and control school cross-sectional samples. They include the following:

1. Schools must be willing to participate, must agree to accept their randomization assignment, and must agree to a Memorandum of Understanding with the TAAG Field Center (see Appendix 3 for a prototype).
2. Schools must have or be willing to develop through an Memorandum of Understanding process a) routine school procedures for responding to acute injuries and medical emergencies that may occur on school grounds or during student participation in school-sponsored activities; and b) a procedure for reporting to study personnel acute injuries or emergencies, related to physical activity, that may occur on school grounds or during student participation in school-sponsored activities. If routine procedures do not already exist, the TAAG Field Center will assist in their development.
3. Schools will not anticipate closing or merging with other schools for at least three years after entering into the Memorandum of Understanding.
4. Size: within field sites, 8th grade classes will have a minimum of 90 girls. At endpoint (8A) in 8th grade, we will invite 120 girls to participate in CSA measurements, with the goal of obtaining no fewer than 80% (N= 96-120).
5. Transiency rates: no more than 35% of the girls are expected to leave the school between baseline measures in 6th and posttest measures in 8th grade, and 28% in any given year, based on the school's past data.
6. There must be a PE requirement, whether it comprises a) full or partial week, and b) one or two semesters (at approximately 15 or more weeks/semester). PE must be offered during each semester of the 6th, 7th and 8th grade. However, girls need only to be required to take PE for one of two semesters, as long as they have an equal likelihood of taking PE in either semester.
7. PE class frequency must be either a) minimum of two classes per week (for year round schools), or b) minimum of three classes per week (for one semester-only students).
8. No site- or school-specific requirement is made with respect to the schools' ethnic makeup. However, in tandem the national sample of 36 schools must include at least 25% non-whites (Asian or Pacific Islander, Black or African American, Hispanic or Latino, American Indian or Alaskan Native, Native Hawaiian).

9. Any school used as a pilot facility is ineligible for use in the main trial.

5.2. Girl measurement eligibility criteria

1. All 6th and 8th grade girls in TAAG eligible schools can participate: grade rather than age will be used as an eligibility criterion. Other language requirements in obtaining informed consent, although far less likely to be encountered, would be far more difficult to address and may result in exclusion from eligibility.
2. Girls with any physical or medical condition that might affect ability to participate in the fitness test are excluded from the fitness measurement. These conditions include: 1) muscle, bone, or joint problems that limit the ability to ride a bike, 2) a heart problem that requires a limitation in physical activity, 3) fainting with exercise in the past six months, 4) uncontrolled asthma, 5) very high blood pressure that is not controlled on medication, 6) diabetes with frequent very low or very high blood glucose levels, 7) thyroid problems not controlled with medication, 8) seizures not controlled with medication, 9) sickle cell disease, cystic fibrosis, anorexia nervosa, severe kidney problems, or severe liver problems, and 10) a blood condition that increases the risk of bleeding.

5.3. Recruitment of girls and schools

Each site recruits 6 schools to participate in the study. For the primary outcome measure in the 8th grade (8A and 8B), each site randomly selects an average of 120 girls per school to be measured. At all schools a minimum of 90 girls are selected. Efforts are made to measure all girls selected, and within each school a minimum of 80% of the girls selected are measured. For baseline measurements of the primary outcome (in 6th grade), 60 girls per school are randomly selected to participate and measurements are obtained on at least 80% (i.e., 48) of those girls.

The key to successful recruitment is the manner in which the importance of the study is communicated to school administrators. The importance of studying of physical activity in girls is communicated, but not how important it is to improve activity. Nevertheless, the content of our message and the enthusiasm with which we promote it will help to recruit and maintain an adequate number of schools and girls.

Each Field Center uses optimal strategies for obtaining parental consents and student assents for their individual communities; these include direct mail to parents and having forms sent home with participating students. Teachers are likely to play a crucial role in this effort by prompting and encouraging students to ensure that consent and assent forms are completed. Teacher enthusiasm for TAAG is optimized through the use of small, up-front “tokens of our appreciation” gifts to each of them as we discuss with her or him the consent process, due date, and the nature of the consent form. Emphasis to teachers on getting the forms back with or without consent to participate is critical, not that the girls actually consent to participate. Tokens of appreciation for teachers include "gift baskets" with post-its, pens, tape, etc., and other items that they often buy themselves for use in their classrooms; small canvas TAAG duffle bags or tote bags, and movie passes. The actual gift will vary by site. Incentives are not provided to motivate girls to return their consent forms.

A non-binding Memorandum of Understanding will be entered into with each school agreeing to participate in TAAG (see prototype in Section 19). All participating schools are given a relatively large gift (e.g. of a $500 value) at the end of each school year.

Girls receive incentives after having enrolled in the study and completing measurements. The incentive value is relatively small (e.g. movie passes) and unrelated to physical activity.

5.4. Community agency partners

To be a community agency TAAG partner for intervention schools, an organization must potentially be able to offer one or more programs and activities at the school site or at the agency that focuses on middle school girls, have adult supervision, and a duration of 30 minutes of MVPA per session, or be able to offer resources for such programs. Parental permission slips are provided to partner agencies to enable TAAG students to participate in their programs. Partner agencies must have or be willing to develop through an Memorandum of Understanding process a protocol for response to emergency incidents or accidents. They should also have or be willing to develop a procedure for reporting to study personnel acute injuries or emergencies, related to physical activity, during student participation in TAAG-sponsored activities. The TAAG Field Center may assist in their development.

6. FORMATIVE ASSESSMENT

6.1. Background and rationale

TAAG formative assessment provides information needed to design the trial to maximize its feasibility and effectiveness. TAAG formative assessment goals are:

1. To gather information used to select, design, and implement interventions to promote physical activity in adolescent girls.
2. To provide information to develop the most effective recruitment and retention strategies.
3. To supply information to develop and adapt appropriate primary and secondary outcome assessment instruments.
4. To gather information needed to select and recruit schools, community agencies, and participants into the trial.

To meet these goals, formative assessment plans were developed to determine:

- the influences on girls' physical activity practices, with particular reference to schools, community agencies, parents, siblings, and friends
- salient subgroups of girls, along with messages, physical activities, and programs that are favored by the subgroups
- intervention approaches that are more likely to lead to increased physical activity in girls
- policies and practices in schools and community agencies that support or create barriers to girls' physical activity
- availability of physical activity programs and opportunities for girls
- the acceptability of TAAG intervention strategies and materials
- barriers and opportunities related to girls wearing the Computer Science Application (CSA) accelerometers.

Formative assessment approaches include focus groups, in-depth interviews, structured interviews, and surveys.

There are two phases of TAAG formative assessment. The objectives for each phase, strategies for meeting objectives, results, and key recommendations are discussed below. The formative assessment working group, with representatives from each Field Center and the Coordinating Center, met with the Intervention Subcommittee and its working groups, as well as other Subcommittees, to gather information requests, prioritize these requests, develop appropriate instruments, train data collectors and conduct data collection, interpret results, and make recommendations.

6.2. Phase 1 (Summer 2001 – Winter 2002)

6.2.1. Phase 1 background and rationale

Phase I formative assessment was completed in March, 2002. The primary objective of this phase was to provide information helpful for developing the overall intervention strategy and materials. Information was gathered from potential TAAG schools at each Field Center, community agencies located in proximity to these schools, parents, and girls and boys in middle school. Factual data, rather than probing questions on girls' physical activity that could influence attitudes, behaviors, or program offerings, were collected in potential TAAG schools and community agencies. Parents, girls, and boys were recruited from schools not used in the TAAG main trial. The rationale for collecting information from individuals not associated with TAAG main trial schools was to avoid potential contamination on attitudinal or behavioral factors.

6.2.2. Phase 1 methodology

Table 6.1 provides information on the specific purpose of each instrument, informants who were sampled for data collection, and overall sample size.

Table 6.1

Instrument	Used to Determine and Assess:	Informants	Sample Size
School survey	physical education requirements, physical activity facilities, health education requirements, after school programs, transportation, internet access resources	Principals (or designees)	66
Community agency survey	Community agency resources, facilities, marketing and communication strategies, the role of agency staff in developing and administering programs, internet access, physical activity programs and community partnerships	Community agencies	141
Parent survey	Parent/girls physical activity participation, girls' access to resources, parental perceived barriers to girls' involvement in physical activity, parents' preferred methods of learning about school-related programs and activities	Parents of 7th and 8th grade girls	87
Physical activity checklist	Prevalent and favorite physical activities	6th and 8th grade girls	129

Instrument	Used to Determine and Assess:	Informants	Sample Size
In-depth interviews	Favorite activities, barriers to being physically active, the social and environmental contexts of being physically active, attitudes and experiences in physical education	7th and 8th grade girls	80
Focus groups	Perceptions of girls being active, potential barriers to girls activity and participation in TAAG	7th and 8th grade boys	12 groups of 5 – 10 boys

6.2.3. Phase 1 results and key recommendations

Main results from Phase 1 formative assessment are:

1. There is considerable variability across sites regarding how physical education and health education are taught in schools, but virtually all schools have certified physical education specialists teaching PE classes. Physical education is coed in some schools, single sex in others, and may be taught in one semester or during the whole school year. Health education is taught in health education class, physical education class, science class, and other classes, such as home economics or family and consumer sciences. Both physical education and health education classes may include any combination of students from 6th, 7th, and 8th grades. Most schools offer physical activity programs through interscholastic and intramural sports programs, usually after school. Less than a quarter of the student population participates.
2. The community agencies that were surveyed conducted physical activity programs in the afternoons. Some of the agencies do not offer programs in the evenings. Few agencies offer programs on weekends or have summer programs. All agencies have at least a multipurpose room, basketball court, gymnasium, or sports field. Most of the children participating in programs arrive by car (usually driven by parents). There is considerable variation across sites regarding types of activity programs offered, but basketball, soccer, and dance programs are the most common across all sites. Programs are most often funded from user fees.
3. Girls like physical activity because it keeps them in shape and healthy, gives them energy and a positive self-image, and provides them with opportunities to be social. They like the challenges that playing on sports teams provide and being able to show the boys what they can do. They want choice in physical activity offerings and to be able to participate and learn a variety of sports in physical education class.
4. Barriers to physical activity for girls include concern about becoming injured, transportation to programs, getting sweaty, getting involved in rough or aggressive play, the time it takes from other required (e.g., homework, childcare) and pleasurable activities, being embarrassed in front of the boys, and being verbally discouraged by boys.
5. According to girls and their parents, family members provide the biggest influence on girls' participation in physical activity.

6. While the boys generally prefer being with physically active rather than inactive girls, they negatively perceive girls who are very active or who are involved in "boy" activities (i.e., those that are rough, dangerous, aggressive). Boys like co-ed PE because they can watch and flirt with girls. They also dislike it because they perceive the quality of PE is lowered because the girls are not as skilled as the boys. Boys also perceived that PE teachers have lower expectations for the girls.

From these results, key recommendations for the intervention are:

1. Classroom-based intervention components should be flexible enough to accommodate different class formats from which they can be delivered, and be structured to be appropriate for all grade levels.
2. Priorities for TAAG community partners should include providing a variety of safe programs in the evening, weekends, and during the summer, problem-solving to arrange transportation for the girls, and ways to reduce or subsidize user fees.
3. Intervention activities should provide girls with physical activity choices in physical education class and after-school programs. These opportunities should include sports, non-competitive activities, physical activity that meets social needs, unstructured activities, co-ed activities, girl-only activities, indoor and outdoor activities, and ways to be active while performing childcare duties.
4. Parental support for physical activity should be developed through regular communication via flyers and school newsletters, by providing opportunities for parents to visit TAAG-sponsored physical activity programs, and by encouraging family members to participate in physical activity with the girls.
5. TAAG materials should appeal to both boys and girls because much of the intervention will be delivered in co-ed settings. The intervention should not alienate boys as the girls become more active in PE class and other co-ed activities. TAAG messages and activities should include appropriate and effective ways for boys to support girls' physical activity involvement.

Site-specific and overall data are available for review on the TAAG web site and are disseminated to each Field Center. Key recommendations, in greater depth than reported here, are provided to the Intervention Subcommittee and Intervention Working Groups for use in designing the intervention. A formal report from Phase 1, titled "TAAG Phase 1, Formative Assessment Draft Report, June 6, 2002" is undergoing final modifications. This report contains study-wide and site-specific results of all Phase 1 data.

6.3. Phase 2 (Spring 2002 – Fall 2002)

6.3.1. Phase 2 background and rationale

The overall objectives of Phase 2 formative assessment are to refine the development of intervention materials, define meaningful segments of girls for tailoring intervention messages, explore potential channels for delivering intervention messages, and determine specific barriers for girls wearing the CSA monitors during structured physical activity programs. Focus groups and interviews are used to collect this information. To

avoid contamination of potential TAAG participants but still collect pertinent information, participants for the girls' focus groups are recruited from schools that are demographically similar to the main trial schools, but are not the TAAG main trial schools. The interviews of teachers and community program leaders are conducted with individuals from the TAAG main trial schools or those who led programs in TAAG main trial school catchment areas.

6.3.2. Phase 2 methodology

All Field Centers participate in all data collection. The methods described in the table provide information on the specific purpose of each instrument, informants, and overall sample size.

Table 6.2

Instrument	Purpose To Determine:	Informants	Sample Size
Focus groups (conducted Spring, 2002)	Segments for delivering messages, preferred channels within segments, which messages are preferred, acceptability of intervention strategies	7^{th} and 8^{th} grade girls	12 focus groups of 5 – 10 girls
Physical education teacher interview (to be conducted Fall, 2002)	Barriers and enhancing factors for the TAAG intervention	PE department heads	36 (6 from each site)
Interview (conducted Spring-Summer, 2002)	Barriers to wearing the CSA monitor, develop problem-solving skills to overcome barriers	Community program leaders and PE teachers	≥ 30

6.3.3. Phase 2 results and key recommendations

Data are being collected and analyzed in Spring, Summer, and Fall, 2002. Site-specific and overall results and key recommendations are presented to the Steering Committee, Intervention Subcommittee, Measurement Subcommittee, and Intervention working groups. Similar to the Phase 1 dissemination process, results are posted on the TAAG web site and disseminated to each Field Center. When all data collection and data analysis are complete, a formal report is prepared, which is posted on the TAAG web site and disseminated to each Field Center.

Throughout the formative assessment period of TAAG, members of the formative assessment working group meet with members of the Intervention Subcommittee and working groups, both formally and informally, to discuss formative assessment results and determine how best to incorporate recommendations into the intervention. This includes joint face-to-face meetings and teleconferences with members of both groups to discuss results and concur on relevant recommendations.

6.4. Training/Support

In-depth trainings for each data collection instrument were conducted by telephone, with representatives from all Field Centers participating on the training conference calls. The Manual of Operations for each instrument describes the requirements needed for certification, which in some cases includes producing a completed instrument/interview for review by the trainer prior to being eligible for certification.

7. INTERVENTION

7.1. Introduction

The purpose of the TAAG intervention is to foster school and community environments that encourage and support the full involvement of girls in every aspect of physical activity, including physical education, recreation, sport, and an active lifestyle. The TAAG intervention is developed to be effective and sustainable, creating immediate school-based opportunities for girls to be more physically active while also: 1) affecting organizational change and empowering communities to enhance and expand physical activity programming for girls; 2) creating normative environments supportive of girls being active; and 3) instilling community-wide commitment to helping youth be physically active.

7.2. Foundations of the intervention

7.2.1. Theoretical underpinnings

The development of the TAAG intervention plans began with a focus on potential theoretical models and existing empirical evidence for correlates or predictors of adolescent physical activity. The first steps in Perry's planning process (Perry, 1999) and Intervention Mapping (Bartholomew, 2001) were used to begin our process. Both intervention planning models begin by specifying the behavior to be changed, examining the determinants of the behavior in question and identifying appropriate theory-based intervention methods and practical strategies. Determining program components and implementation plans follow with maintenance, sustainability and evaluation plans built into the planning process. The planning process is iterative, rather than linear, with formative assessment, the evolving scientific literature, and pilot experiences helping to identify the most potent strategies and effective channels for change.

Besides considering the theoretical basis for our intervention, we also conducted an extensive literature search to identify empirical evidence for correlates and predictors of physical activity in adolescents. Our choice of a social ecological model was substantiated by this review as individual, social, and physical factors emerged in the literature as being associated with physical activity. In a collaborative process, investigators from each site developed a list of intervention objectives and grouped them according to: 1) physical environment, 2) social environment and 3) adolescent girl; these groupings correspond to our "Targets for Change" delineated in the TAAG Social-Ecological Model (see Figure 7.1). The objectives resulting from the predictive factors identified in the literature are found in Table 7.1. These preliminary steps lead us to the next levels of detail for the intervention: the creation of our TAAG Intervention Planning Framework, and plans specific to intervention components.

Figure 7.1

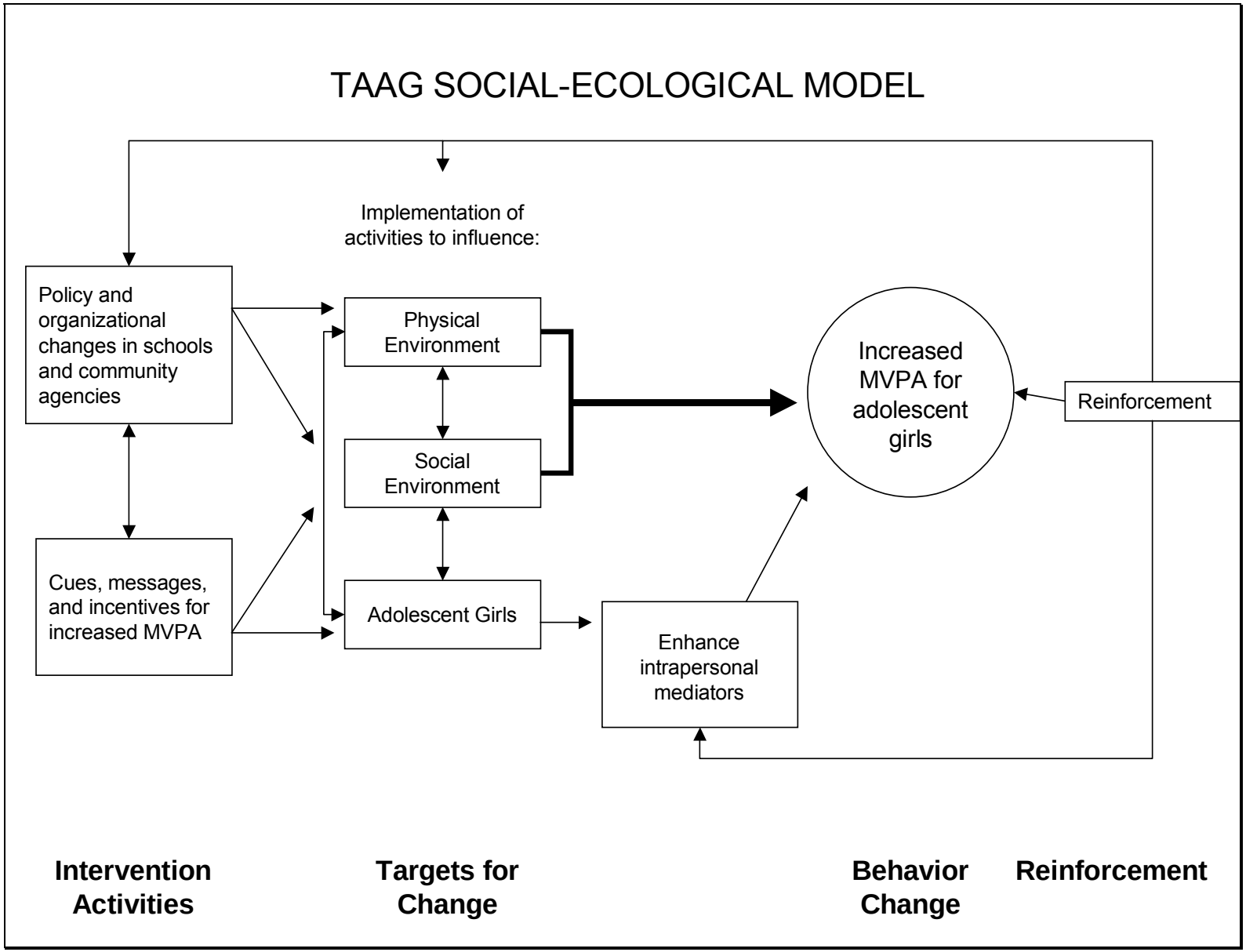

TAAG SOCIAL-ECOLOGICAL MODEL
Implementation of activities to influence:
Policy and organizational changes in schools and community agencies
Cues, messages, and incentives for increased MVPA
Physical Environment
Social Environment
Adolescent Girls
Enhance intrapersonal mediators
Increased MVPA for adolescent girls
Reinforcement
Intervention Activities
Targets for Change
Behavior Change
Reinforcement

Table 7.1. Intervention Objectives Identified Through the Planning Process

Physical Environment Objectives

P1: Increase the number of school and community venues and choices for physical activity in which girls will feel comfortable participating, including structured and non-structured activities, team sports and individual sports, active leisure time activities, out-of-door activities, and girls-only options for activities.
P2: Increase affordable, convenient, and safe transportation to physical activity opportunities for girls and availability of equipment that will facilitate increased activity levels in girls.
P3: Increase girls' and families' awareness of opportunities in the school and community to be active.

Social Environment Objectives

S1: Foster positive family, peer, and school normative beliefs concerning physical activity for adolescent girls.
S2: Enhance social support for girls to be physically active by promoting physically active social activities and by encouraging adult and adolescent role models to provide social support including instrumental, appraisal, and positive affective support.
S3: Expose girls to a range of different types of physically active role models.

Adolescent Girls Objectives

A1: Develop physical, behavioral, and communication skills that will facilitate girls' involvement in physical activity.
A2: Help girls value a strong and fit body.
A3: Increase girls' confidence in their ability to be physically active and to choose activities that they will enjoy.
A4: Increase girls' perceptions that being physically active will result in more positive benefits (e.g., having fun, being social, controlling stress), relative to their perceived barriers to being active (e.g., time, money, appearance while being active).
A5: Increase girls' enjoyment of physical activity by providing programs, activities, and other opportunities to be active that are fun for girls.

There is not conclusive research to explain why physical activity begins to decline in early adolescence, and particularly so in girls. A review of the literature as part of the intervention planning process did, however, identify factors found to be related to girls' physical activity levels. Intervention strategies were designed to specifically address those factors.

1. Opportunities to be physically active affect participation: The research suggests that real or perceived lack of access to safe, fun, acceptable physical activity opportunities negatively impact girls' activity levels. TAAG directly addresses this through the Programs for Physical Activity that will offer more programs in the school and community as well as increased access to existing community programs. In addition, TAAG PE will positively influence the PE environment so that girls feel more comfortable participating in PE class and find more opportunities to be active in PE class that are fun and socially safe.
2. Transportation barriers affect physical activity: Transportation is identified as a barrier to physical activity in several studies. TAAG addresses this through its partnership activities where problem-solving transportation issues are considered with program and action plans.
3. Family and girls' awareness of opportunities affects activity levels: TAAG promotions addresses this issue identified in the literature through regular announcements to students and school staff of activity opportunities. Keeping families informed of activities occurs through the existing school-family channels in place such as school newsletters, information shared with families at school meetings and email messages to families.
4. Perceived normative beliefs for girls being active: Research suggests that influential others as well as culture and social norms affect girls' participation in physical activity. TAAG addresses this through the social marketing approach used in the creation of the intervention that includes targeting a variety of stakeholders that influence the perceived norms and using multiple channels for messages. Positive normative messages are disseminated through TAAG promotional messages, health education lessons and PE instruction. Positive experiences that provide concrete normative messages about girls' participation in recreation and sport occur through activity in PE class and through TAAG sponsored school and community activities.
5. Social support and role modeling affect girls participation in sport and recreation: TAAG facilitates social support for being active by encouraging girls to bring a buddy to TAAG events, by developing several TAAG Activity Challenges that focus on being active with a buddy and through TAAG promotional messages to girls, families and school staff that encourage support and being positive role models for girls. Attention is paid to engaging role models that represent a wide variety of skill level and body type and size.
6. Physical and behavioral skills affect girls' involvement in physical activity. Feeling competent to participate in physical activity has been identified as a factor. These factors are addressed in TAAG primarily through TAAG PE where PE specialists are trained to help girls develop physical skills in a safe and fun

setting. Behavioral skills related to self-monitoring and goal setting are addressed in both TAAG PE and in TAAG Health Education lessons.

7. Perceived benefits and barriers related to being physically active affect girls' participation. These factors are addressed by the TAAG Programs for Physical Activity and TAAG PE by helping to reduce the physical barriers to be active (lack of appropriate programs or opportunities, lack of transportation, financial issues), providing tangible benefits (incentives offered in TAAG promotional special events) and through TAAG Health Education and TAAG promotions by offering verbal support, encouragement, and awareness of the benefits of being active.
8. Perceived enjoyment of being active affect girls. Research shows that if programs are not fun, girls are less interested in participating in activities. TAAG uses extensive formative assessment with girls to identify the programs that they will enjoy. In addition, girls are involved on the Programs for Physical Activity groups to give input to programming plan. TAAG PE focuses on PE class being a venue for all students to be active in activities that they enjoy doing.

7.2.2. TAAG Conceptual Model as operationalized by the intervention

Based on Social Ecological Theory, our Social Ecological Model includes multi-level targets for change (See Figure 7.1). The TAAG intervention is designed to prevent the decline in MVPA in adolescent girls by positively affecting their physical and social environments, as well as directly affecting the adolescent girls themselves. Intervention activities that generate change in the environment and change in the girls include both organizational and community components, as well as interpersonal and individual components, consistent with an ecological approach (Richard, 1996).

The intervention activities are classified into two main categories: 1) policy and organizational changes in schools and communities; and 2) cues, messages, and incentives for increased MVPA. The components work together to positively affect the physical and social environment, as well as the adolescent girls. These changes create environments at school and in the community that facilitate physical activity, enhance social support in those environments, and provide the girls with the motivation and skills to take advantage of physical activity opportunities in all settings. The physical environment includes facilities, programs, and equipment in school and community settings, and reinforcers that facilitate increased levels of MVPA. The social environment includes social support, social influences, encouragement and both direct and vicarious reinforcement by school staff, community agency personnel, and peers. It also includes increasing the presence and awareness of active peer and adult role models and outcome expectations that being active is normative behavior for adolescent girls. Policies are creations of the social environment that can stimulate changes in the physical environment and support all program components. Intervention components also engage adolescent girls directly though educational, motivational and reinforcing messages.

Intervention activities are implemented to increase opportunities for physical activity in the physical environment including the number of available, accessible, and appealing structured and unstructured physical activity programs and opportunities in schools and

communities both during the school day and outside of regular school hours. In addition, the implementation of the intervention may include reducing barriers to participation, such as lack of transportation and lack of equipment, as well as provide physical activity "friendly" training for PE teachers and community activity leaders.

A major focus of the TAAG intervention is to increase opportunities in the social environment including encouragement, modeling, and social support to facilitate adolescent girls' participation in physical activity. These factors apply to school staff, community agencies, families as well as students, affecting and helping to sustain organizational change as well as individual change. A more supportive social environment can make activity programs more reinforcing and enjoyable. The intervention works to reduce social barriers such as gender discrimination, gender stereotyping, and misperceptions of appropriate behavior. Changes in the social environment can be accomplished through training PE teachers and community activity leaders; assisting schools and community agencies to adopt policies to provide more resources for physical activity opportunities for girls; and assisting schools in health education interventions. Girls' social environments are affected by the change in the norms in their schools and communities, the exposure to positive female role models in programming and promotional messages and through health education lessons and competitions that enhance social support by encouraging activities by using and promoting buddy systems for being active.

Intervention activities are implemented to directly influence adolescent girls' beliefs, physical and behavioral skills, knowledge and motivational levels using behavioral skill training in a classroom or PE setting and through messages used in promotional activities. Skills are built through active involvement in physical activities, thus increasing self-efficacy through performance attainment. Other individual factors include: value of being active, behavioral capability, perceived barriers, decision making and problem-solving skills, self-monitoring, and goal setting. Physical activity challenges are a part of all health education lessons and directly provide reinforcement for physical activity. Targeting multiple levels (physical and social environment and adolescent girls), in addition to providing reinforcement for change at multiple levels, maximizes our potential to directly impact MVPA and to impact intrapersonal mediators, which should result in increased MVPA for girls.

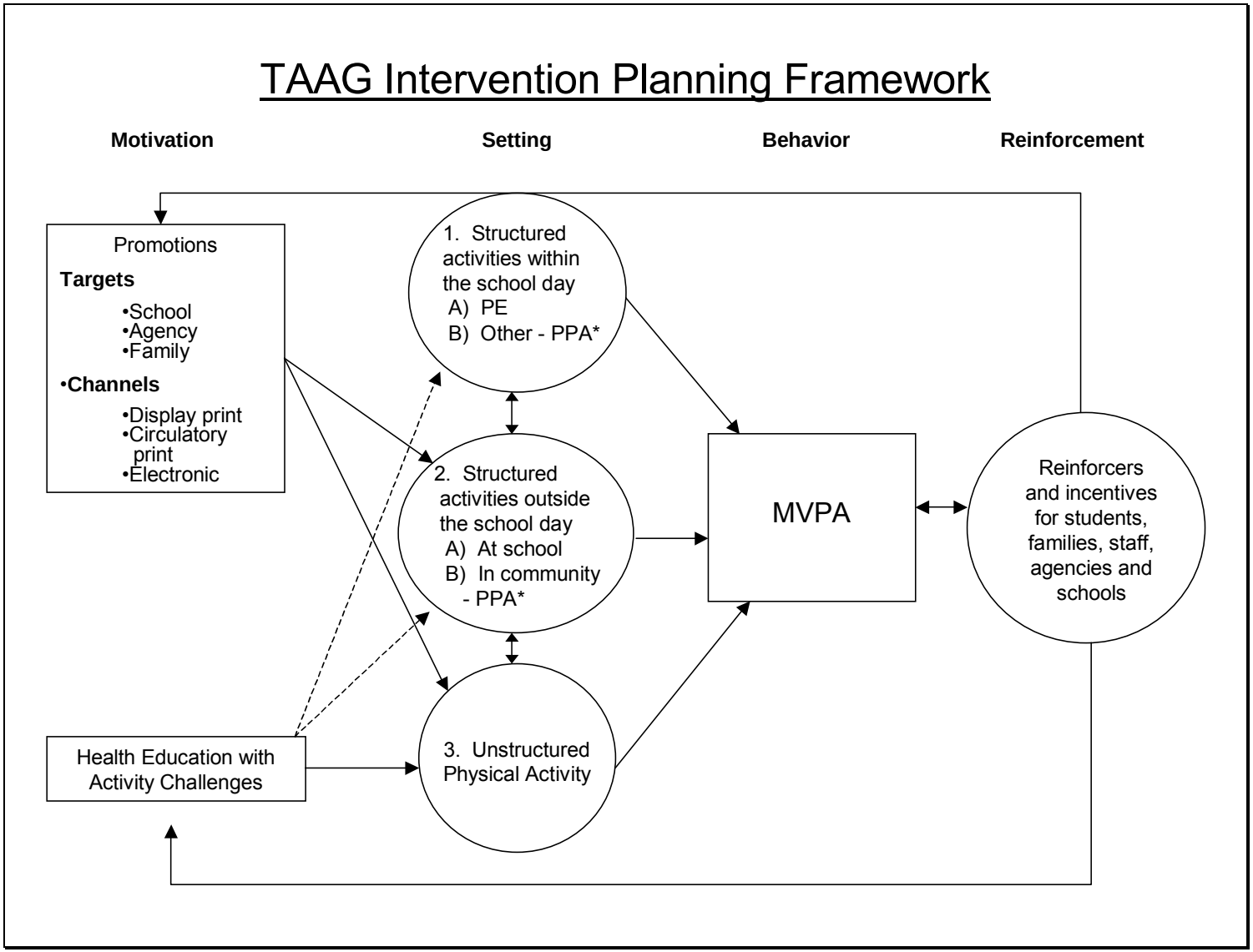
7.2.3. TAAG intervention planning framework

The TAAG Intervention Planning Framework (See Figure 7.2) was developed with the goal of further delineating motivational and setting aspects of the intervention and to identify viable components of the intervention. Motivational aspects of the TAAG intervention include promotions of specific physical activity opportunities and more general promotional efforts to positively affect the social and normative environment around being an active adolescent girl. Promotions target students, staff, and visitors to the school, community agencies, and families and emphasize participation in out-of-school activities and unstructured physical activity opportunities. A variety of channels are used to connect with the target audiences, including electronic and print media. (See Section 7.3.1 for more information on TAAG Promotions). In addition, Health Education with Activity Challenges is a core intervention component that specifically

targets physical activity in unstructured settings, but also encourages girls to participate in structured activities that are available within and outside of school (See Section 7.3.2. for more information on TAAG Health Education with Activity Challenges). Reinforcers and incentives for students, families, staff, agencies and schools help sustain the motivation for maintaining change in the intervention settings.

The TAAG intervention focuses on increasing girls' levels of physical activity by increasing opportunities to be active through structured activities in school (including PE class and other times during the school day); through structured activities outside of the regular school day (including activities occurring on the school grounds, but not during regular school hours, activities off the school grounds, and weekend and summer activities); and through an increase in unstructured activities by girls in a variety of settings including school, home, and in the community. Structured activities refer to activities where there is an adult leader such as intra-mural sports, a dance class or a church volleyball league. Unstructured activities refer to activities that girls

Figure 7.2



* Programs for Physical Activity

can do by themselves individually or in small groups, and that do not require a group leader, such as walking, biking or roller-blading. TAAG PE focuses on creating girl-friendly PE classes and increasing the time spent in MVPA during PE (See Section 7.3.3. for more information on TAAG PE). TAAG Programs for Physical Activity focuses on increasing structured activity outside of school, by creating links between community and school stakeholders interested in physical activity for girls, and by seeking other opportunities during the school day to increase active options and promote physical activity through policy and environmental change. (See Section 7.3.4. for more information on TAAG Programs for Physical Activity).

Increasing the availability of and access to structured activities in and outside of school positively influences both the physical and social environments. The degree to which such activities are positive experiences for girls also increases intra-individual factors influencing activity levels. Increasing unstructured activities requires a safe physical environment for girls, a supportive social environment (including positive role models, affirmative normative expectations, and social support and encouragement) and sufficient motivation for the girls.

7.3. TAAG intervention components

The primary aim of the TAAG intervention is to increase minutes of MVPA. To achieve this aim intervention activities must be of sufficient intensity, duration, and reach and must have targeted objectives for the behavior change desired. Our intervention activities must also affect organizational change, result in community ownership, and establish structures that can support the goals of TAAG after the formal intervention is complete.

Achieving both behavior change at an individual level and institutionalization at the organizational level in a single intervention trial is an ambitious, but important goal. We have developed the TAAG intervention to achieve both purposes. Some TAAG intervention components focus more specifically on behavior change at the individual level, while other components are designed to create sustainable organizational change. The following discussion of the TAAG intervention components is organized to move from the components that specifically target individual behavior change to those that are designed to enhance the institutionalization of the TAAG intervention in schools and communities.

The TAAG intervention uses state of the science intervention strategies, including the Health Education lessons with Activity Challenges and TAAG Physical Education, building on approaches previously found to positively influence youth health behavior. In addition, several innovative elements are being developed and evaluated. Working with schools and communities to increase access to and availability of physical activity programming is the signature feature of the TAAG research. Establishing a coalition with the school as the hub creates this linkage. Schools are the institution in the community with youth as the primary focus. By making them the hub of coalition and

community partnering activities we create linkages that have the potential to be long lasting and vital.

In addition, the TAAG intervention, in general, and TAAG promotions, in particular, are using state of the art social marketing techniques including extensive formative assessment, market segmentation, and attention to the needs and reinforcement of multiple stakeholders. TAAG promotional activities (e.g., the pedometer challenge and the passport program) include innovative activities designed to engage students in fun challenges to get them active.

Although TAAG is considered to be a coordinated whole, there are core components of the TAAG intervention that clearly define it as such and which provide the structure and reproducibility that is required in a multi-centered, group randomized intervention trial. The core components of the TAAG intervention are: TAAG Promotions, TAAG Health Education with Activity Challenges, TAAG Physical Education (PE), and TAAG Programs for Physical Activity.

Table 7.2 provides an overview of the TAAG intervention components, showing each component's goals and objectives, a brief summary of the intervention strategies, materials produced for the component, the primary implementers of each component, and the TAAG intervention objectives targeted by each component.

Table 7.2. Intervention Overview

Core Component	Goals/Objectives	Summary of Intervention Strategies	Primary Material/ Producibles	Primary Implementer(s)	Intervention Objectives Targeted* (see Table 7.1)
TAAG Promotions	Promote awareness of and participation in specific TAAG intervention activities and events through print and electronic channels that successfully reach diverse segments of girls. Create programming (including student competitions and school reward programs) that reinforce girls' participation in physical activity or schools' involvement in TAAG intervention objectives. Inform families of TAAG events and encourage them to facilitate their daughters' choices to be active.	Direct messaging via print and electronic media Possible promotional activities: • School-wide kick-off event • School Recognition Program • Passport Program • Pedometer Challenge	Promotional Materials (print and electronic) Manual of Operations	TAAG Field Center Interventionists School groups/contacts involved with promotional activities	P3 S1-3 A2-5
TAAG Health Education with Activity Challenges	Develop behavioral and communication skills to increase physical activity. Increase awareness and utilization of community-based physical activity resources. Promote the enjoyment of physical activity	Provide a multiple unit, 2 year (7^{th} and 8^{th} grade) health education curriculum focusing on physical activity that can be taught in either a traditional classroom setting or in PE class Provide in-service training and regular on-site consultation with the designated teachers	Teachers' Manuals Student workbooks/ supporting material Task Card File Manual of Operations	Classroom teachers or PE specialist (schools' decision)	P3 S1-3 A1-5

Core Component	Goals/Objectives	Summary of Intervention Strategies	Primary Material/ Producibles	Primary Implementer(s)	Intervention Objectives Targeted* (see Table 7.1)
TAAG Physical Education	Provide a PE experience where girls are engaged in MVPA 50% of class time Provide a PE experience where girls experience many opportunities to successfully participate in a choice of activities, increase competence in skill development, and enjoy physical activity during PE class Encourage girls to participate in physical activity outside of PE class	Provide in-service training (one full day training each year; 2 booster trainings each year) Provide regular on-site consultation to PE specialists	PE Resource Manual TAAG PE Activity Box Task Card File Manual of Operations	Schools' PE specialists	P1-3 S1-3 A1-A5

Core Component	Goals/Objectives	Summary of Intervention Strategies	Primary Material/ Producibles	Primary Implementer(s)	Intervention Objectives Targeted* (see Table 7.1)
TAAG Programs for Physical Activity	Provide and promote a variety of accessible, safe and fun physical activity programs and opportunities during the school day, after school, on the weekends and in the summers, with multiple options available at all times. Provide a minimum of 30 minutes MVPA per day in TAAG sponsored and/or promoted physical activity programs. Work to advance school-wide change, including policy change, that promotes and supports physical activity.	Develop and maintain school, community, and university partnerships that work to: 1) increase the number of available programs involving physical activity in schools and the community (including developing new programs and enhancing existing programs) 2) improve access and reduce barriers to program participation 3) promote attendance and reinforce participation in programs and activities	Partnership Materials/Resource Manuals Manual of Operations	Committed partners from school and community with Field Center facilitator	P1-3 S1-3 A1-A5

* P1 – P3 are the objectives for the Physical Environment
S1 – S3 are the objectives for the Social Environment
A1 – A5 are the objectives for Adolescent Girls

7.3.1. Promotions

The objectives of the TAAG Promotion intervention component are to: 1) promote awareness of and participation in specific TAAG intervention events and activities through print and electronic channels that successfully reach diverse segments of girls; 2) create programming (e.g., student competitions and school reward programs) that reinforce girls' participation in physical activity or schools' involvement in TAAG intervention objectives; and 3) inform families of TAAG events and encourage them to facilitate their daughters' choices to be active.

TAAG promotion intervention strategies:
The TAAG Promotional strategies include direct messaging to girls. They also include promotional events that heighten awareness of TAAG and provide motivation and incentives for girls to participate in TAAG programming. Specifically, formative assessment has been used for market segmentation and to create "TAAG lines" used to help motivate different segments of the female target audience through a variety of print and electronic media. In addition to promotion of activity in a general sense, a variety of print communications, such as flyers, posters. TAAG events. Electronic media also promote activities and events and help with communication to families, the girls and community partners. For example, a TAAG calendar may be included in existing school newsletters and email notices of events may keep families informed of TAAG opportunities and events.

Based on TAAG pilot experiences, other promotional activities may include a TAAG kick-off event and a school recognition program. The kick-off event is a school-wide fair held in the fall of the first intervention year to increase awareness of TAAG and to promote TAAG activities. A school recognition program rewards schools for creating supportive environments that promote physical activity among girls. Finally, two activity challenges are being piloted for feasibility and acceptability: the TAAG Passport Program and the TAAG Pedometer Challenge. The primary goal of the TAAG Passport Program is to motivate and reward girls for participating in a variety of moderate to vigorous physical activities in the community and on their own. Passport "stamps" are awarded to students who complete such activities as hiking a local trail, attending a TAAG sponsored Fun-Run, or attending a basketball clinic at the YWCA. As passport activities are completed, students receive a reward to reinforce their progress. The goal is to develop a system that motivates students to achieve passport activities and to have girls compete within and across schools for prizes and incentives. The TAAG Pedometer Challenge involves a challenge between classes, schools, and ultimately the TAAG Field Centers for achieving the most number of steps.

TAAG promotions materials:
Materials for the TAAG promotions component include print and electronic media messages designed for use by the Field Center's intervention coordinator and school groups involved with promoting activities and the TAAG Manual of Operations. The TAAG Manual of Operations includes a CD-ROM with print material templates and instructions so that Field Centers can tailor materials to advertise specific events, print materials such as posters and stall-talkers promoting MVPA in general, and print

material for other activities such as the Passport Program and the Pedometer Challenge. The Manual of Operations also includes information on how to organize and implement the special events including the kick-off event, the school recognition awards, the Passport Program and the Pedometer Challenge.

TAAG promotions implementation:
Templates and guidelines for promotional activities and materials are produced at the national level. Field Centers utilize the materials to produce promotional materials and events that appeal to local interests and needs. Although the Passport Program is centrally produced, Field Centers and schools have flexibility in developing the nature of the activities and incorporate local events and opportunities rewarded as part of the Passport Program.

A centralized training for the Intervention Coordinator provides guidance on TAAG Promotions implementation. The TAAG Intervention Coordinator at each Field Center works with designated school staff or school groups such as the TAAG Programs for Physical Activity for help in coordinating promotional activities in schools. Schools are asked to identify one or more school staff interested in being involved with the promotional activities. Schools may decide that these are individuals who are involved with other aspects of the TAAG intervention (e.g. , the PE specialists in the school) or may decide to involve other interested school staff in implementation of the promotional activities.

7.3.2. Health education with activity challenges

TAAG Health Education with Activity Challenges provides youth with the knowledge and skills needed to be more active both inside and outside of school. Parallel lessons with the same learning objectives are designed for both classroom and physical education settings, allowing schools to decide where TAAG Health Education with Activity Challenges best fits with their school's curricular needs. Innovative Activity Challenges enhance each lesson and provide opportunities for students to be active and have fun while learning. Because most health education instruction occurs in co-educational classes, TAAG Health Education with Activity Challenges is designed for both girls and boys.

The objectives of TAAG Health Education with Activity Challenges are to: 1) develop behavioral and communication skills to increase physical activity; 2) increase awareness and utilization of community-based physical activity resources; and 3) promote the enjoyment of physical activity.

Health education with activity challenges intervention strategies:
TAAG Health Education with Activity Challenges is a multi-lesson health education curriculum for 7th and 8th grade. Each year of the intervention includes lessons, an associated activity challenge to be done outside of class and brief follow-up sessions. Each lesson is designed to take between 30-45 minutes to teach. There is a brief follow-up session (taking about 10 minutes) of the next TAAG lesson to review progress on the Activity Challenge that was assigned in the main lesson. The lessons have a scope and sequence with one lesson building on the previous one and year two lessons

building on year one lessons. Teachers are trained to teach all lessons in the appropriate sequence. Included in the health education lessons are topics such as the benefits of physical activity, enlisting social support for being active, setting goals for activity, reducing barriers to being active, and self-monitoring techniques for assessing physical activity.

Each lesson includes behavioral objectives, an outline for the teacher specifying the activities that occur as part of each lesson and the amount of time to devote to each activity, and the materials needed for each activity. The lesson plan details the information to present and provides suggestions for engaging the students in the activities. For the lesson versions that are taught in a traditional classroom, didactic presentations are minimized and the focus is on interactive, problem solving or creative experiences. For the lessons taught in PE, a proportion of each lesson is designed to get students moving. Each lesson finishes with an activity challenge for the following week. Activity challenges range from behavior modification-type assignments to challenges involving wearing pedometers and setting goals for movement. The activity challenges support the content presented in the lessons and act to carryover lessons outside of class into their daily routines. Reinforcement for behavior change occurs as challenges are met.

Health education with activity challenges materials:
There are four types of materials for this component: A Teachers Manual (one for Grade 7 and one for Grade 8), a Task Card file, student workbooks for each year, and a Manual of Operations. The Teachers Manual includes all the lessons (both the physical education and classroom versions of each lesson) and copies of all handouts and overheads needed for each lesson. The Task Card file contains visual supporting material to show the class. The Student workbook includes all the handouts and the materials that the student will need for the lessons and the activity challenge. The Manual of Operations is a manual for the TAAG intervention staff that includes details on implementing the Health Education with Activity Challenges component, selected process evaluation materials, outlines for teacher training and other supporting materials.

Health education with activity challenges implementation:
TAAG Health Education with Activity Challenges lessons are designed to be flexible in accordance with the needs and structure of individual schools. The lessons may be taught as part of the health education curriculum, as a part of science or family and consumer science or as part of the physical education curriculum. In schools where the advisory or homeroom period is of sufficient duration (at least one regular class period), the Health Education with Activity Challenges lessons may be offered there, as well.

After schools are randomized, Field Center staff meet with intervention school administrators and other appropriate school staff to describe the content and format of the Health Education with Activity Challenges lessons. Field Center staff allow for a great deal of flexibility in where these lessons are delivered. For example, one school may decide that the PE specialists deliver all of the lessons. In that case, PE specialists

are trained to deliver the physical education version of each lesson. Other schools might decide that all of the lessons are taught in health and the format of the classroom does not permit active lessons. In that case, health teachers are trained to deliver the classroom lessons. It is conceivable that a school might want to offer the lessons in both PE and a more traditional classroom environment. In that case, both PE and classroom teachers are trained and Field Center staff work with the teachers to help them decide which teachers teach each lesson; teaching students two versions (the physical education and classroom versions) of the same lesson is to be avoided. Teacher training on the Health Education with Activity Challenges occurs prior to the beginning of the school year or soon after school begins. This training describes overall TAAG intervention objectives as well as the Health Education with Activity Challenges objectives followed by an interactive training that includes a review of the Teachers Manual, a walk-through of all lessons, role modeling, demonstration and participant practice of lesson activities. Following the formal training, Field Center intervention staff periodically contact (at least once a month) designated teachers to see how the lessons are going, help problem solve issues and provide support and technical advice.

Those teachers designated to teach the Health Education with Activity Challenges in fall of 2003 are invited to the TAAG Orientation session that occurs in spring of 2003, after randomization. The TAAG Orientation session provides an overview of TAAG and the TAAG intervention. At this session, we assist the teachers in developing the timeline for the next school year's intervention activities, discuss their role in the TAAG intervention and set up dates for the fall training.

7.3.3. Physical education (PE)

The TAAG PE objectives are to: 1) provide a PE experience where girls are engaged in MVPA during 50% of class time; 2) provide a PE experience where girls experience many opportunities to successfully participate in a choice of activities, increase their competence in skill development and health-related fitness, and enjoy physical activity during PE class; and 3) encourage girls to participate in physical activity outside of PE class, including after school programming.

The first two objectives are reached by positively influencing how PE class is conducted including the format of lessons, class management strategies, instructional strategies and the development of social skills that reduce barriers to girls' participation and enjoyment of physical activity. Enjoyment of PE class is enhanced by providing choice to students, including choice of activities, choice of competitive levels and where possible, choice of gender segregated activities. Sample lessons and unit activities are presented during staff development training and in the written materials giving PE staff concrete examples of active lessons and activities. Because most PE classes include both boys and girls, the ideals of TAAG apply to the instruction of all students in class.

The third objective is reached by engaging PE teachers as links to the wider school and community physical activity opportunities that are being offered as part of the TAAG intervention. In some cases, PE teachers also deliver the TAAG Health Education with Activity Challenges lessons positioning them to reinforce activity beyond PE class. PE

teachers promote TAAG after school activities and other TAAG-supported community programs.

TAAG PE intervention strategies:

TAAG PE is not a traditional curriculum, rather it uses a staff development model, training and empowering schools' PE teachers to adapt or revise their current curriculum in ways that increase MVPA and girls' satisfaction with the PE experience. There are two primary intervention strategies for TAAG PE: staff development training and on-site follow-up. TAAG Field Center intervention staff conduct one full day training and several booster in-service trainings to all PE teachers in the intervention schools in each of the TAAG intervention years. PE specialists from all three intervention schools at each Field Center are trained together, enhancing group support, role modeling and problem solving between the PE teachers. These in-service trainings are active trainings, modeling the TAAG intervention concepts and providing the PE teachers with experiential learning. Topics that are covered in training include: gender equity in physical activity, barriers girls encounter in being physically active, adapting existing lesson plans to meet the TAAG PE objectives, introducing more choice into PE lesson plans and reducing non-active time during PE.

Following initial training, TAAG Field Center intervention staff provide regular, on-site follow-up. The purpose of these visits is to provide support for the adoption and institutionalization of TAAG PE. This consultation includes feedback, modeling, and technical support to PE teachers.

TAAG PE materials:

Materials developed for TAAG PE are a TAAG PE Resource Manual, TAAG PE Activity Box, and Task Cards for use by school staff, and a Manual of Operations for TAAG Field Center staff. The TAAG PE Resource Manual is given to staff at the first staff development training and includes: 1) an overview of TAAG; 2) the rationale, vision, and objectives of TAAG PE; 3) recommended lesson format; 4) tips on building a positive learning environment; 5) information on health-related fitness; 6) physical activity promotion beyond PE; 7) planning and assessing for progress; 8) commonly asked questions; 9) resources and professional information; and 10) references.

The TAAG PE Activity Box provides a wide variety of sample unit activities focusing on health-related fitness such as aerobic games, bench aerobics, power walking, and resistance and strength training. These sample unit activities give concrete examples to teachers on how to adapt their current units to meet TAAG objectives and examples of new units to introduce to their classes. The Task Card file contains handouts, task cards and a CD to assist with implementing the TAAG sample activities.

The TAAG PE Manual of Operations is a manual for Field Center intervention staff that describes the implementation of the PE component, including staff development objectives, objectives, and agendas for staff development training and booster sessions, process evaluation measures, and guidance on interacting and collaborating with teachers.

Implementation of TAAG PE:
After randomization but prior to the first intervention year (Spring 2003), the PE teachers convene in each intervention school for a TAAG orientation session that provides an overview of TAAG and the TAAG intervention. At this session, Field Center investigators assist the PE teachers in developing a timeline for the next school year's intervention activities, discuss their role in the TAAG intervention and set up dates for the first staff development training. School PE equipment is inventoried and orders placed to purchase needed equipment for the next school year.

All PE teachers in the intervention schools are trained and supported to implement TAAG PE. Training of all PE teachers in a school, rather than just those teaching the 7th and 8th grades, enhances the possibility that TAAG PE principles are adopted by the school's entire PE department, increasing the chances for institutionalization.

The first staff development training is conducted immediately prior to the beginning of the school year (August or September 2003). TAAG Field Center staff conduct the training. One or two half-day booster training are conducted each school year. Topics for the booster trainings may include strategies on motivating girls, which includes providing choice and positive socialization, incorporating cooperative learning into PE classes and strategies to encourage participation in out-of-school activities.

Following the formal training, on-site visits begin. Field Center intervention staff visit each school at least twice each month, observe PE class and arrange for an informal discussion with the PE teachers about problem-solving, increasing activity or participation in lessons, and progress towards reaching the TAAG PE objectives. During these on-site visits, intervention staff may help demonstrate how a new TAAG activity works, help the PE teacher adapt a previous lesson to help it meet TAAG objectives, or help to create more choice options in PE class so girls have more opportunities to find enjoyable, active options. Working toward gender equity and reducing gender bias is an important goal stressed both in trainings and during on-site visits.

7.3.4. Programs for physical activity

The TAAG Programs for Physical Activity component draws from Organizational Change Theory and direct action community organizing in developing a process by which schools, communities, and the TAAG intervention staff form partnerships to accomplish a common goal of increasing girls' participation in physical activity at school and outside of the regular school day. A unique aspect of this partnership is that it school-based rather than state or other community-institution-based. It may be argued that using the school as the hub of the partnership limits its scope and reach. However, since schools are the primary institutions in the community that focus on youth needs, and since schools are relatively stable institutions with a constant mission, we believe that this model has great potential to be effective in resulting in more physical opportunities for girls locally and may serve as the impetus for wider community change that expands beyond the local school. School district or state-level policy change (i.e., district or state-level requirements for daily PE, state or district level funding for

transportation or programming) may occur as a result as the demonstrated successes of the school-based activity partnerships. The objectives for the TAAG Programs for Physical Activity are to:1) provide and promote physical activity programs during the school day, after school, on the weekends, and during the summer in both school and community-based venues; 2) provide a minimum of 30 minutes of MVPA during each program period of TAAG-sponsored activities; and 3) work to advance school-wide change including policy change, that promotes and supports physical activity.

Programs for Physical Activity intervention strategies:
For each school catchment area, the school-community-university partnership works to increase the number of available and/or accessible programs in the school and in the community. These programs might be new programs that are developed as part of TAAG intervention activities or might be modifications or special promotions of existing programs. The TAAG Programs for Physical Activity also works towards decreasing barriers, improving access to programs, promoting attendance, and reinforcing participation in programs and activities. The goal of the partnership process is to develop a shared vision and purpose among a diverse group of stakeholders so that this group may work toward the common goal of increased physical activity opportunities for girls in the school and community.

The Programs for Physical Activity objectives include enhancement of physical activity opportunities both outside of school and during the school day. Increasing the availability of out of school programming is a formidable task for schools with significant challenges in transportation, space, personnel, and financial resources. Partnering with other community agencies and individuals to provide help and resources is a logical solution, but one that most schools have difficulty initiating. TAAG Programs for Physical Activity builds partnerships between school and community agencies and individuals, providing strong and sustainable links between schools, girls, and community.

The types of out-of-school programs as well as the number and type of partners are involved are expected to vary widely from site to site. Our objective is to standardize the process as much as possible, while allowing the partners to develop plans that best meet the needs and desires of girls and schools in their community. The programs that are promoted through the Programs for Physical Activity might be new programs or existing programs that are modified to meet TAAG objectives. Programs supported by Programs for Physical Activity are all supervised programs, and provide a variety and range of physical activity choices, from very structured to unstructured, competitive to leisure time activities, for the very athletic and for the very inactive. Partners may contribute in a variety of ways including: offering direct programming in a community agency, such as a new kickboxing class at the YWCA advertised to TAAG girls; offering direct programming in the school after hours, such as a jazzercise instructor in the community offering a new class after school; or supporting physical activity in other ways, such as a health maintenance organization providing funds for transportation to a community center or providing funds for bike racks at the school.

Realizing that convening and mobilizing community groups takes time, and, facing the reality that out-of-school programming must begin quickly in this two-year intervention trial, information collected during the formative assessment phase and from one-on-one interviews are used to generate a jump-start menu of out-of-school programs that can be promoted as TAAG activities in the fall of 2003. These jump-start activities not only provide some programming immediately, but also give the Programs for Physical Activity some concrete examples of the types of programming that the partners might implement and provide the model for a proactive and vital partnership that produces a tangible and important outcome.

In addition to out-of-school programming, Programs for Physical Activity also considers ways to increase activity options during the school day and to reduce barriers to TAAG intervention objectives. Programs for Physical Activity subgroups that focus on in-school issues are modeled after school advisory groups advocated by Centers for Disease Control (Centers for Disease Control and Prevention, 2000a) and NASPE (NASPE Middle and Secondary School Physical Education Council, 2000) for helping to create school-wide change, including policy change. A menu of possible in-school Programs for Physical Activity projects might include:

- Develop a system for storing and checking out PE equipment so that after-school programs can use PE equipment;
- Organize a “TAAG Girl of the Week” recognition event;
- Organize a lunch time activity fair with games and special events;
- Help problem-solve how to deal with the loss of the activity bus due to budget cuts;
- Work on a petition to the school district for daily PE.

Materials for Programs for Physical Activity:
The materials for this component include a Manual of Operations for TAAG Field Center staff on how to help create and maintain the partnership. Materials for school and community partners include materials and support, such as the a summary report of formative assessment information, start-up funds information, an action planning document, mini-grant applications, and materials describing methods of collaboration and support.

Implementation of Programs for Physical Activity:
The Programs for Physical Activity process begins immediately after randomization with a goal of having programming begin by the fall of the first year of the intervention either through Jump-Start Activities or in conjunction with activities implemented as a result of the partnership decisions. The number of programs is anticipated to grow rapidly during the first year and by the second year of the intervention daily programs or opportunities can be identified that are a result of the Programs for Physical Activity. Programming is anticipated to occur during the summer between the first and second year of the intervention.

We start the partnership development by compiling formative assessment information from the school, community agencies, girls, and parents and by conducting one-on-one interviews in the community. One-on-one interviews are conducted by TAAG intervention staff with a variety of stakeholders in the community (e.g., school personnel, community agency personnel, private business owners, and parents) to hear their perspectives on the issue and to assess their interest and potential commitment to being involved in the partnership.

The TAAG Field Center interventionist compiles information gathered from the formative assessment and the one-on-one interviews into a Summary Report. This is a brief overview of current physical activity opportunities in the school and community for use in educating and motivating potential partners. A first meeting of the potential partners (identified through formative assessment and one-on-ones) is convened. At a minimum, one school, community, and a TAAG intervention staff member make up the initial Planning committee. Other interested stakeholders may be involved as programming objectives are set and operationalized. The Summary Report is shared and other stakeholders are identified.

Once the set of partners is determined, empowerment of the partnership is substantiated by the provision of start-up funds for the partnership. These funds are provided by the university partner and are used as seed money to begin projects delineated by the partnership. The partners begin developing recruitment and retention plans and considering ways to deal with challenges in programming such as transportation and costs. The Programs for Physical Activity meets as a large group at least twice a year. Much of the work of the Programs for Physical Activity is expected to occur in subcommittees or as smaller action planning teams.

As the partners move into the action phase, they develop and carry out plans for programs and enhanced opportunities. This includes identifying and preparing staff for specific programs; tending to program implementation details such as location, scheduling, facilities, and equipment needed; addressing safety and supervision issues; addressing barriers to participation; recruiting participants, carrying out programs, and monitoring programs. One mechanism to be used to encourage innovative programming is the mini-grant. The mini-grants provide small stipends of money to individuals, school or community groups to facilitate a programming idea. The partnership would oversee the grant process and make awards.

As the ongoing implementation step, the TAAG Programs for Physical Activity assesses progress, revisits goals and plans as needed, maintains and expands existing programs and opportunities, implements new ideas and recognizes and celebrates success. Elements of process evaluation and formative assessment findings are shared with the partners to give them feedback on girls' responses to programming; challenges encountered and need for additional programming. The Summary Report from baseline is updated periodically and reviewed by the group to help evaluate their progress.

7.4. Implementation of the TAAG intervention and quality control

A Memorandum of Understanding signed during school recruitment delineates the intervention activities that schools must agree to facilitate or conduct if randomized to the intervention condition. After randomization to the intervention condition, TAAG Field Center staff meet with the school administrator and other school staff to determine communication channels and procedures for coordinating, organizing and implementing TAAG intervention activities in the school. Implementation of community-based TAAG intervention activities is coordinated through the Programs for Physical Activity. The coordination of TAAG intervention activities may vary from school to school and site to site in order to meet local needs.

The TAAG Field Center staff are responsible for assessing and monitoring the quality of the intervention components. The quality of the TAAG intervention activities are maintained through regular interaction between the TAAG intervention coordinator and designated school personnel and groups involved with intervention activities, through use of standardized training and intervention materials and manuals, and through process evaluation documentation and review of data (See Process data, Quality control, section 10.5)

7.5. Use of formative assessment and pilot testing in planning the TAAG intervention

7.5.1. Formative assessment

The Intervention Subcommittee and working groups conducted formative assessment during the development of intervention plans. As formative assessment results became available, they were shared with the intervention subcommittee and working groups by both written and oral presentations. Intervention plans were revised and refined accordingly. See section 6 for more information on Formative Assessment results and recommendations.

7.5.2. Intervention pilot testing

TAAG PE, TAAG Health Education with Activity Challenges and selected elements of TAAG Promotions are piloted beginning in the fall of 2002. Training of the trainers for these pilot elements is scheduled for early fall of 2002 and training of the pilot schools is scheduled for fall of 2002. Passport and Pedometer activities for TAAG Promotions are piloted in winter 2002.

The pilot testing of the Programs for Physical Activity includes two components. Each site works with a pilot intervention school using the protocol described above to develop community partners. Training for the partnership process occurred in February 2002. In addition, as part of the pilot work, each Field Center piloted at least one activity for girls in either a school or community setting. The purpose of this element of the pilot was to give sites experience in facilitating the enactment of activities and getting practice and experience in promoting activities. Some of the activities piloted were: girls boxing, training for running or walking a community 5K race, a dance and drama program, girls

3-on-3 basketball, hip-hop dancing, and cardiofunk dancing. These programs were implemented drawing from local resources or community agencies.

The intervention timeline is developed so that there is some time between the end of the pilot activities and the completion of all the formative assessment and the final development of materials for the main trial.

7.6. Working toward institutionalization: A Program Champion approach

The TAAG 8B measurements evaluate the extent to which environmental changes have been maintained in TAAG schools and communities after the end of the active TAAG intervention activities by assessing elements of the school and community environments and by evaluating student-level outcomes in a cross-sectional sample of 8th grade girls.

In year 2 of the intervention (2004-2005) we will develop a process to identify and train school and community program champions as an intervention strategy to support the institutionalization of TAAG intervention components. The concept of a program champion is not new to school-based health promotion programs. However, the majority of the research on program champion is post hoc; when identifying factors related to the institutionalization or sustainability of programs frequently a "self-appointed" program champion emerges as a key factor in sustaining the intervention. TAAG will develop a process to identify potential program champions during the active intervention phase and will work with them to implement and adapt TAAG intervention strategies so that they will be sustainable after the active intervention phase of TAAG.

7.6.1. Background and Rationale

The empirical literature contains some reports on the sustainability of school-based health promotions research. The question of sustainability is informed by the theory of Diffusion of Innovation that posits that there are several phases in the diffusion of an innovation. Innovations are defined as ideas, practices or objects that are perceived as new by units of adoption and four stages are posited: 1) Dissemination- schools are made aware of programs and encouraged to adopt them; 2) Adoption- schools make a commitment to adopt the program; 3) Implementation- when the program is first delivered and 4) maintenance or institutionalization of the program. Kanter describes institutionalization by, "..when the structures surrounding a change also change to support it, .. we way that a change is institutionalized- that it is now part of legitimate and ongoing practice, infused with value and supported by other aspects of the system." (page 299 as reported on page 64 of Goodman and Steckler, 1989.) Obviously, in the active intervention phase of TAAG, we will get schools to phase 3 of implementation. The challenge we face in 8B is one of making the activities that are TAAG part and parcel of how schools "do business".

Two research trials were funded in the 1980s specifically to examine how health promotion innovations were diffused in schools: 1) the North Carolina School Health and Tobacco Education project (SHTEP) (Smith et al, 1995) and 2) The Smart Choices Diffusion Study (Parcel et al, 1995). Other research trials including CATCH (Institutionalization of a school health promotion program: the CATCH-ON experience,

Special Issue, Health Education and Behavior, August, 2003; Osganian et al, 2003) and SPARK (McKenzie et al 1997) have also studied the institutionalization of health promotion programs in schools after the active intervention phase of the research is complete. Across the board, research on institutionalization shows that sustainability of programs is very difficult to achieve.

Smith et al (1995) and Loughlin et al (1998) offer the most comprehensive factors found to be predictive of the diffusion of programs. Among the factors they identified were program champions or "patron saints". Loughlin (1998) conducted a meta-analysis to investigate factors related to the perceived sustainability of 189 heart health promotion interventions initiated by public health departments or research. They interviewed key informants about programs meeting study criteria and then examined correlates of sustainability. "Independent correlates of perceived sustainability included intervention used no paid staff (OR= 3.7 ;CI= 1.8,7.5), there was a good fit between the local provider and the intervention (OR= 2.4; CI= 1.2-5.0) and there was the presence of a program champion (OR=2.3; CI= 1.2,4.4) " pp 702.

Diffusion of innovation theory also talks about the "critical mass" and the S-shaped curve of the adoption process at which there often is an upsurge of new adopters. This Program Champion intervention, which occurs in the second year of the TAAG intervention, will take advantage of this development of a critical mass and in our ability to identify school and community individuals who might help fuel the institutionalization process.

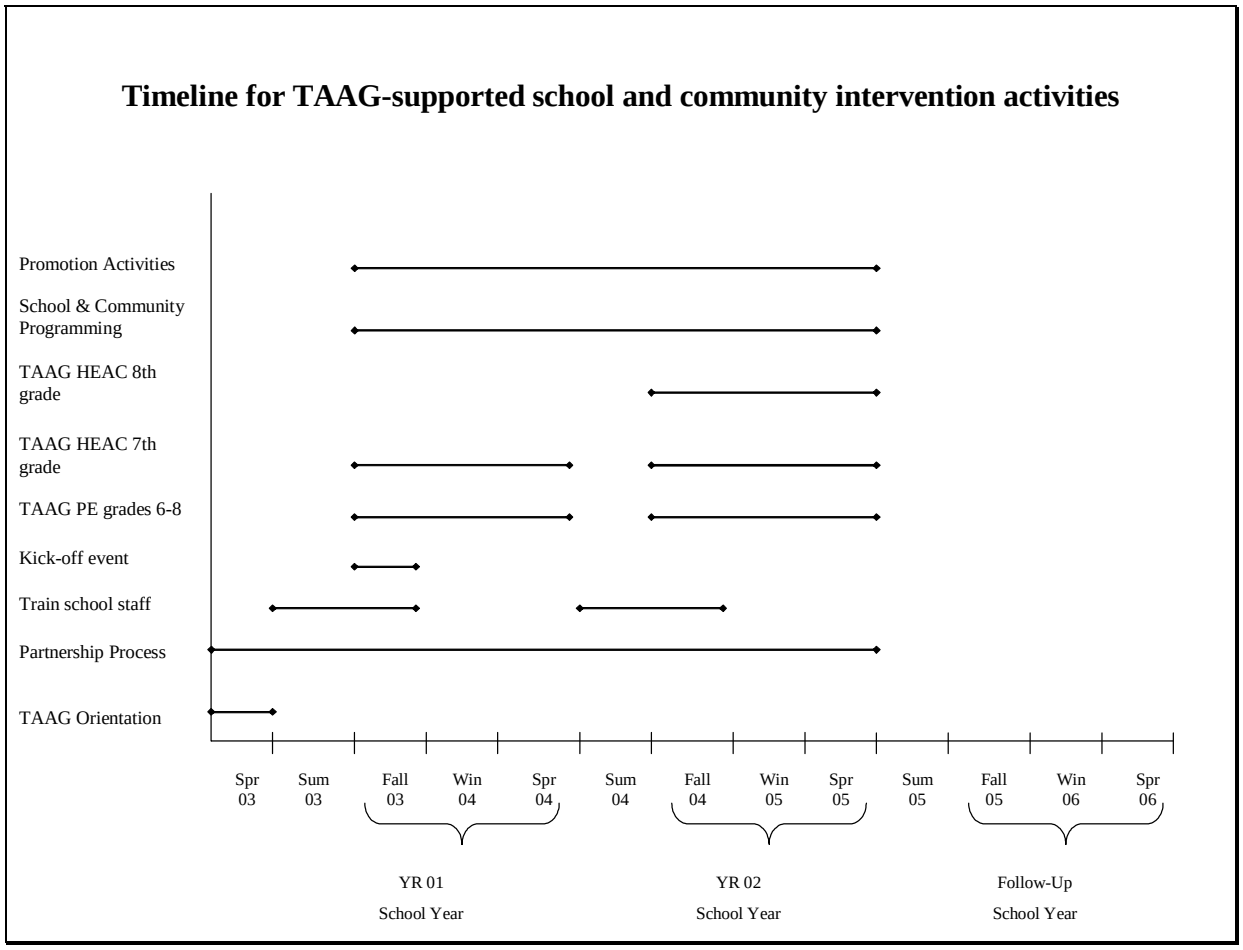
7.6.2. Goals of the Program Champion intervention

The goals of the Program Champion Intervention are to:

1. Identify individuals within schools and communities who have the interest, energy, abilities and time to help maintain TAAG intervention objectives after the active intervention phase of the grant
2. Develop a system for training program champions to continue TAAG intervention components
3. Develop a system for helping program champions problem solve barriers to institutionalization and to adapt the TAAG intervention to better fit the needs of the school and community
4. Develop a system for helping program champions meet the challenges of implementation including to 1) continue to work with community stakeholders to provide more PA opportunities for girls outside of the school day; 2) continue promotional events such as the passport and pedometer challenges; 3) finding resources and overcoming logistical challenges to reproduce TAAG intervention materials including student and teacher materials, promotional materials, and other supporting materials; and 4) continuing PE and HEAC training
5. Develop guidelines for TAAG sites on ways to continue to offer technical assistance (without additional TAAG resources) to schools after the active intervention phase is completed.

7.7. Intervention timeline

Figure 7.3



8. CONTROL SCHOOLS

At the end of the follow-up period (Spring 2006) the schools that were originally randomized to the control condition receive materials that have been developed for the TAAG intervention. Relevant school staff receive at least one full day of training on TAAG PE and TAAG health education with activity challenges. Materials on how to create and sustain school and community partnerships and promoting physical activity programs will be developed. They are shared with control school personnel in a single training.

9. OUTCOME MEASURES

9.1. Introduction

TAAG is designed to determine the effects of a school- and community-linked intervention on moderate to vigorous physical activity in middle school girls. Hence, the primary outcome variable in TAAG is moderate to vigorous physical activity (MVPA). In addition, the trial examines the effects of the intervention on several secondary outcomes. Also, the study determines the influence of several factors that may mediate or moderate the effects of the intervention on physical activity. Further, several variables are measured for the purpose of describing the samples of girls in whom measures are applied. This section of the TAAG protocol describes the procedure for measurement of the primary outcome variable, MVPA, as well as procedures for measurement of the variables that are considered secondary outcomes, mediators, moderators, and descriptors (Table 9.1). The candidate variables included in the student questionnaire are shown in the Table. In order to be feasible, the questionnaire must be administered in one classroom period. Field-testing is planned to determine the length of time required to complete the full instrument. The number of variables assessed in the questionnaire may be reduced depending on the results of that testing.

Table 9.1. TAAG Measurements for Primary Outcome, Secondary Outcomes, Mediators, Moderators, and Descriptors

Variable Type	Variable(s)	Method	Level	Times Measured
Primary Outcome	Daily intensity-weighted minutes of MVPA	Accelerometry (CSA activity monitor)	Girl	Grades 6, 8A, 8B
Secondary Outcome	Cardiorespiratory Fitness	PWC-170	Girl	Grades 8A
	Body Composition: • Percent body fat • Fat-free mass	Height (ht), Weight (wt), Triceps Skinfold	Girl	Grades 6, 8A, 8B (ht & wt only)
	Types and Contexts of Physical Activity	Modified 3DPAR	Girl	Grades 6, 8A, 8B
	School Achievement	Standardized test scores	School	Grades 6, 8A, 8B
	Smoking Initiation	Student Questionnaire; Modified scale, 6 items	Girl	Grades 6, 8A
	Physical Activity in PE Classes	Modified System for Observing Fitness Instruction Time (SOFIT)	Classroom	Grades 6, 8A. 8B
	Depressive Symptoms	Student Questionnaire; CES-D scale, 20 items	Girl	Grades 6, 8A
	Total Physical Activity	Accelerometry	Girl	Grades 6, 8A, 8B

Variable Type	Variable(s)	Method	Level	Times Measured
	Physical Activity on weekdays, weekends, in-school, out-of-school	Accelerometry	Girl	Grades 6, 8A, 8B
Mediator	Self-efficacy	Student Questionnaire; Modified scale by Saunders, 8 items	Girl	Grades 6, 8A
	Change Strategies	Student Questionnaire; Modified PACE + scale, 9 items	Girl	Grades 6, 8A
	Enjoyment of Physical Activity	Student Questionnaire; Adapted PACES scale, 7 items	Girl	Grades 6, 8A
	Enjoyment of Physical Education	Student Questionnaire; Motl et al. scale, 1 item	Girl	Grades 6, 8A
	Perceived Benefits and Barriers	Student Questionnaire; Modified Amherst scale and Attitude Questionnaire, 19 items	Girl	Grades 6, 8A
	Social Support	Student Questionnaire; Modified Amherst scale, 9 items	Girl	Grades 6, 8A
	Perceived Environment & Recreational Facilities	Student Questionnaire; Modified Amherst scale; 24 items	Girl	Grades 6, 8A
	School Climate for Physical Activity	Student Questionnaire; New scale, 6 items	Girl	Grades 6, 8A
Moderator	Body Composition	Height, Weight, and Triceps Skinfold	Girl	Grades 6, 8A, 8B (ht & wt only)
	Sports/Activity Participation History	Student Questionnaire; 33 items	Girl	Grades 6, 8A
	Home Alone	Student Questionnaire; 2 items	Girl	Grades 6, 8A
	Transportation	Student Questionnaire; 3 items	Girl	Grades 6, 8A
	Ethnicity	Student Questionnaire; 1 item	Girl	Grades 6, 8A, 8B
	Address	Consent form	Girl	Grades 6, 8A, 8B
	Socio-Economic Status	Student Questionnaire of Parent Employment, Parent Education, Household Structure, and Reduced/Free Lunch; 4 items	Girl	Grades 6, 8A, 8B
	Ethnicity	Reported by Schools/ Public archives	School	Grades 6, 8A, 8B
	Address – School and Community Partners	Reported by Schools/ Community Agencies	School	Grades 6, 8A, 8B
	School Socio-Economic Status	% free/reduced price lunch reported by Schools/ Public archives	School	Grades 6, 8A, 8B

Variable Type	Variable(s)	Method	Level	Times Measured
Descriptor	Age	Consent Form, Date of Birth	Girl	Grades 6, 8A, 8B
	Grade	Student Questionnaire	Girl	Grades 6, 8A, 8B
	School Enrollment	Student Questionnaire	Girl	Grades 8A, 8B
	PE Enrollment	Student Questionnaire	Girl	Grades 8A, 8B

9.2. PRIMARY OUTCOME – Physical activity assessed by accelerometry

9.2.1 Background and rationale

The primary outcome variable of the TAAG study is moderate to vigorous physical activity (MVPA). This variable is operationally defined as intensity-weighted minutes of physical activity above the threshold for moderate intensity (expressed per day). It is measured using the Computer Sciences and Applications (CSA) uniaxial accelerometer. The CSA accelerometer is a small, electro-mechanical device that records acceleration and deceleration of movement. The CSA records these accelerations and decelerations, time of day, and activity counts, and provides data for different intensities of physical activity. Because monitors do not rely on self-report, they provide an objective measure of physical activity.

The CSA monitor has been used in several studies to assess physical activity in children (Janz, 1994; Janz, 1995; Trost, 1998; Trost, 2000). Reliability reflects the stability of a measure over time, and is affected by the measurement error of the instrument as well as real (day-to-day, week-to-week) variation in physical activity. Taking multiple days of CSA measurements and averaging them has been reported to increase reliability from r=0.42-0.47 for one monitored day to r>0.7 when four or more days of monitoring are used (Janz, 1995; Trost, 2000). In children and adolescents, Janz (Janz, 1994) examined reliability of the CSA by looking at the stability within three days of measurement. Correlations between days for counts/min ranged from r=0.32 to 0.53 (Janz, 1994). In the same children, the correlation between average heart rate and average activity counts (across three days) was r=0.57; the correlation between average heart rate and average time spent above activity count threshold selected to represent the lower end of moderate to vigorous physical activity was r=0.64. A high correlation (r=0.86 and r=0.87) between activity counts from two CSA monitors (worn on each hip) and energy expenditure measured by calorimetry while the children walked at different speeds on a treadmill has also been reported (Trost, 1998).

Prior to using the CSA monitor as the basis for measurement of the primary outcome variable, it was essential to calibrate the device against a criterion measure of physical activity. Some previous studies have established calibration factors for the CSA monitor; these factors allow a conversion of raw CSA accelerometer counts to an expression of physical activity intensity such as VO_2 (oxygen consumption) or METS

(measure of energy expenditure). However, few of these studies used VO_2 as the criterion measure or included a large, representative sample of middle-school girls. The TAAG Calibration Substudy was conducted with 75 girls to examine the relationship between counts and a recognized unit of physical activity intensity (i.e., VO_2) and to identify a CSA cut-point for defining the primary outcome variable for TAAG. In the calibration substudy, CSA counts were calibrated against VO_2 during many activities, ranging from rest to running. The CSA threshold of 1500 counts/half-minute for the lower end of the moderate intensity range in middle school girls was established from this substudy.

The CSA Variance Components Substudy was conducted with 448 girls and was designed to estimate the components of variance for CSA measures of physical activity (averaged over all days of monitoring) for schools and for residual error. These variance components were necessary for computation of the intraclass correlation that was essential to define the sample size for the TAAG main trial. An additional objective was to measure inter-individual variation and individual day-to-day variability in order to determine the optimal and feasible number of days needed for data collection. Both of these substudies have an impact on data analysis for the CSA measures, as well as the sample size/power for the TAAG main trial. Data analysis information is included in section 14.

9.2.2 Objective

To determine if the TAAG intervention affects MVPA as the primary outcome variable.

9.2.3 Methods

The CSA measure requires six or seven study days (at the discretion of the site) and two school visits for each participant. Each girl wears the monitor for six or seven complete days, except at night while sleeping or during any water activity (e.g., bathing, swimming). Girls may receive a reminder phone call during the monitoring period to make sure that they are wearing the monitor and to answer any questions.

9.3. SECONDARY OUTCOME VARIABLES

Introduction

Secondary outcomes in TAAG are either targeted or non-targeted. A targeted secondary outcome includes all measures of physical activity other than the primary outcome (e.g., self-reported physical activity, direct observation of physical activity during physical education class). A targeted environmental secondary outcome is change in the organizational policy, physical or social environment – in schools, community agencies, and/or other community settings – that is targeted by the intervention and is related to supporting or promoting physical activity. Environment refers to the physical environment (i.e., the built environment); the social environment (e.g., of girls, of schools, of families); the organizational environment (e.g., of schools, communities, community agencies); or the policy environment (e.g., of schools and school districts, community agencies, communities, etc.). Environmental outcomes are presented in section 10. A non-targeted secondary outcome is a variable that is not targeted by the intervention, but may be changed by some exposure to the intervention

or changed by the primary outcome (e.g., school achievement, body composition, cardiorespiratory fitness).

9.3.1. Cardiorespiratory fitness

Background and rationale

Maximal oxygen uptake (VO_2max) indicates the functional capacity of cardiorespiratory function and is often considered as the benchmark indicator of cardiorespiratory fitness (McArdle, 1996). In addition to evaluating functional capacity, VO_2max can be used to prescribe endurance exercise and monitor physical training adaptations. Low VO_2max relative to mass has been observed in obese children and youth (Sothern, 2000; Loftin, 2001). Also, youth with low VO_2max values have been found to have higher than normal blood pressure and elevated insulin (McMurray, 1999; McMurray, 2000). Thus, VO_2max reflects many aspects of physiologic function and performance in children and youth.

Direct measurement of VO_2max is not feasible in large-scale, field-based studies; therefore, predictive tests are often used to assess indirectly aerobic power in children and youth. The cycle ergometry physical work capacity (PWC) test has often been used to test this population (Boreham, 1990; Corbin, 1972; McMurray, 1998; Pate, 1999; Trost, 1996; Vaccaro, 1978). In this procedure, estimates of power output at a heart rate of 170 bpm is either absolute (watts) or weight-relative units (watts/kg body weight or watts/kg fat free mass). PWC-170 (watts/kg body weight) is known to be significantly related to VO_2max (ml/kg body weight/min)

Objective

The objective of the PWC 170 test is to determine if the TAAG intervention affects cardiorespiratory fitness.

Methods

PWC at a heart rate of 170 bpm is predicted from a multi-stage cycle ergometry test. Each participant will exercise on a mechanically-braked Monark cycle ergometer. The girls pedal at 60 rpm for three, two-minute stages at progressively increasing workloads, depending on the girls' heart rate response at the end of the previous stage. Heart rate is measured by a Polar heart rate monitor. The protocol is designed to elicit heart rates in the range of 160 bpm during the final stage. Heart rates measured during the three stages are used to extrapolate to the power output at a heart rate of 170 bpm. This power output (watts) is reported in absolute (watts) and relative units (watts/mass or watts/fat free mass).

9.3.2. Body composition

Background and rationale

Measures of body size and composition can be used to follow the physical growth of girls, to assess the effects of an intervention on body composition, and to interpret changes in fitness. BMI reflects body size and is a weight (kg):height (m^2) ratio that is often used as an indicator for body composition. Body composition is measured by any of several methods that determine fat mass (e.g., dual energy x-ray absorptiometry, skinfolds, bioelectric impedance analysis). Once fat mass is determined, fat free mass and percent fat can be calculated.

The TAAG Body Composition substudy was designed to validate and compare field methods for body composition assessment against dual energy x-ray absorptiometry (DXA). Height, weight, bioelectrical impedance parameters (resistance and reactance), and triceps and calf skinfolds were measured in 172 adolescent girls. Criterion measures of percent fat and fat free mass were obtained by DXA. A multiethnic sample, which included African-American (n=58), non-Black Hispanic (n=40), non-Hispanic White (n=59), and mixed race/ethnicity (n=15) girls in 6th and 8th grades, was recruited from schools at three TAAG Field Centers (San Diego State University, Tulane University, and The University of Arizona). The main aim was to develop an approach to measuring body composition that was feasible and accurate for adolescent girls of diverse race and ethnicity. The feasibility and accuracy of two impedance analyzers (RJL Systems, Detroit, MI and American Weights Body Composition Scale, San Diego, CA) were also evaluated, since the standing protocol used with the Body Composition Scale was potentially more efficient than the lying supine protocol used with the RJL Systems analyzer.

Although BIA and skinfolds have been shown to give valid estimates of body composition in girls (Heyward, 1996; Houtkooper, 1989; Houtkooper, 1992; Slaughter, 1988), no study had previously tested whether ethnic specific equations for estimation of fat free mass were needed, or whether a single equation would give equally valid results for all groups participating in TAAG. In our prediction equations we found the intercepts were different in African American girls versus non-African American girls and an equation that included an ethnicity contrast gave the most accurate (lowest root mean square error) estimate of fat free mass. Equations that included ethnicity, age, height, weight and either BIA or a skinfold gave more accurate predictions compared to BMI.

Almost identical estimates of body composition (percent fat and fat free mass) were obtained when either BIA or a skinfold was included in the equation. Also, estimates of percent fat that used one skinfold site proved as good as estimates based on two skinfolds (triceps and calf). The triceps site is accessible without disrobing, and limits touching to the posterior upper arm, making it acceptable in schools. Based on these results and considerations of cost, acceptability, and school and participant burden, the decision was made to estimate body composition in TAAG girls from an equation that includes ethnicity, age, height, weight and triceps skinfold thickness measurements. Our prediction equation predicts percent fat (PF) with an R^2 of 0.91 and a root mean square error of 2.1.

Objectives

To provide accurate measures of fat-free mass and percent fat for the purposes of:

1. Determining if the TAAG intervention affects body composition;
2. Providing for expression of a measure of cardiorespiratory fitness relative to fat-free mass.

Methods

Body composition will be assessed in the same girls selected for CSA measurements at baseline and endpoint. Measures include assessments of age, weight, height and triceps skinfold, as required for the prediction equation. Age is calculated from the child's birth date and the date of the survey. Weight is assessed by use of a balance beam scale. Height is assessed using a fixed rule attached to a Shorr measuring board vertical surface. Triceps skinfold thickness is measured with Lange calipers. percent fat will be estimated using equation #1, developed for this study, and fat free mass will be calculated from percent fat and body weight:

Equation 1.

$$PF = 1.09617(BMI) + 2.01320(Triskf) – 0.03740(Triskf^2) – 0.37363(age) – 2.96995(race/ethnicity\ contrast) – 11.57041$$

Where BMI = body mass index ($kg \cdot m^{-2}$), Triskf = triceps skinfold, $Triskf^2$ = square of triceps skinfold, and race/ethnicity contrast = African American girls versus non-African American girls

9.3.3. Types and contexts of physical activity

Background and rationale

Physical activity is a complex behavior that can be examined in a variety of ways. It is typically characterized by type, intensity, frequency, and duration, but can also be characterized by the context in which it occurs. While objective information is available from the CSA to assess the intensity, frequency, and duration of activity performed, information is also needed on the type of physical activity that is performed and the context in which it is performed. The inclusion of a self-report measure of physical activity enables a full interpretation the ways in which the intervention influences activity behavior.

The Physical Activity Self-Report Substudy (PASR) was designed to compare the reliability and validity of two physical activity recall instruments. Both instruments were designed for a three-day recall. Participants were 197 sixth and eighth grade girls from all six of the Field Centers. Results indicated that the Three Day Physical Activity Recall instrument was more reliable and valid than the Three day self-administered checklist for assessing physical activity.

Objectives

To measure types and contexts of physical activity for the purposes of:

1. Determining if the intervention influences participation in specific physical activities and sedentary behaviors.
2. Quantifying participation in the activities that are not assessed accurately by the CSA (e.g., cycling) or are performed when the monitor cannot be worn (e.g., swimming).

Methods

The self-report instrument is administered in a group setting during one class period using a paper and pencil format. Students recall their past physical activity behavior from each of the three previous days, beginning with the most recent day. To help students recall their activities more accurately, each day is segmented into 34, 30-minute time blocks from 7:00 a.m. until 12:00 a.m. (midnight). These blocks are also grouped into broader time periods such as before school, during school, lunchtime, etc. The instrument provides a numbered list of commonly performed activities grouped into categories such as eating, work, after-school, physical activities, etc.

For each 30-minute time block, girls are instructed to record the number corresponding to the main activity they performed during that time interval (provides type of activity). They are also asked to rate the relative intensity of the activity as light, moderate, hard, or very hard. The instrument includes pictures to help students determine intensity. Further, there are two columns for describing where and with whom any physical activities occur (provides context of physical activity). Numeric codes are also used for the where and with whom columns.

9.3.4. School achievement

Background and rationale

Indicators of school achievement are of great importance to school administrators and teachers. A common barrier to recruitment of schools for intervention trials is a concern that intervention activities will compete with academic instruction time, to the detriment of students' learning and performance. It is hypothesized that the TAAG intervention will not have a strong measurable effect on school achievement.

Little information exists in the literature concerning the effect on school achievement of expanding/enhancing school-based physical activity programs. In a review of school health programs, Symons et al. (Symons, 1997) cited a small number of reports suggesting that student physical activity was associated with improved academic achievement, but the data sources were school districts or administrators rather than scientific studies. Other evidence is mixed. For example, Pate et al. found positive correlations while Daley and Ryan found either no association or weak negative correlations for young adolescent (Pate, 1996; Daley, 2000). Most studies have been cross-sectional, and have looked at individual students' self-reported participation in physical activity rather than school physical activity programming.

Objectives

To measure school achievement for the purpose of determining whether changes in school achievement or performance are a secondary outcome of the intervention.

Methods

School-level mean standardized test scores, stratified by grade and sex, are collected for all three of the time points (grades 6, 8A, and 8B) during Year 6 to assess the impact of the intervention. School-level data on mean achievement test scores, stratified by grade and sex, are obtained. The data are collected by the Field Centers in a manner that is feasible and acceptable to the schools. At some Field Centers, the data are

available through state or local government databases; other Field Centers request the data from school districts or individual schools. Standardized achievement tests vary across the Field Centers; therefore, percentiles are requested along with mean raw scores to facilitate comparisons.

9.3.5. Smoking initiation

Background and rationale

More than 4700 adolescents experiment with cigarettes for the first time each day and close to 3000 youth become established smokers daily. (Gilpin EA, 1999) Nationally, 12.8% of middle school students are current smokers (CDC, 2000). Adolescent smoking rates among girls have now caught up with rates for boys, and non-Hispanic white female adolescents smoke at higher rates than Hispanic or African American adolescents (Anderson C, 2000).

A few studies show relationships between smoking and other health behaviors, including physical activity. For girls, the factors are primarily related to weight control behavior. Dieting, weight concerns and weight control behaviors have recently been linked prospectively to smoking initiation in adolescent girls (Klesges 1997, Camp 1993, Tomeo, 1999; Austin, 2001). Research among adults has shown that physical activity may be helpful in quitting smoking (Emmons, 1994); however little is known about the relationship between physical activity and smoking in *adolescent girls*. Only one study investigated the prospective relationship between physical activity and smoking in adolescent girls. This study showed that the most active (leisure-time physical activity) or most fit (levels of aerobic fitness) adolescent girls were less likely to initiate smoking over 3-years in a population based cohort (n=1245) aged 12-16 (Aaron, 1995). A cross-sectional study of male and female high school students found that students who had participated in interscholastic sports were less likely to be regular and heavy smokers than were others who had not participated. (Escobedo, 1993). No study to our knowledge has investigated whether increasing physical activity among girls will be related to decreased likelihood of smoking initiation.

Objective

The objective of the smoking measures is to answer the following three research questions:

1. Are TAAG girls less likely to initiate smoking compared to control girls?
2. Is smoking initiation delayed as a result of the TAAG intervention?
3. Is smoking initiation associated with moderate/vigorous PA, participation in after school activities, and outside school activities?

Methods

All students enrolled, and with permission slips, in the sixth grade in the participating schools during the fall, 2002 will participate in the baseline survey. Smoking measurements will be included in the TAAG Baseline Questionnaire that is administered during the fall semester of sixth grade. Post-intervention assessments of smoking will be conducted in the spring semester of the 8th grade year (spring, 2005). All girls participating in the baseline measurement will be re-measured at this time.

The proposed smoking behavior questions are commonly used by tobacco control researchers and are currently used in two large-scale national surveys, the National Youth Tobacco Survey (YTS) and the National Youth Risk Behavioral Survey (NYRBS). The NYTS is asked of students in grade 6-8 and 9-12, and the NYRBS is asked of students in grades 9-12. The tobacco questions are now identical on the YTS and YRBS. Six items are proposed to establish current smoking status (ever smoking, amount smoked in lifetime), frequency of smoking, quantity smoked, age of initiation, and smoking for weight control.

9.3.6. Physical activity in physical education classes

Background and rationale

Enhanced girl-oriented physical education (PE) is a central component of TAAG. One important element of TAAG physical education is the objective of optimizing the girls' participation in MVPA during classes. Accordingly, measurement of physical activity in PE is needed to fully evaluate the effects of the TAAG intervention.

The measure of physical activity in PE is one component of the System for Observing Fitness Instruction Time (SOFIT). SOFIT is an objective tool for assessing the quality of physical education instruction (McKenzie, 1992). It is a comprehensive system that provides a measure of student activity levels, lesson context, and teacher behavior during class time. SOFIT was selected because direct observation allows for an evaluation of multiple variables of interest for both outcome measurement and process evaluation purposes. Direct observation is considered an objective measure when inter-observer agreement is high.

SOFIT involves the direct observation of lessons by trained observers and has been used to assess physical education in over 1000 schools throughout the United States. These include the schools that participated in CATCH (McKenzie, 1994a; McKenzie, 1995; McKenzie, 1996; McKenzie, 2001), M-SPAN (McKenzie, 2000a), and SPARK (McKenzie, 1997; Sallis, 1997a), three intervention studies supported by the National Institutes of Health. It is also being used to study the physical education experiences of over 1000 children in a NICHD longitudinal study.

SOFIT student physical activity codes have been by validated heart rate monitors (McKenzie, 1992; Rowe, 1997; Pope, 2000) and accelerometers (Pope, 2000; McKenzie,1994b). Lesson context and teacher behavior categories have been developed from definitions used commonly in physical education evaluation research (Siedentop, 2001).

Reliabilities for observations by trained independent observers have typically exceeded 90% agreement on all SOFIT categories, which indicate that the measures can be used accurately in diverse school environments (McKenzie, 1992; McKenzie, 1997; McKenzie, 1995; Sallis, 1997a; McKenzie, 2000a). Intraclass correlations in middle school classes were 0.97, 0.99, and 0.97 for estimates of Energy Expenditure Rate,

Total Energy Expenditure, and proportion of time students were engaged in MVPA, respectively (McKenzie, 2000a).

Objective

To measure girl physical activity levels during PE classes for the purpose of determining if the TAAG intervention affects moderate to vigorous physical activity in girls attending PE classes.

Methods

As children enter the physical education setting, observers record the time and randomly select four girls whose activity levels are coded. The activity level of an observed child is recorded every 20 seconds for four consecutive minutes. During the next four minutes a second student is observed; this rotation continues until the lesson is over. Observers are paced by a tape recorder, and data are entered on Scantron forms.

Activity codes 1 through 4 describe the body position of the student (lying down, sitting, standing, walking), and code 5 (very active) identifies when the student is expending more energy than during ordinary walking. Coding is based on the observed activity of the individual student at the moment the 10-second observation interval ends (momentary time sampling). Approximately 12% of the lessons are observed by two certified assessors to determine reliability of measures.

Observation Schedule

SOFIT observations are made during visits to each Intervention and Control school on three days during each measurement time period. A minimum of four PE lessons will be observed during each school visit.

9.3.7. Depressive symptoms

Background and rationale

The World Health Organization has projected that by the year 2010 depression will be second only to cardiovascular disease as the world's leading cause of death and disability (Murray, C. 1996). The annual rate of depression among teenagers and young adults in the U.S. is nearly twice that of adults 25-44 years old, and about four times the rate among those over 65 (Kessler, 1994). Moreover, females have twice the prevalence of depression as males at all ages (Weissman, 1996; WHO International Consortium in Psychiatric Epidemiology, 2000). Depression is especially prevalent among girls and women under age 25; they experience twice the rate of depression of boys and men under age 25, and six times the rate of women ages 25 to 54 (Regier, 1988).

Evidence from more than 25 population-based epidemiological studies and nearly 60 intervention studies of adults suggests that participation in physical activity reduces the risk of depression and may be an effective treatment in individuals diagnosed with depressive disorders (Lawlor, 2001; O'Neal, 2002). Though few studies have examined physical activity and depression in adolescents, a quantitative synthesis of five published studies suggests that physical activity might confer a protective effect in this

population as well (Brown, 1992; Brown, 1986; Garrison, 1993; Keats, 1999; Norris, 1992). Further research is needed to examine the role of exercise in the prevention and treatment of depression in adolescents.

Preliminary data from Teens Eating for Energy and Nutrition at School (TEENS), a nutrition intervention study in middle schools, suggest that depressive symptoms in adolescent girls can be validly measured using the Center for Epidemiological Studies Depression Scale (Radloff, 1977). The data also suggest that depressive symptoms are inversely related to leisure-time physical activity (Birnbaum, 2002; Schmitz, 2002). Over 3000 students, half of them female, comprised the ethnically diverse, urban and suburban TEENS cohort, followed from 7th grade through the end of 8th grade. The cohort was surveyed at three time points: Fall 1998, Spring 1999 and Spring 2000. Among females, the mean (sd) Center for Epidemiological Studies Depression Scale scores on the three surveys were 13.76 (10.16), 14.43 (10.91) and 15.57 (11.58), respectively. The median score among females in Fall 1998 and Spring 1999 was 11; the median score in Spring 2000 was 13.

The standard criterion for depressive symptomatology on the Center for Epidemiological Studies Depression Scale is a score of 16 or greater (out of a possible 60 points). Higher cut points (e.g., 22) have been recommended when the Center for Epidemiological Studies Depression Scale is used as a screen for major depressive disorder (MDD), particularly in community-residing adolescent populations (Garrison, 1991a). Using the cutpoint of 16 or higher, the prevalence of elevated depressive symptoms (rather than MDD) in the girls in the TEENS cohort ranged from 34.6% in Fall 1998 to 39.9% in Spring 2000.

Objectives

To measure depressive symptomatology for the purposes of:

1. Determining whether the TAAG intervention confers a protective effect against depressive symptoms in girls as a secondary outcome.
2. Determining whether changes in girls' physical activity levels predict changes in their Center for Epidemiological Studies Depression Scale scores.
3. Examining the types of physical activity that are most strongly related to depressive symptoms.

Methods

The Center for Epidemiological Studies Depression Scale is included as part of the Student Questionnaire. The questionnaire is administered at baseline (Fall 2002) and in the spring semester of the 8th grade year. The instrument includes 20 questions representing major symptoms of depression based on a 4-point Likert scale format indicating that symptoms are present rarely or none of the time (0) to most or all of the time (3).

9.3.8. Total Physical Activity

Background and Rationale

Total physical activity, including light intensity activity in addition to MVPA, because of its influence of total caloric expenditure may be a key determinant of body composition and the overall effect of physical activity on health. Some intervention studies have observed that reduced time spent in sedentary activities has a beneficial effect on body composition despite not influencing MVPA. These findings suggest that an increase in light activity may have important health effects.

Objective

To measure total physical activity for the purpose of determining if the TAAG intervention affects overall participation in physical activity.

Methods

CSA accelerometry as described in 9.2.3.

9.3.9. Physical Activity on Weekdays, Weekends, In-School and Out-of-School

Background and Rationale

Physical activity interventions may influence patterns of physical activity as well as overall participation in physical activity and MVPA. Because the TAAG intervention targets increased physical activity during the school day as well as after-school and on weekends, it is of interest to determine if the intervention alters the pattern of physical activity participation across days of the week and across settings.

Objective

To determine if the TAAG intervention affects physical activity performed on weekdays, weekends, in-school, and out-of-school.

Methods

CSA accelerometry as described in 9.2.3

9.4. Mediating variables

A mediator is defined as a variable that is hypothesized to fall in the causal pathway. Mediators are targeted by the intervention and are expected to change as a result of the intervention's potential influence on MVPA. By specifying mediator variables it will be possible to determine if the intervention changes the mediator and if the change in the mediator is associated with the change in MVPA. Mediators are selected based on the following criteria: 1) consistency of the construct with the TAAG theoretical model; 2) empirical evidence to support inclusion of the construct; 3) confidence that the construct could be adequately measured in 6^{th} and 8^{th} grade girls; 4) analytic strategies utilizing the construct could be specified; 5) innovation; and, 6) potential cost of not measuring the construct would be high.

All mediators in TAAG are part of the Student Questionnaire. Mediation analysis is performed using the cross-sectional samples of girls and a longitudinal sample of girls who provide data on both baseline and follow-up surveys.

9.4.1. Self-efficacy

Background and rationale

Self-efficacy is one of the most frequently studied correlates of physical activity (Sallis, 2000c). True self-efficacy, often referred to as perceived self-efficacy (Bandura, 1997), is defined as "beliefs in one's capabilities to organize and execute the courses of action required to produce given attainments." However, in familiar activities that must be performed regularly to achieve desired results, Bandura suggests that self-regulatory efficacy becomes more salient (Bandura, 1997). This type of efficacy is often operationalized as "barriers efficacy" or the confidence a person has in overcoming barriers to changing his or her behavior. Helping girls overcome barriers to being physically active is a major component of the TAAG intervention. Because self-efficacy will be specifically targeted in the intervention, there is a strong rationale for assessing it.

Self-efficacy is assessed in TAAG with a version of a previously validated scale (Saunders, 1997). A recent study evaluated the factorial validity of the scale with structural equation modeling (Motl, 2000). The study provided evidence that use of the entire original set of 15 items may not be appropriate for children/adolescents of all ages, but a subset of eight items produced a reasonable fit in eighth grade girls. Covariance modeling was used to test theoretically-based relationships among latent variables (unpublished results). Self-efficacy was related to moderate ($\gamma = .24$) and vigorous physical activity ($\gamma = .20$), and it accounted for the effect of intention on physical activity. The strength and direction of the observed relationships were comparable across black and white adolescent girls. Cronbach's alpha for internal consistency across two cohorts was .78. Test-retest reliability of the scales across a one-year period resulted in an intraclass correlation coefficient (ICC) of .66. For separate samples of 50-100 girls, Cronbach alpha was .81 and the intraclass coefficient across a one-week period was .57.

Objectives

To measure physical activity self-efficacy for the purposes of:

1. Evaluating whether the TAAG intervention is effective in promoting change in self-efficacy.
2. Examining whether self-efficacy mediates the intervention's effects on physical activity.

Methods

Items from the self-efficacy scale are assessed as part of the Student Questionnaire. The original scale contains 15 statements rated on a 5-point Likert scale, anchored by disagree a lot (1) and agree a lot (5). After confirmatory factor analysis was performed in the Student Questionnaire pilot study, eight questions from the original scale remain and are included in the Student Questionnaire. These eight items are the same items found in the Motl et al. analysis.

9.4.2. Change strategies

Background and rationale

Components of the TAAG intervention teach girls to use cognitive and behavioral strategies to adopt and maintain regular physical activity. Use of these strategies is hypothesized to mediate behavior change.

A direct method of assessing this mediator is to inquire about use of the specific cognitive and behavioral strategies that are taught in the educational intervention. In the GRAD study, a study of physical activity promotion in college students, investigators created a simple assessment of each cognitive and behavioral change strategy that was taught in the curriculum. Simple ratings of frequency of use explained small but significant amounts of variance in physical activity at the various post-test and follow-up assessments.(Saelens, 2000) Cognitive and behavioral strategies were highly correlated (r=.60).

In TAAG, cognitive and behavioral change strategies are targeted as part of the health education curriculum. Use of cognitive and behavioral change strategies, as well as changes in these strategies, is measured with an adapted version of a scale previously used with adolescents. (Saelens, 2000)

Objectives

To measure change strategies for the purposes of:

1. Evaluating whether the TAAG intervention is effective in promoting the use of targeted cognitive and behavioral change strategies
2. Examining whether the use of change strategies mediates the intervention's effects on physical activity.

Methods

Girls' self-reported use of targeted cognitive and behavioral change strategies is assessed as part of the Student Questionnaire. The scale contains nine statements rated on a 5-point Likert scale, anchored by never (1) and very often (5).

9.4.3. Enjoyment of physical activity

Background and rationale

Enjoyment can be described as a positive affective state that reflects feelings such as pleasure, liking, and fun (Scanlan, 2000; Wankel, 1993). It can be conceptualized as the perceived reinforcing value of physical activity. Although enjoyment of physical activity has seldom been studied (Sallis, 2000c), some studies have found that enjoyment may be associated with physical activity in youth (Sallis, 2000c; Stucky-Ropp 1993). The Surgeon General's Report on Physical Activity and Health suggested that enjoyment may be the major reason that young people engage in physical activity (U.S. Department of Health and Human Services, 1996).

Enjoyment of physical activity has often been measured using only a single item (Sallis, 2000c; Stucky-Ropp, 1993). Recently the Physical Activity Enjoyment Scale (PACES)

(Kendzeirski, 1991) was modified and examined in 1797 black and white 8th grade girls (Motl, 2001). Results of this study indicated that there is evidence of factorial validity and evidence for construct validity of PACES. Follow-up analyses using structural equation modeling demonstrated that enjoyment mediated the effect of a school-based intervention to increase physical activity in that sample of girls (Dishman, 2002). These findings indicate that the PACES is a valid measure of physical activity enjoyment in adolescent girls and is suitable for use as a mediator variable in interventions designed to increase physical activity.

Objectives

To measure enjoyment of physical activity for the purposes of:

1. Determining whether the TAAG intervention results in a higher enjoyment of physical activity in girls in the intervention schools versus control schools.
2. Determining whether enjoyment of physical activity mediates the effects of the intervention on physical activity of girls.

Methods

Physical Activity Enjoyment items are assessed as part of the Student Questionnaire. The scale contains seven statements rated on a 5-point Likert scale, anchored by disagree a lot (1) and agree a lot (5).

9.4.4. Enjoyment of physical education

Background and rationale

A component of the TAAG intervention will focus on increasing girls' enjoyment of physical education. A measure of factors influencing enjoyment of physical education has been developed for use with black and white adolescent girls (Motl, 2001). Confirmatory factor analysis has demonstrated adequate factorial validity of the scale, and structural equation modeling has shown that scores on the scale influence physical activity enjoyment, as measured by the modified PACES.

Objectives

To measure enjoyment of physical education for the purposes of:

1. Determining whether the TAAG intervention results in a higher enjoyment of physical education among girls in the intervention schools versus control schools
2. Determining whether enjoyment of physical education mediates the effects of the intervention on girls' physical activity.

Methods

The Physical Education Enjoyment instrument is included as part of the Student Questionnaire. The scale contains one statement rated on a 5-point Likert scale, anchored by dislike a lot (1) and enjoy a lot (5).

9.4.5. Perceived benefits and barriers

Background and rationale

Most social learning theories are based on an expectancy-value framework in which behavior is determined largely by expected outcomes and the value placed on them.

This construct is often operationalized as a cost/benefit or barriers/benefits assessment. Perceived benefits of physical activity is a commonly-cited correlate of physical activity in youth (Sallis, 2002). The theoretical framework for TAAG places considerable emphasis on decreasing barriers to physical activity in girls and increasing the perceived benefits in order to increase MVPA. Many components of the intervention are aimed at getting girls to problem solve barriers and consider numerous benefits.

TAAG assesses perceived barriers and benefits with two scales. The barriers scale was adapted from Sallis and colleagues, developed for the Amherst Study. The Amherst study provides some reliability information. The sample was boys and girls (n=60) in grades 6-8, 60% non-white. The test-retest reliability of the barriers scale was r=.90 with an average test interval of 16 days. The Amherst Study scale was adapted for TAAG by a mediators, moderators, and secondary outcomes working group. This group adapted the Amherst scale by deleting items deemed inappropriate for young adolescent girls, adding items addressing barriers identified through formative assessment, and simplifying language to facilitate readability.

The benefits scale was adapted from both the benefits scale from the Amherst Study (Sallis, 2002) and the Attitude Questionnaire (Motl, 2000). For the Attitude Questionnaire, analysis of the factorial validity of the scale with structural equation modeling revealed the original set of 22 items could be reduced to eight (Motl, 2000). Cronbach's alpha for internal consistency across two cohorts was 0.73 and the test-retest intraclass correlation coefficient was 0.64. Values from separate samples of 50-100 girls yielded Cronbach alpha=0.72 and an intraclass correlation coefficient of 0.72 for one-week stability.

Objectives

To measure perceived benefits and barriers for the purposes of:

1. Evaluating whether the TAAG intervention increases the number of perceived benefits and decreases the number of perceived barriers to physical activity
2. Determining if increasing the perceived benefits or decreasing the perceived barriers or both mediates the effects of the intervention on physical activity.

Methods

Girls' self-reported perceived barriers and benefits are assessed as part of the Student Questionnaire. The barriers scale contains 10 statements rated on a 5-point Likert scale, anchored by never (1) and very often (5). The benefits scale contains nine statements for which the participants rate agreement on a 5-point Likert scale, anchored by disagree a lot (1) and agree a lot (5), followed by a rating of importance on a 5-point Likert scale, anchored by very unimportant (1) and very important (5).

9.4.6. Social support

Background and rationale

Social support is a psychosocial construct that has been strongly implicated in health behavior initiation and maintenance. Social support can be defined as "a system by which an individual receives assistance, reinforcement and/or stimuli in daily living

especially when that individual perceives disadvantages or a deficit in resources to meet needs."(Cobb. 1976; Berkman. 1986; Minkler. 1986) Social support, therefore, is a potentially important mediator of increased physical activity in adolescent girls in TAAG and is targeted by several components of the TAAG intervention.

Social support facilitates participation in physical activity. (Taylor, 1999) According to Garcia, et al. (Garcia, 1998) girls report decreased support for physical activity during the transition from elementary school to middle school, as well as decreased levels of physical activity. In the Child and Adolescent Trial for Cardiovascular Health (CATCH), Johnson, et al. (Johnson, 2000) demonstrated that positive social support in third grade predicted levels of moderate to vigorous physical activity (MVPA) in fifth grade and that levels of MVPA in fifth grade predicted positive social support in seventh grade. Some aspects of social support have been consistent correlates of adolescent physical activity, particularly parental support and direct help from parents (e.g., providing transportation) (Sallis, 2000c).

The parent and peer social support scales were initially developed for the Amherst Health and Activity Study (Sallis 2002). Two-week test-retest reliability of the parent scale was strong (intraclass correlation coefficient = 0.88), with parent-child reports correlating significantly (r = 0.61). Cronbach's alpha for internal consistency of the items was 0.77 (Prochaska, 2002). Test-retest reliability for the peer scale was also strong (intraclass correlation coefficient = 0.86), with parent-child reports correlating significantly (r = 0.57). Cronbach's alpha for internal consistency of the items was 0.81 (Prochaska 2002).

Objectives

To measure social support for the purposes of:

1. Estimating girls' perceived social support before and after the intervention.
2. Determining if the TAAG intervention was effective in enhancing girls' perceived social support for physical activity.
3. Determining whether social support mediates the effects of the intervention on physical activity.

Methods

Items from the modified Amherst study scale are assessed as part of the Student Questionnaire. The scale was designed to measure both parent and peer social support in terms of how often study participants receive support during a typical week. The parent scale contains five statements, and the peer scale contains four statements, all rated on a 5-point Likert scale anchored by none (0) and every day (4).

9.4.7. Perceived environment and recreational facilities

Background and rationale

The TAAG Social Ecological model indicates that environmental interventions can have direct effects AND be mediated by individual perceptions. The TAAG intervention may be able to change perceptions of the environment through several means. By providing more girl-friendly activities in community agencies, girls and their parents may learn

about the existence of recreational facilities and use them more often. Exposure to new settings could change knowledge of, and perceptions about, recreational facilities. If girls become more active in their neighborhoods, girls and their parents may perceive them as safer. The intervention could also change the home environment by encouraging girls and parents to acquire or start using activity equipment.

It is important to note that some environmental variables can also be moderators of the intervention's effect. For example, girls with a park or recreation center near their homes could respond better to the intervention than girls without such resources. The intervention will not change the actual location of these resources, so they are true moderators.

This is a new area of measurement in the physical activity field. The items we propose came from three main sources, with modifications specific to the TAAG population. The first source is the Amherst Reliability Study, which was conducted in Houston, TX by Wendell Taylor using a take-home questionnaire (personal communication). The average interval between tests was 16 days. The sample (n=60) was from grades 6-8, and 60% were non-white. An index of student-reported environmental variables had a reliability of r=0.92. The parent-reported environmental variables had these reliabilities: neighborhood safety (r=0.86), access to parks/gyms (r=0.77), park distance (r=0.70), and park use frequency (r=0.68). The second source is a modification of questions used in a study which examined distance between home and exercise facilities among San Diego adults (Sallis, 1990). The third source is the Survey of Neighborhood, Life Satisfaction, and Physical Activity (NLS and PA), which is a survey currently under development by Sallis.

Objectives

To assess perceived environment for the purposes of:

1. Determining if perception of the physical activity environment is related to baseline physical activity participation.
2. Determining if perceived physical activity environment mediates the effects of the intervention on physical activity.
3. Determining if proximity of recreational facilities moderates the effects of the intervention on physical activity.

Methods

Girls' perceived environment and recreational facilities are assessed as part of the Student Questionnaire. Questions are framed in two ways. One set of 10 questions addresses neighborhood characteristics on a 5-point Likert scale from disagree a lot (1) to agree a lot (5). The other set of questions, answered by Yes or No, addresses if girls think it is easy to get to and from different types of physical activity resources (facilities).

9.4.8. School climate for physical activity

Background and rationale

Because girls spend a considerable amount of time at school, the potential effect of school climate on girls' physical activity is great. Creating a school climate that supports

physical activity may be one of the mechanisms by which the TAAG intervention affects MVPA. School climate for girls' physical activity may be important as both a secondary outcome of the environmental interventions and a potential mediator of the effect of TAAG interventions on the final outcome. The distinction between using the school climate as a mediator or a secondary outcome will be made at the time of analysis, depending on the focus of the research question and model(s) of interest. Although data on school climate could be collected on a variety of levels and from a wide range of sources, TAAG data collection for this variable will focus on measuring girls' perceptions and obtaining school-level data from process evaluation measures.

A literature review yielded no publications of school climate measures specific to physical activity. The School Health Index for Physical Activity and Healthy Eating Module #1 (Centers for Disease Control and Prevention, 2000a) has some relevant items, as does the Physical Education Program Improvement and Self-Study (NASPE Middle and Secondary School Physical Education Council, 1998). However, neither is appropriate for use on a student survey. Several general school climate measures were identified, and one study examined the relationship between general school climate and students' self-reported physical activity in 115 Australian schools and found no association (McLellan, 1999). It is unlikely that TAAG will intervene on or affect general school climate. For all these reasons, we developed a new instrument to assess girls' perceptions of the quality of the school climate specifically related to girls' physical activity.

Objectives

To assess school climate for the purposes of:

1. Determining if the TAAG intervention affects the extent to which girls perceive that the school climate supports girls' physical activity.
2. Determining if the school physical activity climate mediates the effect of the intervention on physical activity.

Methods

School climate is assessed as part of the Student Questionnaire. Based on items suggested in the School Health Index and the PE Program Improvement and Self-Study Guide, as well as formative assessment with the target population, we developed an original scale to assess girls' perceptions of the school climate. The six items are based on a 5-point Likert scale from disagree a lot (1) to agree a lot (5).

9.5. Moderating variables

For the purpose of the TAAG study, a moderating variable is defined as a variable that is not targeted by the intervention and, in most cases, is not expected to change during the course of the study. Moderating variables are included in this study because they could influence the primary or secondary outcomes and/or interact with the intervention to change study outcomes. These variables are evaluated at both self-report study periods, and some of them will be evaluated again at the second 8th grade year. It is recognized that there may not be adequate statistical power to assess some of these

variables as true moderators. However, they are still classified as moderators in order to maintain fidelity to the TAAG conceptual model.

9.5.1. Body composition

Body composition will be examined as a moderating variable. See section 9.3.2. for a description of the measurement of body composition.

9.5.2. Sports/activity participation history

Background and rationale

Previous exposure to physical activity programs is a consistent correlate of physical activity behavior in both children and adolescents (Sallis, 2000c). Because previous exposure cannot be controlled, it is possible that sports and activity history can serve as a moderator of the TAAG intervention. Within TAAG, we hypothesize that girls who were highly active in the recent past may be more likely to respond to the TAAG intervention than girls with a more sedentary history. Because this is a potentially important construct that can help to explain intervention outcomes, there is strong rationale for including this measure in the TAAG protocol.

Quantifying previous sports participation is challenging because it is difficult to capture the accumulated exposure to sports over time. Baseline physical activity at the start of TAAG would be an imprecise indicator of activity history, because it will be a sample of one week (or less) in one season of the year. Sports team and activity class participation in the past year provides a better indicator of activity history. Asking for recall of longer periods of time is likely to reduce measurement quality and produce a very high baseline.

Objective

To measure sports participation for the purpose of determining if previous or current physical activity participation moderates the effects of the TAAG intervention.

Methods

Sports participation is assessed as part of the Student Questionnaire. Two questions, including 33 total item choices, representing a one-year recall are included.

9.5.3. Home alone

Background and rationale

Many students of middle school age spend some amount of time in the evening after school home alone before parents return from work or other activities. It has not been definitively determined if this situation has any impact on the physical activity levels of girls.

Objective

To measure frequency of being home alone for the purpose of determining if it moderates the effects of the TAAG intervention.

Methods

Home Alone is assessed as part of the Student Questionnaire. Two questions are used to determine the frequency of days during the week and hours during the day in which a

participant takes care of herself in the afternoon or evening without an adult being there. Choices range from (a) zero days a week to (f) five days a week, and from (a) zero hours a day to (f) five or more hours a day.

9.5.4. Transportation

Background and rationale

Lack of transportation to and from physical activity events may be a barrier to participation in those activities.

Objective

To assess girls' transportation to and from physical activity events for the purpose of determining if it moderates the effects of the TAAG intervention.

Methods

Transportation is assessed as part of the Student Questionnaire. Three questions assess girls' difficulty level in obtaining transportation home from after-school activities at school, to after-school activities in a location other than school, and home from after-school activities from a location other than school. Responses are made on a 4-point Likert scale ranging from (1) not at all difficult to (4) impossible.

9.5.5. Ethnicity

Background and rationale

Ethnicity will be measured in order to characterize the participants but also to determine if ethnicity is a moderating influence on the physical activity levels of middle school girls.

Objective

To assess ethnicity for the purpose of determining if it moderates the effects of the TAAG intervention.

Methods

Girl-level ethnicity: As part of the Student Questionnaire, girls identify their ethnicity on a checklist which includes (1) Caucasian (White, non-Hispanic), (2) Black, (3) Hispanic, (4) Asian/Pacific Islander, (5) American Indian, and (6) Other. Girls also identify their ethnicity in the spring semester of the second 8th grade year. Participants are asked to check as many categories as apply.

School-level ethnicity: TAAG measurement staff members work with school staff members to determine the percentage of girls in each race/ethnic group (listed above) in each school.

9.5.6. Address

Background and rationale

The measurement of demographic variables will be necessary for describing study participants and organizations. Address will provide basic descriptive information.

Objective

Address will be recorded in order to characterize the participants but also to determine if it is a moderating (environmental) influence on the physical activity levels of middle school girls.

Methods

Girl-level address: Parents/guardians are asked to provide their daughter's home address on the informed consent form.

School- and community organization-level address: Each TAAG Field Center obtains addresses from schools and community partners.

9.5.7. Socioeconomic status

Background and rationale

Comprehensive reviews of determinants of physical activity in children and adolescents consistently demonstrate an association between socioeconomic indicators and physical activity or physical inactivity. Socio-economic status variables are necessary for describing schools (measured at the school level) and study participants in TAAG (measured at the girl level).

Regarding girl-level measurement, an socio-economic status index created by combining items from the proposed four questions was found to have a test-retest reliability coefficient of 0.80 in middle school children in the TEENS study.

Responses to each of the proposed four socio-economic status questions have been reported to be associated with physical activity and/or sedentary leisure habits in middle school children from the TEENS study (Schmitz, 2002). There is also unpublished evidence of agreement of answers given by students and their parents regarding parental employment and education from the TEENS study. The weighted Kappa statistic for agreement between student and parent for education and employment variables include:

Variable	Weighted Kappa
Mom's education	0.56
Mom's employment	0.72
Dad's education	0.70
Dad's employment	0.70

Objective

To measure socio-economic status indicators in TAAG participants and participating TAAG schools for the purpose of determining if socio-economic status moderates the effects of the TAAG intervention.

Methods

Girl-level socio-economic status: Four questions are included in the Student Questionnaire. Parent employment, parent education, household structure, and reduced/free lunch are assessed by the four questions.

School-level socio-economic status: A TAAG measurement staff member works with school staff to determine the percentage of girls in each school within each of the race/ethnic groups described in section 9.6.5 that receive a free/reduced price lunch. The specific protocol to be used for this data collection procedure is included in the Manual of Operations.

9.6. Descriptive variables

9.6.1. Age and grade

Background and rationale

Documentation of age and grade will be necessary for describing study participants.

Objectives

To assess age, grade, PE class enrollment, and duration of enrollment at the TAAG school for the purpose of describing the sample.

Methods

Age is reported in the consent form. Grade is assessed as part of the Student Questionnaire. They are also assessed during the second 8th grade year. The age question presents a space for date of birth to be written. PE class and school enrollment are assessed as part of the Student Questionnaire. The two PE class enrollment questions, answered by Yes or No, address when the girl took PE. The school enrollment question asks the girl to identify the grade at which she started attending her current middle school.

9.7. Measurement logistics

9.7.1. Measurement timeline

Key Activities	Start	Finish
Baseline – 6th grade measurement training	11/02	11/02
Subject Recruitment – 6th grade	10/02	2/03
Baseline – 6th grade measurements (6)	1/03	3/03
Data entry/transfer – 6th grade	1/03	4/03
Endpoint – 8th grade measurement training	1/05	1/05
Subject Recruitment – 8th grade endpoint	9/04	3/05
Endpoint – 8th grade measurements (8A)	1/05	4/05
Data entry/transfer – 8th grade endpoint	1/05	4/05
Follow-up – 8th grade measurement training	1/06	1/06
Subject Recruitment – 8th grade follow-up	9/05	3/06
Follow-up – 8th grade measurements (8B)	1/06	4/06
Data entry/transfer – 8th grade follow-up	1/06	4/06

10. ENVIRONMENTAL OUTCOMES, AND DESCRIPTORS

10.1. Introduction

Changing the environment is one of the goals of TAAG, as suggested in the TAAG Social Ecological Model. Environmental outcomes are variables that assess the impact of the intervention on physical activity-related organizational, policy, physical or social environments targeted by the intervention. The environmental outcomes assessed in TAAG are those addressed by the Specific Aims (Section 3) and include: structure of physical education class, physical activity programming in schools and school-community partnerships. These are organizational level outcomes and are consistent with the TAAG intervention. TAAG also assesses environmental variables used to explain the contextual backdrop from which the trial operates.

10.2. Environmental outcomes

10.2.1. Physical education class structure

The provision of a class structure that allows girls to enhance their learning and participation in PE is a central component of TAAG. The SOFIT direct observation instrument, previously described (Section 9), is an objective tool for the assessment of the quality of physical education instruction (McKenzie 1992) as well as a measure of girl activity levels. Activity levels in girls are described in section 9 as a secondary outcome. Here we focus on the part of SOFIT that provides assessments of the context in which a PE lesson is conducted. Observers determine if the class time is allocated for general content (e.g., management) or for actual subject matter content (i.e., physical education). If physical education content occurred, it is then coded as knowledge (general knowledge or fitness knowledge) or motor (physical activity) content. The instrument is in the process of being revised so that key concepts relevant to TAAG (e.g., equitable gender opportunities, choice, student/equipment ratio) are also assessed. It is administered in grade 6, at time of the endpoint measure in spring of 2005 (8A) and at the follow-up assessment in the spring of 2006 (8B). Reliability of the revised instrument is determined in Fall, 2002.

10.2.2. School physical activity programs

The TAAG intervention promotes a variety of physical activities, including those that may not be TAAG-sponsored. In order to assess the density of physical activity programs in intervention compared with control schools, the number, type, and participation of girls in physical activity programs offered on the school site are documented. An interview/survey is conducted with school sponsors of physical activity programs that are conducted at the school site. Each sponsor is queried on the length of the program, frequency of the program (per week), number of weeks, number of minutes per session, and the approximate number of girls who attended the program. This information is collected annually (in grades 6, 7, 8A, and 8B). Reliability and validity of the survey is determined from pilot testing conducted in Fall, 2002.

10.2.3. School-community physical activity partnerships

Development of a partnership process to involve community agencies and other community members to provide activity programming to girls is the most innovative component of the TAAG intervention. Thus, an important TAAG outcome is the existence of physical activity-related partnership relationships between schools and communities. To assess the richness of these partnerships, interviews will be conducted with intervention and control schools principals and other appropriate school and community personnel involved in physical activity partnerships. The purpose of these interviews is to determine the density of the school-community relationships. Interviews are conducted in grade 6, 8A, and 8B. The development of the interview script is in progress.

10.3. Environmental Descriptors

School physical activity-related policies may change as a result of the intervention. A structured interview with the school principal or designee is conducted during grades 6, 7, 8A, and 8B to assess current school physical activity-related policies. These include: frequency and duration of PE class schedules, school offerings of intramural and interscholastic sports, activity bus availability, student access to physical activity facilities before, during, and after school, and walk and bicycle to school policies.

Additional environmental descriptors can be viewed as contextual factors that explain the environment in which the intervention is conducted. District curriculum requirements for PE and health education are documented from district records and from a yearly principal survey. Teacher turnover, teaching experience, non-TAAG physical activity training, class size, and gender composition of classes relevant to TAAG are assessed from the same principal (or designee) survey described in the previous paragraph.

11. PROCESS EVALUATION

11.1. Background and rationale

Process evaluation assesses factors that determine whether the intervention was delivered and received as intended. Assessing the extent to which the intervention was implemented as planned is paramount to evaluating trial goals. Process evaluation offers the potential to monitor and assure quality of intervention implementation, and provides information on the depth and breadth of program implementation, contamination of the control group, and secular trends. If primary outcomes are not achieved, process evaluation data can provide information on the extent to which the intervention was implemented as intended, whether the target group actually participated in the intervention, and whether there were other similar programmatic efforts occurring in the environment that dampened the intervention effects.

Process evaluation for TAAG takes a broad approach. It assesses fidelity of intervention delivery (i.e., extent to which the intervention was delivered as intended), the intervention dose (i.e., amount of intervention provided), and reach to the groups targeted by the intervention (i.e., extent to which the intervention was received by the target group) (Baranowski, 2000). By monitoring the delivery of key intervention components, process evaluation data can be used to ensure that the intervention is being implemented as planned (i.e., fidelity). The internal validity of the trial is dependent on adequate intervention implementation (Basch, 1985). Monitoring, providing feedback to study investigators, and making appropriate adjustments ensures adequate implementation of the intervention components. Reach provides information on the ability to impact (penetrate) the intervention target groups. Study outcomes will not be achieved without the intervention strategies getting through to the intended targets.

TAAG process evaluation also assesses environmental variables that explain the context in which the intervention was conducted (i.e., environmental descriptors that can affect intervention implementation), and contamination and/or secular trends that may influence the extent to which the control schools received an intervention similar to those in the intervention schools (Baranowski, 2000). Contextual factors, which modify intervention effects, can explain intervention implementation. These can be especially important in a multi-site trial such as TAAG in which site-specific environmental variables may influence implementation. For example, administrative turnover in a Field Center's intervention schools may influence the ability of the intervention to be fully implemented. Assessing potential contamination effects, or secular trends, is also critical in a multi-year, environmental intervention. It is particularly important for TAAG because of the increasing national awareness of the prevalence of obesity and low physical activity levels among children and adolescents (Burgeson, 2001; Morrison, 1999; Troiano, 1998; U.S. Department of Health and Human Services, 2000a). Current and/or potential local and national recommendations, referenda, and initiatives can influence the primary outcomes in control schools (U.S. Department of Health and Human Services, 2000a).

For TAAG, the process evaluation components are defined as follows:

- *Dose*: The number or amount of intended units of intervention delivered.
  Example: Number of TAAG lessons taught relative to how many were intended.
- *Fidelity*: The extent to which the intervention was delivered as intended.
  Example: Percent of TAAG lesson components that were completed.
- *Implementation*: The combination of dose and fidelity.
  Example: (Percent lessons taught + Percent completed lesson components)/2
- *Reach*: The extent to which the program was received by the targeted groups.
  Example: Percent of girls attending after school physical activity programs.
- *Exposure*: The extent to which participants viewed/read intervention materials.
  Example: Number of promotional print materials the girls viewed relative to how many were distributed.
- *Context*: The environmental aspects that affect intervention implementation.
  Example: School facility availability for after school physical activity programs.
- *Contamination*: The extent to which the control group received a similar intervention.
  Example: A control school implements a PE curriculum similar to TAAG PE.

The TAAG process evaluation was designed to be consistent with the TAAG Social-Ecological Model (see Figure 7.1) and the Intervention Planning Framework (see Figure 7.2). The implementation of intervention activities in the intervention schools and community agencies are monitored, and timely feedback is provided to appropriate TAAG investigative teams. The extent to which these activities influence the physical and social environments of schools and community agencies, as well as that of girls, are assessed. Environmental, contextual, and secular trend factors at the school and community agency level are also assessed. The TAAG process evaluation contextual and secular trends assessments can also be conceptualized as environmental descriptors. For purposes of clarity for the TAAG protocol, descriptions of these variables are included in Chapter 10. This chapter is limited to the TAAG assessment of intervention implementation and reach.

11.2. Objectives

The objectives for TAAG process evaluation are:

1. To evaluate the implementation, or delivery, of the TAAG intervention.
2. To evaluate the extent to which the intervention reached the intended targets and the degree to which the targets were exposed to the TAAG intervention components.
3. To document environmental factors that may have an influence on program (intervention) effectiveness (see section 10).
4. To provide periodic quality control information to intervention planners with the intent of refining the intervention and training to optimize its implementation and effectiveness.
5. To provide information to explain TAAG primary and secondary outcome results.

11.3. Methods

TAAG process evaluation assesses the intervention implementation during the entire intervention period using measures designed for each of the intervention components: physical education, health education/activity challenges, Programs for Physical Activity, promotions, and school action planning teams. Data collected to monitor intervention implementation are collected only in intervention schools and community agencies. These data are collected periodically, summarized in a timely fashion, and presented to relevant TAAG Field Centers and investigative groups for the purpose of improving the implementation of the intervention. Data that are collected in both intervention and control sites for intervention description purposes and to assess contextual factors and secular trends are not shared with TAAG investigators until the intervention is ended.

Quantitative and qualitative methods are used, including structured observations, questionnaires, semi-structured interviews, and logs. Data collection instruments are used during the intervention pilot phase and revised based on "user-friendliness" (including respondent and evaluator burden) and reliability assessment conducted during the pilot.

Consistent with the TAAG intervention, process evaluation data collection occurs at the observer (TAAG process evaluator), implementer (i.e., teacher, program leader, TAAG intervention staff), and student level.

A composite score summarizing individual intervention component implementation may be developed to explain TAAG primary and secondary outcomes. Variables from each intervention component (e.g., PE, Health Education with Activity Challenges, Programs for Physical Activity, Promotions) would be included in this score. The actual variables that constitute the score would be determined after data are collected.

11.3.1. Physical education

TAAG physical education (PE) process evaluation assesses the intervention objectives relating to girls' experiences in PE class and evaluates the intervention activities that TAAG intervention staff deliver that are paramount to influencing the girls' experiences in PE. The specific intervention activities that are assessed are: (a) school staff development training workshops, (b) quality of physical education class; and (c) TAAG materials use. Staff development workshops are evaluated by attendance logs and by workshop observations to assess whether the workshop material was delivered as intended. Adaptation of PE classes to meet TAAG objectives is determined through structured observations of PE class and surveys of teachers. The teacher survey also assesses use of TAAG materials.

The table below summarizes these instruments by providing the process evaluation purpose, the person who completes the form, the frequency of data collection, and during which years the data are collected.

Table 11.1. Process Evaluation Instruments for Physical Education Intervention Component

Instrument	Purpose	Completed by	How often	Times measured
Teacher training workshop attendance log	Reach, dose	Teachers/Workshop attendees	Each training	Grade 7, 8A
Teacher training workshop observation of key content	Fidelity, dose	TAAG process evaluation staff	Each training	Grade 7, 8A
PE class observation of key content	Fidelity	TAAG process evaluation staff	Multiple times per semester	Grade 7, 8A, 8B
Teacher survey	Fidelity, dose, reach	Teacher/TAAG process evaluation staff	Each year	Grade 7, 8A, 8B

11.3.2. Health education with activity challenges

TAAG health education/activity challenges process evaluation assesses the intervention objectives relating to delivering lessons to develop student behavioral and communication skills. The following intervention activities are evaluated: (a) school staff development training workshops; (b) lesson implementation; and (c) activity challenge implementation. School staff development workshops are evaluated by attendance logs and by workshop observations to assess whether the workshop material was delivered as intended. Lesson implementation is assessed by observing each classroom and physical activity lesson at least once, completion of a checklist in which teachers report on which lessons were delivered and the extent to which each lesson component was delivered, and completion of activity challenges. A teacher interview also assesses implementation. A survey completed by school staff assesses overall changes in the schools' health education curricula over time (see Section 10). The table below summarizes the health education/activity challenges process evaluation plan.

Table 11.2. Health Education with Activity Challenges Intervention Component Process Evaluation Instruments

Instrument	Purpose	Completed by	How often	Times measured
Teacher training attendance logs	Reach, dose	Teachers	Each training	Grade 7, 8A
Teacher training observation of key content	Fidelity, dose	TAAG process evaluation staff	Each training	Grade 7, 8A
Lesson completion checklist	Fidelity, dose, reach	Teacher	Ongoing	Grade 7, 8A, 8B
Lesson observation	Fidelity	TAAG process evaluation staff	Multiple times per semester	Grade 7, 8A
Activity challenge completion log	Reach, dose	Teachers	Ongoing	Grade 7, 8A
Teacher survey	Fidelity, dose, reach	Teacher/TAAG process evaluation staff	Each year	Grade 7, 8A, 8B

11.3.3. Programs for Physical Activity

TAAG Programs for Physical Activity process evaluation assesses the intervention objective of providing after school and weekend physical activity programs. The following intervention activities are evaluated: (a) formation and function of the TAAG partnership process, including the use of one-on-ones to identify potential partners; (b) resulting programs and physical activity opportunities; and (c) after school policies at schools. Because a major difference of the TAAG intervention from previous school-based trials is the development of partnerships between schools, community agencies, and TAAG universities, extensive process evaluation is conducted to evaluate this component. How the partnership process is developed, successes, and challenges are documented through a partnership questionnaire. Programs resulting from the partnership are assessed for attendance and participant acceptability. To document changes in physical activity programs not directly resulting from the TAAG intervention, the number, type, and attendance of school-based programs are determined in intervention and control schools (see section 10). The table below summarizes the Programs for Physical Activity process evaluation plan for evaluating implementation.

Because the partnership between community agencies, middle schools, and universities is a unique feature of this trial, TAAG staff will document the partnership process for the purpose of providing in-depth information on successes and barriers to working with community partners. This documentation is combined with existing instruments to

develop site-specific case studies of the partnership process that can be used to inform future work.

Table 11.3. Process Evaluation Instruments for Programs for Physical Activity Intervention Component

Instrument	Purpose	Completed by	How often	Times measured
One-on-one interviews documentation log	Dose	TAAG intervention staff	Ongoing	Grade 7
Meeting attendance documentation log	Dose	Meeting attendees	Ongoing	Grade 7, 8A
School/community partnership questionnaire	Fidelity, dose, reach	Each member of partnership	Semi-yearly, then yearly	Grade 7, 8A, 8B
Program attendance log	Reach, dose	Student participants	Sample of TAAG-sponsored programs	Grade 7, 8A
Participant survey	Fidelity	Student participants	Sample of TAAG-sponsored programs	Grade 7, 8A

11.3.4. Promotions

TAAG promotions process evaluation documents the intervention objectives of promoting awareness of TAAG intervention activities and the creation of programming to reinforce girls' participation in physical activity. Special events and physical activity promotions are assessed through attendance logs and participation records. The table below summarizes the promotions process evaluation plan.

Table 11.4. Process Evaluation Instruments for Promotions Intervention Component

Instrument	Purpose	Completed by	How often	Times measured
Promotional events attendance, participation	Dose, reach	TAAG process evaluation staff	End of each promotional segment	Grade 7, 8A

11.3.5. Exposure and Reach

In order to determine girl-level exposure of the intervention, a brief instrument is administered during the 8A and 8B measurement periods. The questions ask about exposure to key intervention components, such as PE teacher's prompting for out-of-class physical activity, participation in Health Education with Activity Challenges, recognition of TAAG promotional slogans, and perceived opportunities for out-of-class physical activity participation. In order to assess the relative contribution of the intervention above any secular trends, these questions are asked to all girls who participate in the follow-up measurement protocols.

Reach of the Programs for Physical Activity component is assessed through a questionnaire administered only to girls from intervention schools. Girls are asked to identify which TAAG programs they participated in during the prior year.

Table 11.5. Process Evaluation Instrument for Exposure and Reach of Intervention

Instrument	Purpose	Completed by	How often	Times measured
Questionnaire	Exposure	Girls	Twice	8A, 8B
Program attendance questionnaire	Reach	Girls (intervention schools only)	Twice	8A, 8B(?)

11.3.6. Tracking Intervention Costs

The "Intervention Expense" form is currently being developed. The purpose of this documentation is to provide an estimate of costs for future users of the TAAG intervention as part of the dissemination phase of the research. This form will focus on costs schools may incur in implementing the TAAG intervention; costs related to the development of the intervention will not be documented. The following are examples of

costs that may be documented: PE equipment, student incentives as required by health education, activity challenges or promotional activities, costs of partnership activities including seed money for start-up funds and mini-grants, materials that must be produced or purchased such as student work-books, teachers manuals, PE task cards, estimates of staff time required to conduct school staff training and implement the intervention.

11.4. Training

A process evaluation Manual of Operations details all study procedures. In brief, each Field Center has a designated Process Evaluation Coordinator, who receives central (i.e., Coordinating Center) process evaluation training (either face-to-face or by telephone) on overall process evaluation goals and objectives, data collection procedures, instrument completion, and data entry preparation. Training is led by members of the Formative and Process Evaluation Subcommittee. Staff members are certified after training and they, in turn, can train additional site staff as needed. Face-to-face training occurs during study-wide measurement training sessions and/or study-wide intervention "train the trainer" training sessions. In addition, telephone training is conducted prior to the administration of the yearly interviews.

TAAG intervention specialists receive training and certification on appropriate process evaluation procedures and instruments during the national "train the trainer" workshops. TAAG intervention implementers (i.e., intervention school teachers, program leaders) receive training on process evaluation goals and objectives and instrument completion during staff development training. All site-specific training for using process evaluation forms and materials is conducted by the process evaluation Field Center coordinator.

11.5. Quality control

Quality control of process evaluation is maintained in the following ways: a) use of a standardized Manual of Operations; b) standardized training and certification of process evaluation data collectors; c) assessing inter-rater reliability on observed methods of data collection; and d) monitoring by the intervention adherence monitoring group, a working group of the Formative and Process Evaluation Subcommittee. All process evaluation procedures and instruments are described in the Process Evaluation Manual of Operations chapters. These procedures have been pilot tested previously during the development and piloting of the instruments. Procedures are reviewed during process evaluation training. Data collectors are certified as outlined in the Manual of Operations for each procedure and/or instrument. The Coordinating Center documents attendance at trainings and the occurrence of appropriate training activities. Only certified trained staff are able to collect process evaluation data.

The Field Center process evaluation coordinator reviews all forms completed by TAAG intervention implementers and process evaluation data collectors. The Field Center process evaluation coordinator ensures completeness and accuracy of these instruments prior to their submission by the site's Data Managers to the Coordinating Center. All data are sent to the Coordinating Center within the time frame specified in

the Manual of Operations, usually no later than two weeks after completion of data collection.

Piloting of Process Evaluation forms includes testing for efficient and accurate data entry and management. Quality control procedures regarding the capture and verification of these data into the trial's database are described in the Data Management Chapter 13.

11.5.1. Intervention adherence monitoring

Process evaluation data collected with the purpose of monitoring the intervention implementation and providing feedback to ensure protocol fidelity is of the highest importance. These data are collected, sent to the Coordinating Center, and analyzed in a timely manner. Results are sent to the intervention adherence monitoring working group, comprised of study investigators and/or senior staff representing each Field Center, the Coordinating Center, and the NHLBI project office. These individuals are not involved in the day-to-day operations of intervention activities or process evaluation data collection. The working group summarizes and interprets data with respect to intervention fidelity. Results and recommendations are reported to the Steering Committee for appropriate intervention adjustment, as needed. The intervention adherence monitoring group is responsible for ensuring that this feedback system is conducted in a timely manner and that relevant information is conveyed to the appropriate groups to maximize intervention effectiveness.

12. QUALITY ASSURANCE

The overall goal of quality assurance is to assure high quality, accurate data. This is accomplished through training and certification related to execution of the measurement and process evaluation protocols and data management tasks; periodic monitoring of timeliness of data transfer; and monitoring of the quality and consistency of measurements.

12.1. Training and certification of staff

12.1.1. Intervention staff

Central trainings will be held to train intervention Field Center staff. Training is led by members of the Intervention Subcommittee. Staff members are certified after training and they, in turn, can train additional site staff as needed. A record of certified individuals will be maintained by the Coordinating Center. Additional monitoring of the intervention is described in detail in section 11 on Process Evaluation.

12.1.2. Measurement staff

Prior to baseline data collection, a series of central training sessions are held to train Field Center staff responsible for all measurements, including physical activity (using CSA), cardiorespiratory fitness, body composition, SOFIT, and administration of the Student Questionnaire and Physical Activity Self Report questionnaire. Each specific measurement protocol described in section 9 includes information on the mode of training (e.g., telephone conference, train the trainers) and certification. In addition, a detailed Manual of Operations for all measurements is used to assure standardization and quality of data collection. Training includes a review of the eligibility criteria and consent procedures; overview of the measurement protocol; demonstration of the measurement methods; practice by trainees on several subjects; and expert feedback on measurement techniques.

Central training and re-certification is repeated prior to collecting the post-intervention 8th grade measurements, and again in prior to the follow-up 8th grade measurements.

Criteria to examine the adequacy of an individual's training include knowledge of the eligibility criteria and consent procedures, and expertise in the measurement methods. Individuals meeting the specific certification criteria are qualified to execute a protocol or a segment of it. Periodic re-certification is necessary to ensure an acceptable performance standard has been mastered or an adequate knowledge of material has been achieved. The Coordinating Center ensures that the measurement staff perform only those functions for which they are certified, and that re-certification activities are implemented as planned and as scheduled.

12.1.3. Process evaluation staff

Each Field Center has a designated Process Evaluation Coordinator, who receives an initial face-to-face central training on overall process evaluation goals and objectives, data collection and data entry procedures, and instrument completion. A process

evaluation Manual of Operations details all procedures. Training is led by members of the Formative and Process Evaluation Subcommittee. Staff members are certified after training and they, in turn, can train additional site staff as needed. In addition, telephone training is conducted prior to the administration of the yearly interviews. TAAG intervention implementers (i.e., intervention school teachers, program leaders) receive training by the Process Evaluation Coordinator on process evaluation goals and objectives and instrument completion during staff development training.
Data collectors are certified as outlined in the Manual of Operations for each procedure and/or instrument. The Coordinating Center documents attendance at trainings and the occurrence of appropriate training activities. Only certified trained staff are able to collect process evaluation data.

12.1.4. Data coordinators

Prior to baseline data collection, there is a central data management system training session. This session is conducted by Coordinating Center staff. The two staff people from each Field Center who attend are responsible for training other staff from their Field Center involved in the entry or transfer of data to the Coordinating Center. Responsibilities that are reviewed in training include:

1. Understanding of the data collection instruments, output file formats, and the specifics of data entry and transfer for all the primary and secondary outcome measurements
2. Running the web-based data management system, which involves knowledge of data entry and modification and data transmission
3. Running computerized participant and study status reports to monitor adherence to the data collection protocol
4. Serving as a liaison to the Coordinating Center for the editing, updating, and transmission of study data
5. Using word processing and other file management software which may be available and useful.

Emphasis is placed upon the data manager's ability to serve as an effective liaison among the various TAAG staff and the Coordinating Center.

Upon successful completion of training, the data managers are certified as Data Coordinators. The quality of their data forms, timeliness, and completeness of work are routinely assessed.

12.2. Quality assessment

12.2.1 Outcome measures

A major assessment of the quality of measurements is the repeatability of results between and within instruments and technicians. Repeatability of measurements within a student is also of interest because of the effect of this variation on the analysis and interpretation of the data.

All CSA monitors are evaluated at the Coordinating Center prior to being shipped to each of the Field Centers to ensure they are working and that they provide comparable data (activity counts). Monitors are attached to an electronic "shaker" unit. Monitors that record counts that differ from the mean by more than 2 standard deviations are re-tested and if again found unreliable, are returned to the manufacturer for replacement. We considered having every 15th girl wear two monitors during data collection. However, our experience in the Calibration Substudy, where the correlation between CSA counts from duplicate monitors was 0.95, suggests this is not necessary.

For every 15th PWC-170 assessment, heart rate is measured by two monitors as a test of instrument repeatability. In the trial Pilot study only, the same set of girls is re-tested to assess intra-observer reliability (by having the same observer re-measure the same child) and inter-observer reliability (by having the observer and an expert measure the same child).

Quality control of the body composition and skinfold measures is conducted at a number of levels: 1) The weighing scales are calibrated daily before measurement begins; 2) Each day before measurements are taken, members of the Measurement team practice taking measurements on each other, with the Team Leader observing to ensure proper technique; 3) The staff person assigned to record measurements also monitor the measures being taken by the other Research Assistants and provide corrective directions when deviations from protocol are observed; 4) Repeat measurements are taken to assess intra- and inter-observer reliability for every 15th child.

To assess the possibility of observer drift in SOFIT measures, observers are tested during measurement periods using a "gold standard" videotape. Responses are sent to the primary trainer who evaluates the results and guides retraining as needed. Measurement coordinators conduct retraining, in consultation with the primary trainer. Inter-observer agreement scores (reliabilities) are obtained in the field through two independent observers making simultaneous observations during approximately 15% of observed classes.

Measurement staff found to have inter- or intra-observer reliability coefficients below 0.80 (as assessed by kappa statistics or intraclass correlation coefficients) will be immediately retrained. The Coordinating Center will design, analyze and report on these reliability studies.

The physical activity self-report instrument is administered with a structured protocol. The test administrators describe the purpose and procedures for the assessment and provide explanations for how to complete the instrument. Printed instructions assist the children in completing the assessment and test administrators are expected to circulate the room to answer any questions.

Quality control for the Student Questionnaire measures is limited to checking data for incomplete surveys.

12.2.2. Process evaluation measures

Quality control of process evaluation measures includes assessment of inter- and intra-observer reliability on observed methods of data collection, and direct observation by the intervention adherence monitoring group, a working group of the Formative and Process Evaluation Subcommittee. All process evaluation procedures and instruments are pilot tested prior to the main trial.

The Process Evaluation Coordinator reviews all forms completed by TAAG intervention implementers and process evaluation data collectors to ensure completeness and accuracy of these instruments prior to keying them into the study Data Management System. Quality control procedures regarding verification of these data into the trial's database are described in the Data Management section 13 of this protocol.

Qualitative data (e.g., taped interviews) are sent to the Coordinating Center within the time frame specified in the Manual of Operations, usually no later than two weeks after completion of data collection. Process evaluation data collected with the purpose of monitoring the intervention implementation and providing feedback to ensure protocol fidelity are analyzed by the Coordinating Center in a timely manner. Results are sent to the intervention adherence monitoring working group and recommendations are reported to Project Coordinators, the Intervention Subcommittee, and the Steering Committee for appropriate intervention adjustment. The intervention adherence monitoring working group is responsible for ensuring that this feedback system is conducted in a timely manner and that relevant information is conveyed to the appropriate groups to maximize intervention effectiveness.

Specific data management details regarding school, community agency, teacher, and student ID number assignments and labels, consent assurance, and tracking over time are developed by the Coordinating Center, and are thoroughly documented in the Manual of Operations.

12.2.3. Data coordinators

The work of Data Coordinators at the Field Centers is monitored through the completeness and timeliness of data transmissions to the Coordinating Center. A computer-generated report on adherence to the data collection protocol is sent to the Principal Investigators at regular intervals.

The Principal Investigator is expected to observe the data collection process for all measurements at least once for each round of measurements. This may require multiple trips to the school, depending on the measurement schedule.

12.3. Monitoring visits

The Coordinating Center staff visits the Field Centers at least once during each data collection phase to help resolve problems, to observe measurements and to verify adherence to the protocol. The Coordinating Center develops a set of checklists encompassing key aspects of the procedures to aid the review. The following data audits are performed:

1. Documentation of informed consent is verified.
2. Consistency of information on paper forms with what has been keyed into the database (for a subset of forms).
3. Appropriateness of data alteration or correction by Field Center staff of data on paper forms.

The Coordinating Center staff meets with the Data Coordinators and reviews data management practices, unobtrusively observes measurement procedures, and then holds a debriefing meeting with the Field Center staff. Based on our previous experience, the debriefing session is important for providing immediate feedback and gives an opportunity for anyone on the staff to raise questions or discuss problems. If egregious problems are observed, they are addressed by the Coordinating Center immediately through communications with the Field Center Principal Investigator and Project Officer. However, it is our experience that most protocol violations are minor and this type of action is not necessary. Routinely, within two weeks of the visit, a formal site visit report is distributed to the Field Center Principal Investigator and the Project Officer. The Field Center Principal Investigator is asked to send a written response detailing corrective actions to the Coordinating Center within one week of receipt of that report. Usually, corrective actions are taken at the time of, or soon after the debriefing sessions, and the written reports provide documentation of these actions.

12.4. Quality of study data

The methods to monitor the quality of the TAAG data collection process include analyses of the study data itself. Variables in the TAAG database are analyzed periodically, by Field Center, in terms of:

1. status of the variables for each participant record (no problem, skipped due to skip rule, problem with the entry).
2. frequencies for categorical variables, or means, standard deviations and selected percentiles for continuous variables.

The first item, especially, allows a view of the prevalence of data entry problems.

Summary statistics by Field Center, or by period of observation (month or quarter) are generally not sufficient for quality control purposes, due to the large amount of explained variation in a small amount of data. For example, the means of weight measurements may differ simply because of age differences between the groups examined. Differences among Field Centers may reflect differences among the underlying populations each is sampling. To adjust for such known sources of variation, the Coordinating Center periodically examines selected items of study data in terms of age-adjusted means by Field Center.

In addition to looking at differences among measurement staff within a Field Center in a given reporting period, the Coordinating Center also examines trends in adjusted means and in variability after adjustment over time. Relatively sudden shifts in the mean for a

given Field Center or increases in measurement variability after adjustment may indicate that changes in measurement technique have occurred which should be examined.

Certain items of data give information on protocol adherence and the validity of data obtained from each participant. The Coordinating Center periodically analyzes these data items by Field Center.

12.5. Monitoring of the Coordinating Center

The primary quality assessment at the Coordinating Center involves assessment of the data management and data analysis systems and procedures.

Standard transaction validity checks are applied to all updates to the database (e.g., to prevent the addition of records with duplicate keys, etc.). A journal file of all updates to the database is maintained. Database backups are made daily. Before each major analysis, the database goes through a series of closure checks to insure the completeness and correctness of data processing. These checks are performed on a "frozen" version of the database defined by a specific time cut point. All computing is documented using the Coordinating Center's statistical computing request system. This system requires the project statistician to produce a written specification of each analysis to be done. The specification, the resulting analysis program, and the output produced are all cataloged and archived (in paper and electronic format) to provide complete documentation of each computing task. All computing requests whose output are distributed outside the Coordinating Center (e.g., to the investigators or Data and Safety Monitoring Board) are independently reviewed by a second programmer for accuracy.

A team of investigators and NHLBI staff visit the Coordinating Center at least once during the baseline and post-intervention data collection phases to review data management, quality control, statistical computing, manuscript tracking and preparation, communication procedures, and staffing needs associated with those tasks.

13. DATA MANAGEMENT

13.1. Introduction

A web-based data management system allows paper forms to be keyed by Field Center staff, and facilitates the process of downloading and transferring CSA monitor data to the Coordinating Center. The Student Questionnaires are sent to the Coordinating Center for scanning, and the resulting data are uploaded to the Consolidated database. Other data management system features include a navigation tool for finding participant-level or process evaluation data, and a reporting tool for quality control (e.g., missing forms report) or other purposes (e.g., printing labels).

13.2. Data collection and recording

Informed consent is documented on the student tracking form. This form allows linkage of the participant to their study ID. TAAG uses registration and tracking forms to document all measurement activities. These forms, to be completed and maintained throughout the intervention and data collection period, include the following types of forms: student tracking, teacher tracking, school registration, program registration, partner agency registration. The Program Registration Form will register each TAAG partner or after-school program associated with the intervention schools. The Partner Agency Registration and Form will register, assign an ID to, and track administrative changes at each TAAG partner agency.

Information on physical activity levels collected using the CSA monitor is downloaded to one of the laptop PCs at the Field Center, using the interface board and software provided by the vendor and transferred to the Coordinating Center via the data management system. Completed physical activity recall questionnaires and process evaluation forms are keyed at the Field Center into the data management system. During the Physical Work Capacity ergometer test (PWC-170), the heart rate at three workloads and the predicted power output at a heart rate of 170 bpm are recorded on a data collection form. Height, weight and skinfold (triceps) measurements are also recorded on a paper form and then keyed at the Field Center into the data management system. All Student Questionnaires are express-mailed in weekly batches to the Coordinating Center where they are scanned. All other data entry, editing, and correction are performed at the Field Center.

The Coordinating Center provides the Field Centers with laptop computers for connecting to the Internet-based data management system. Digital subscriber lines or cable modems are used for high speed, reliable Internet access. An Internet-based data management system allows 1) access from any location with an Internet-connected computer; 2) immediate updating of the study database upon data entry; and, 3) easy updates to the data management system by the Coordinating Center for immediate access of new forms by the study sites.

The data management system provides all of the capabilities required for research data management, including data entry, data validation, database updating, data transfer,

database closure, data retrieval, data inventory, security and confidentiality, and archiving.

For data entry by Field Center staff, the data management system displays data entry screens that closely resemble the paper data collection forms. The system is menu driven, with context-sensitive help available at any time. At the time of entry, the user is notified of data values falling outside the valid range. If the invalid value is accepted by the user, it is flagged in the database. The system is configured to allow users to update data values as appropriate. A journal file of all updates to the database is maintained.

The data management system provides each Field Center with the ability to generate a variety of reports. These include reports to review indicators of data completeness and participant tracking reports. The first allows the study coordinators to monitor the quality of their Center's performance, to facilitate timely identification and resolution of problems in data collection and processing and assist Field Centers in establishing the effectiveness of corrective actions. The reports on participant tracking also assists the process of locating students as they move from grade to grade, allowing for identification of the cohort girls on whom baseline measurements were obtained.

13.3. Consolidated database

Data from all Field Centers comprise the study's consolidated database. The consolidated database is stored in an Oracle database and managed on the Coordinating Center Novell Local Area Network (LAN). Standard transaction validity checks are applied to all updates to the database (e.g., to prevent the addition of records with duplicate keys, etc.). In addition, automated checks ensure that data batches are not lost or processed out of sequence. Logs are generated which show receipt of data. Reports produced by the update program are printed, filed and archived electronically. Updating of the consolidated database by any means other than the data management system or data transfer files is disallowed. Thus, audit logs from the data management system, audit logs received from the study sites and processing logs produced by the update program provide complete documentation for changes to the consolidated database. Backups of the consolidated database as well as the transfer files and processing reports are made daily.

13.4. Transfer of data from the Field Centers to the Coordinating Center

The data from the CSA monitors are downloaded from the monitors onto computers at the Field Centers and then transferred electronically to the Coordinating Center via the data management system and ultimately loaded into the consolidated database. Output files that contain data from the scanned Student Questionnaires are similarly loaded into the consolidated database. Data that are keyed at the Field Centers are automatically transferred to the consolidated database upon completion of the data entry session.

13.5. Database closure

Periodically the consolidated database goes through a series of closure checks to ensure the completeness and correctness of data collection and processing. These

checks are performed on a 'frozen' version of the database defined by a specific time cut point. Typical closure checks include classifying the universe of IDs, assuring all expected forms were received and assuring all queries generated were resolved.

Data are frozen after completion of baseline data collection and resolution of all data queries and again after completion of each subsequent measurement period.

13.6. Data retrieval and statistical computing

Data are retrieved from the consolidated database and converted to SAS datasets. The resulting SAS datasets are permanently archived on magnetic tape cartridge.

All statistical computing is done using the SAS system, and is documented using the Coordinating Center's statistical computing request system. This system requires the project statistician to produce a written specification of each analysis to be done. The specification, the resulting analysis program, and the output produced are all cataloged and archived (in paper and electronic format) to provide complete documentation of each computing task. All data distributed outside the Coordinating Center (e.g., to the investigators or DSMB) are independently reviewed by a second programmer for accuracy.

13.7. Data security and confidentiality

With the exception of the Student Questionnaire, all paper data collection forms are stored at the Field Centers. They are stored and handled like confidential medical records. Access to the files of forms is restricted to TAAG study staff. Each user of the data management system at the Field Centers needs an individual user ID and password to use the data management system. Individually identifying fields within the database are encrypted, and decrypted only for display on-screen.

All data received from the Field Centers are stored, processed, and analyzed within the Coordinating Center's office space. At the Coordinating Center, all access to office space containing data is controlled through manned reception areas. Visitors are screened by the receptionists and cannot move about without a Coordinating Center escort. All office space is locked after working hours. Access to computer data files is controlled by passwords released only to those Coordinating Center personnel who use the files. In addition, critical data files are encrypted.

A backup of the consolidated database is made daily to a separate file server on the Coordinating Center LAN. Magnetic tape backups of the database are made weekly (using a father/grandfather cycle with five generations). Once a month, the current backup tape is removed from the cycle and permanently archived at the Coordinating Center's off-site data storage facility.

Each girl will be assigned a unique ID. Output mailed to Field Center staff identifies participants only by ID number. No individually identifiable information is distributed.

When printed material containing confidential information is to be discarded, it is stored under supervision until the material can be recycled into paper pulp.

Policies regarding the confidential nature of the data collected, processed, and stored at the Coordinating Center, are explained to all personnel upon employment, who must then sign a "confidentiality certification" before being allowed access to confidential information. In addition to this initial training, the Coordinating Center reinforces the need for careful and confidential handling of data at staff meetings. Confidentiality precautions are monitored on an ongoing basis by the Coordinating Center professional staff.

13.8. Data quality assurance

Many of the features of the web-based data management system described above are designed to ensure the quality and completeness of the study data. In addition, the Coordinating Center has an ongoing quality assurance program to evaluate and document the data quality and accuracy of both Field Centers and the Coordinating Center. The program involves double-keying or double-scanning a random sample of 5% of all forms entered by each Field Center, or scanned by the Coordinating Center during baseline data collection. Reports of discrepancy rates are tabulated for the study overall, and where appropriate, by Field Center.

In addition, the Coordinating Center routinely generates reports regarding the frequency of missing or overdue forms, and outstanding queries, that facilitate timely corrective action and resolution of data quality issues.

13.9. Installation, maintenance, and support

The Coordinating Center purchases the required hardware and software for the Field Centers, and installs the data management system, communication system, and all other software.

The Coordinating Center provides all the necessary documentation, user support, and user training of the TAAG data management system. Training includes instruction, demonstration, and hands on practice with TAAG data collection instruments. All Field Center staff participating in the Coordinating Center training sessions are evaluated and certified for use of the TAAG data management system.

The Coordinating Center Data Manager is the primary contact for support concerning the data management system. This staff member can call on the programming staff for technical support as needed.

13.10. Public use data files

A limited access database is prepared at the close of the study to fulfill NHLBI's requirement for a public dataset to be shared with investigators outside TAAG. This dataset is made available upon request, to those meeting NHLBI requirements, three years after the main results paper for TAAG is published. The dataset is constructed to assure confidentiality of TAAG girls and schools.

14. DATA ANALYSIS

14.1. Introduction

TAAG is a multi-center group-randomized trial. Group-randomized trials are often chosen to evaluate interventions that operate at a group level, modify the social or physical environment, or cannot be delivered easily to individuals. Group-randomized trials are characterized by the random assignment of identifiable groups rather than individuals to study conditions (Murray, 1998a). The presence of different groups in each condition and different members in each group gives group-randomized trials a nested (or hierarchical) structure for the design and for the data. Importantly, group-randomized trials often involve a small number of groups assigned to each condition. These characteristics create a number of problems for the design and analysis of group-randomized trials. The major design problem is that the limited number of often heterogeneous groups makes it more difficult for randomization to distribute all potential sources of confounding evenly among the study conditions in any single realization of the experiment. This increases the need to employ design strategies that limit confounding and to consider analytic strategies to deal with confounding when it occurs. The major analytic problem is that members of the same identifiable group share some physical, geographic, social or other connection (Kish, 1965), so that there is an expectation for a positive intraclass correlation reflecting an extra component of variance attributable to the group. This extra variation increases the variance of any group-level statistic. Moreover, the degrees of freedom (df) available to estimate group-level statistics are limited by the number of groups in each condition. Any test that ignores either the extra variation or the limited df has a Type I error rate that is inflated, often badly (Cornfield, 1978; Murray, 1996; Murray, 1998b; Zucker, 1990).

The design and analytic plans for TAAG are structured with these considerations in mind so as to provide an unbiased and precise estimate of the effect of the TAAG intervention. The design is described in Chapter 4. This section describes the plans for data analysis.

14.2. Primary and secondary endpoints

As described in Chapter 9, the primary endpoint for TAAG is the number of MET-minutes per day of moderate to vigorous physical activity (MVPA). Secondary endpoints include unweighted minutes per day of MVPA, physical fitness, body composition, and types and context of physical activity, physical activity in PE and self-reported physical activity related variables.

14.3. Primary and secondary hypotheses

The primary hypothesis is that between 6th and 8th grade, physical activity will decline less among girls enrolled in schools randomized to the intervention condition than among girls enrolled in schools randomized to the control condition. One important secondary hypothesis is that the intervention effect in TAAG will be sustained a year later, as evidenced in a survey of 8th graders one year after the intervention sponsored by TAAG is completed.

14.4. Type I error rate

The Type I error rate is 5% and all tests are two-tailed.

14.5. Primary analysis

14.5.1. Statistical model

The primary analysis has two stages. In the first stage, we regress each girl's MET-weighted minutes of MVPA on school, time (baseline and follow-up), their interaction, ethnicity and week of data collection; neither condition nor Field Center is included in this analysis. From this first-stage, we generate 36x2=72 time x school means for MET-weighted minutes of MVPA, adjusted for ethnicity so that all 72 means are standardized to the average ethnicity distribution observed across the two surveys. In the second stage, we use those 72 means as the data in an analysis in which we regress the follow-up school mean on study condition, adjusting for the baseline school mean and stratifying on Field Center. This two-stage analysis ignores any overlap among the girls measured in the 6^{th} and 8^{th} grade surveys. It provides a mixed-model analysis of covariance with individual-level adjustment for ethnicity, school-level adjustment for baseline MET-weighted minutes of MVPA, and with proper consideration of the intraclass correlation expected among observations taken both within the same school and within the same week of data collection and of the over-time correlation expected among means computed for the same school. Details on the statistical model are provided in the Appendix.

14.5.2. Assumptions

The primary analysis involves assumptions regarding the number and distribution of sources of random variation, regression adjustment for covariates, homogeneity of intervention effects across Field Centers, variance inflation due to errors in measurement, bias associated with occasional missing CSA data, and bias associated with non-ignorable refusals. Those assumptions are explained in detail in the Appendix to Chapter 14, as are procedures for their evaluation.

14.5.3. Intention to treat

The primary analysis employs intention-to-treat principles (Newell, 1992; Peduzzi, 1991; Phillips, 1991). The Intention to Treat analysis reflects the original randomization performed for the study. Because randomization carries the expectation of creating treatment groups equivalent with respect to known and unknown prognostic factors, removing randomized participants from the analysis, even for the best of intentions, runs the risk of tampering with this balance and introducing bias into the treatment comparisons. The following Intention to Treat principles are applied in TAAG: (1) All schools randomized into the study are included in all analyses irrespective of protocol violations and events arising post randomization. (2) Participants are analyzed according to the treatment assignment for the school in which they were measured. To implement these principles, we propose a procedure based on the expectation maximization (EM) algorithm to replace occasional missing CSA data for girls who participate in the data collection. As a secondary analysis, we propose multiple imputation to provide CSA data for girls who are selected for the CSA data collection

but refuse to participate at the follow-up survey. Details on these plans are provided in the Appendix to Chapter 14.

14.5.4. Power

The assumptions underlying the power analysis for MET-weighted minutes of MVPA are summarized in Table 14.1.

- The mean and standard deviation for MET-weighted minutes of MVPA are taken from the variance components substudy of 8th grade girls (n=426) selected to represent 12 schools from the six Field Centers. Both are based on a cutpoint of 1500 CSA counts per half-minute to define MVPA, a figure drawn from the findings of the CSA calibration substudy.
- As noted above, the Type I error rate for the primary analysis is 5% and two-tailed.
- Given 60 girls per school invited to the baseline survey, we conservatively estimate the overtime correlation among schools at zero (the correlation among measures taken on the same schools two years apart). We make no provision for overtime correlation among the girls (the correlation among measures taken on the same girls two years apart), due to our plan to ignore any overlap in the 6th and 8th grade samples.
- We plan to randomize 18 schools to each of two conditions.
- We assume each Field Center will average 60 girls per school selected for invitation to the baseline survey and 120 girls per school selected for invitation to the follow-up survey. Schools with fewer girls available for CSA measurements may participate in TAAG so long as there is a minimum of 90 girls who are eligible to be selected for invitation to each survey and so long as each Field Center averages 60 girls per school at the baseline survey and 120 girls per school at the follow-up survey.
- We anticipate that girls enrolled in the intervention schools during 7th and 8th grade will display an intervention effect of 15.6 more MET-weighted minutes of MVPA than their counterparts in the control schools; this effect is equivalent to 10% of the mean MET-weighted minutes of MVPA and to a 50% reduction in the decline anticipated between the 6th and 8th grades. We anticipate that girls enrolled in the intervention schools only in the 8th grade will display an intervention effect of 9.4 more MET-weighted minutes of MVPA; this effect is equivalent to 6% of the mean MET-weighted minutes of MVPA and to a 30% reduction in the decline anticipated between the 6th and 8th grades.
- Our eligibility criteria are designed to limit the two-year attrition to 36%.
- Based on our experience in the variance components substudy, we anticipate a refusal rate for CSA measurements at 8th grade of no more than 20%.
- Also based on that experience, we assume six 24-hour days of CSA observation per girl, with girls measured in approximately equally sized weekly groups over a period of three weeks in each school. This can be accomplished by taking the monitors off of the girls on the same day of the week on which they were put on. Analysis of the variance components substudy data indicated that reducing the number of days from seven to six has little effect on any of the estimated parameters. If that plan is adopted, the data suggest that Monday is the

preferred day to avoid, because there was lower compliance than on other days.

- The power calculations assume that occasional missing CSA data within a girl's 7-day records are replaced via imputation based on the EM algorithm; details are provided in the Appendix to Chapter 14.
- The power calculations ignore refusals. Refusals that are unrelated to study condition or physical activity level will not bias the estimate of the intervention effect. We anticipate that no more than 25% of the refusals are non-ignorable. Separate analyses suggest that power declines by about 3% if we impute values for 25% of the refusals, assuming no intervention effect for those cases. At the same time, the intervention effect is overestimated by only about 5% if those refusals are ignored. Given this minor adverse effect in terms of bias, we do not believe it is necessary to impute for refusals in the primary analysis. We propose imputation for refusals in a secondary analysis.
- The observed value of the school-level ICC for MET-weighted minutes of MVPA is 0.000, based on an analysis of the variance components substudy data consistent with that proposed above for the primary analysis. We view that estimate as optimistic and prefer to be cautious, given that we had a small sample of schools in the variance components substudy, thereby limiting the precision of our estimate. Separate analyses suggest a 50% probability that the true value is below 0.003 given an observed value of 0.000, and so we propose 0.003 as our realistic estimate of this Intraclass Correlation. Prior experience with Intraclass Correlations in other school based studies suggests a value of 0.01 as a conservative estimate, and we note that there is a 62% probability that the true value is below 0.01 given an observed value of 0.000. With these considerations in mind, we used these three values to perform the power analyses summarized in Table 14.2.

Table 14.1. Assumptions Underlying the Power Analysis for MET-Weighted Minutes of MVPA

Mean MET-weighted minutes of MVPA, based on 1500 cpm	156.4 MET minutes
SD MET-weighted minutes of MVPA, based on 1500 cpm	94.9
Two-tailed Type I Error Rate	5%
Over-time correlation among schools	none
Over-time correlation among girls	none
Schools per condition	18
Girls per school selected for CSA measurement at posttest	Average 120, Minimum 90
Intervention effect	
for girls enrolled in intervention schools in 7th and 8th grade	15.6 MET min (10% of mean)
for girls enrolled in intervention schools only in 8th grade	9.4 MET min (6% of mean)
Attrition rate over two years	36%
Refusal rate at follow-up for CSA measurements	20%
CSA measurement schedule	
days per girl	6 24-hour days
weeks per school	3
Imputation of occasionally missing CSA data	EM algorithm
Imputation for non-ignorable refusals	none
School-level Intraclass Correlation	
observed estimate	0.000
realistic estimate	0.003
conservative estimate	0.010

Tables 14.2 summarizes power for TAAG based on these assumptions. These results indicate that even if the Intraclass Correlation is as high as 0.01, if we invite 120 girls from each school to participate in the follow-up survey, and no more than 20% of that sample refuse to provide CSA data, we have 89% power for the projected intervention effect, given the assumptions noted in Table 1.

Table 14.2. Power Projected for TAAG

ICC	Girls/School Invited to Participate at Follow-up				
	90	105	120	135	150
0.010	81%	85%	87%	89%	90%
0.003	92%	95%	97%	98%	98%
0.000	96%	98%	99%	99%	100%

14.6. Secondary analyses

14.6.1. Confounding

Randomization of 18 schools from within Field Centers to each of two study conditions reduces the risk of substantial imbalance on important prognostic factors between the two conditions. Even so, such imbalance is more likely in a group-randomized trial involving only 36 schools than in most randomized clinical trials involving hundreds of participants. Left alone, such imbalance could confound the true relationship between condition and the primary endpoint in the primary analysis. As a result, we propose a series of secondary analyses designed to explore the potential for confounding, and where found, to control for it statistically.

As noted below in the section on preliminary analyses, we propose to examine the baseline data for evidence of imbalance between the two study conditions on factors of potential prognostic significance. Factors that may prove to be potential confounders include race/ethnicity and socio-economic status, for example. Where found, we plan to add those variables to the models used in the primary and secondary analyses to estimate effects computed as though the two study conditions were balanced on those factors.

One important series of secondary analyses explores the potential confounding influence of differential refusals at the 8th grade survey. It is possible that girls in the intervention schools are more likely to refuse to participate in the follow-up survey if they have been relatively inactive. Ignored, this pattern could bias the estimate of the intervention effect away from the null hypothesis. We propose to explore this possibility in several ways. First, we plan to examine the baseline data of girls who are selected at follow-up to compare those who participate and those who refuse to participate at follow-up. If a net difference of more than 10% is observed in the average MET-weighted minutes of MVPA between the two study conditions, we plan to repeat the primary analysis using multiple imputation of missing values due to refusal. The multiple imputation procedure builds on a regression equation that uses school- and individual-level data to predict MET-weighted minutes of MVPA.

14.6.2. Mediation

As noted in section 4, the TAAG design provides 8th grade data from all girls who participated in the 6th grade survey and who are still present in the participating schools. Even though attrition may be as high as 36% over two years, this approach provides a modest sample (likely 25 girls per school) and one that is well suited for exploration of girl-level mediation effects. As a result, we plan to pursue girl-level mediation analyses in those cohort data.

In mediation analyses, potential mediating variables are examined to determine whether they change in response to the intervention and whether they predict subsequent activity change. They are also examined to determine whether they diminish the intervention effect when added to the primary analysis, as substantial diminution is evidence for mediation (Baron, 1986; Judd, 1981). Leading girl-level candidates as mediators in TAAG include self-efficacy, change strategies, enjoyment of physical activity, enjoyment of physical education, perceived benefits and barriers to physical

activity, perceived competence for physical activity, social support, perceived environment and recreational facilities, and school climate for physical activity.

As elaborated in the Appendix to Chapter 14, we plan to calculate propensity scores to predict the likelihood of leaving the original school between 6th and 8th grade. This allows us to repeat the girl-level mediation analyses adjusting for the propensity score to obtain effect estimates computed as though the propensity to leave was the same in the two study conditions.

In addition to girl-level mediation, we will explore school-level mediation. School-level mediators can be either measured independently from measures taken in girls or calculated by taking the mean of girl-level measurements across a school. An example of the former would be a score assigned by an observer to rate the physical activity facilities for a school. An example of the latter would be a mean score calculated for the school based on the rating of those same physical activity facilities by each girl during the school survey. School-level mediators will be examined both in the cohort data and in the serial cross-sectional data, and the methods are parallel to those described above for girl-level mediation. For example, in a cohort analysis, we might enter both the girl-level score rating physical activity facilities and the observer's score rating those same facilities as mediators to gauge whether they explain a portion of the intervention effect on physical activity. In a cross-sectional analysis, we might enter the observer's rating or the average of the girls' ratings to gauge whether they explain a portion of the intervention effect. As noted by Raudenbush & Bryk (2002) environmental- and individual-level mediators often have different coefficients, and so different interpretations, even when they appear to measure the same general construct (e.g., quality of physical activity facilities). Examining both separately and together rather than just either alone is likely to provide a clearer understanding of how the intervention effects are mediated, so long as care is taken in the interpretation of the results.

14.6.3. Effect modification

We propose effect modification (moderation) analyses in the serial cross-sectional data and in the cohort data. In the former, we compute time x school x stratum means in the first stage, and then perform a stratified analysis of covariance on the 8th grade data, adjusting for 6th grade school means. In the latter, we perform a stratified analysis of covariance, but adjust for individual-level MVPA. For each potential moderator, we test for homogeneity of the intervention effect across subgroups of girls defined by the levels of that variable. The effect modifier is added as a main effect and as an interaction with condition in the fixed-effects portion of the model, and as an interaction with school in the random-effects portion of the model; details on these interaction models are in the Appendix to Chapter 14.

We note of course that power for interactions is always less than for main effects, and so examination of effect modification is primarily to help us understand the pattern of findings and not to test *a priori* hypotheses. The variable we consider of most interest as an effect modifier is baseline weight status (below the median, above the median). Other descriptive variables that we consider as potential effect modifiers include demographic characteristics, sports activity participation history, acculturation, whether an adult is home after school, and whether transportation is available after school. A

significant interaction between any of these variables and study condition provides evidence of effect modification.

As elaborated in the Appendix to Chapter 14, we plan to calculate propensity scores to predict the likelihood of leaving the original school between 6th and 8th grade. This allows us to repeat the moderation analyses adjusting for the propensity score to obtain effect estimates computed as though the propensity to leave was the same in the two study conditions.

14.7. Preliminary analyses

14.7.1. Baseline comparisons

Analyses are performed using the baseline data to compare the two study conditions with respect to demographic characteristics and important prognostic factors. The 6th grade data have the same hierarchical structure as the 8th grade data, because both involve observations taken from girls nested within schools which are in turn nested within the cells defined by the Field Center x condition interaction. As a result, we can expect the same kind of correlated data at baseline that we expect at the end of the study, and the methods used for baseline comparisons need to reflect that correlation. For variables distributed Gaussian, we propose the same kind of two-stage analysis described above for the primary analysis. The first-stage analysis is based on the General Linear Model and is appropriate for endpoints that are related to one or more fixed-effect independent variables when all remaining variation is appropriately allocated to a single residual error that has a Gaussian distribution (Searle, 1971). Many variables of interest at baseline have other distributions, such as data from dichotomous variables (e.g., gender) or data representing counts (e.g., servings of fruits and vegetables). For these variables, we propose variations of the first-stage analysis based on the Generalized Linear Model (McCullagh, 1989), which allow us to specify a binomial error distribution and logit link, as is appropriate for dichotomous variables, or a Poisson error distribution and log link, as is appropriate for count variables.

The results of these analyses allow us to characterize the similarities and differences between the two study conditions at baseline. Given random assignment from within Field Centers of 18 schools to each of two conditions, we do not anticipate substantial differences between the two conditions at baseline, though it is important to look for them so that we can avoid potential confounding in the primary analysis.

14.7.2. Interim analyses

The benefits of the intervention, while significant in a public health context, are expected to be modest in terms of the clinical impact on any single girl. Moreover, the risk to girls in the control schools from not obtaining an effective intervention are considered to be minimal over the period of the study. As a result, we do not plan to collect or analyze interim data for primary or secondary endpoints.

15. ADVERSE OUTCOMES AND SAFETY

15.1. Background and rationale

Protection of study participants from risks related to the study is a major concern to investigators and institutions participating in TAAG. Each institution must seek site-specific Institutional Review Board approval for TAAG. A signed and dated statement that the protocol and informed consent form have been approved by an Institutional Review Board is forwarded to the Coordinating Center and archived.

15.2. Monitoring physical activity-related injuries

NIH guidelines indicate that an adverse event is "any untoward medical occurrence in a study participant." A serious adverse event is "any event that is life-threatening, requires an inpatient hospitalization, results in significant disability, results in congenital anomaly, results in death, requires intervention to prevent impairment or damage, or is an otherwise important medical event." In TAAG, an adverse event is operationally defined as "an event that causes bodily or psychological damage and that requires either treatment by medical personnel or causes the student to miss school" (Anderson, 1994). TAAG encourages changes in physical activity. Although unlikely, these changes could lead conceivably to adverse effects. Adverse events are monitored in all girls attending TAAG intervention and control schools. Since boys are exposed to certain aspects of the TAAG intervention (e.g., physical education classes in some schools), they are included in monitoring procedures when feasible.

An increase in time spent in physical activity at school and out of school could lead to an increase in the number of injuries. This is probably the most common event that might be considered an adverse effect; in rare cases, children may suffer injuries that are debilitating or fatal. Each school will have a procedure for recording and reporting any injury resulting from physical activity during participation in school-sponsored activities. A copy of this log is kept at the school, at the site TAAG offices, and at the Coordinating Center. A log, to be completed by physical activity program personnel, monitors adverse events among participants in TAAG-sponsored after-school or weekend physical activity programs. The adverse events reporting scheme is outlined in Figure 15.1.

Specific possible injuries include strains, tears, or fractures (Surgeon General Report on Physical Activity and Health, 1996). Adolescents with developing bodies are at risk of permanent physical damage if injury occurs to the growth plates of long bones or to other connective tissue structures. Most musculoskeletal injuries related to physical activity can be prevented by gradually working up to the desired level of activity. The specific type of injury is recorded on the adverse events logs described above and reported to the Coordinating Center.

Severe exertion in hot, humid conditions can cause electrolyte imbalance or dehydration. Timely fluid intake and replacement can prevent or ameliorate such conditions. Regular physical activity can improve cardiorespiratory fitness and reduce

the risk of cardiovascular disease mortality over the long term. Over the short term, sudden cardiac deaths, while possible, are very unlikely in this age group.

Another category of potential adverse effects would be disorders of eating behaviors that result from increased attention to physical activity, fitness, and weight. Among the conceivable adverse effects are binge eating, bulimia, and anorexia. Other potential adverse effects are difficult to predict; they might include the possibility of psychological problems stemming from increased attention to health, fitness, or weight. The difficulties of attribution and the *a priori* low expectation of these problems developing due to the TAAG interventions argue against surveillance for these conditions.

15.3. Procedures for monitoring adverse events

Four procedures are used to monitor adverse events in girls attending TAAG middle schools:

1. A form, to be completed by measurement staff, records adverse events and serious adverse events reported by each girl upon her completion of the measurement procedures.
2. A form, to be completed by TAAG staff, monitors serious adverse events occurring in both girls and boys on school grounds or during participation in school-sponsored activities.
3. A student recall survey, to be completed by girls completing the measurement protocol, captures serious adverse events occurring among participants in TAAG-generated after-school or weekend physical activity programs in intervention catchment areas.
4. A log, to be provided by school personnel, records all missed days in TAAG schools.

The flowchart in Figure 15.1 was adapted from that provided by the NHLBI and describes the reporting flow for both Adverse Events and Serious Adverse Events. One person in each measurement team is designated as the person who assumes responsibility for all adverse events reporting associated with measurement activities (Measurement Adverse Events Coordinator).

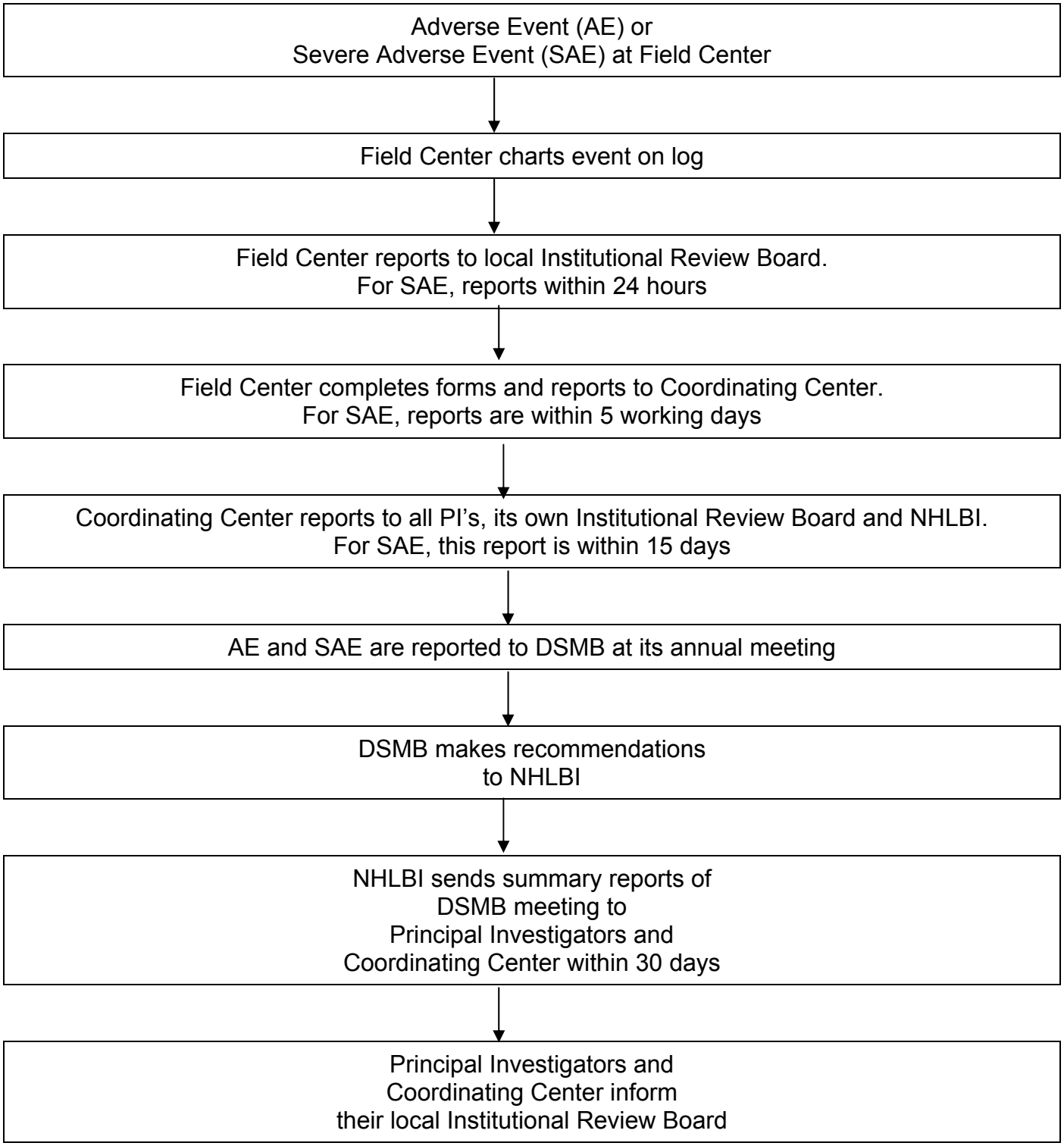
15.4. Ethical and privacy considerations

The TAAG Steering Committee is determined to go beyond the required informed consent process, and actively protect the rights of all girls participating in the program. Among the measures that are included are:

To insure that girl's modesty is respected during anthropometric measurements and while training the girls to wear the CSA monitor, only female staff perform these tasks, and always in the presence of another person. Privacy screens are used. All TAAG personnel who will have direct contact with the girls will complete a state-level criminal background check. The nature of this check varies depending on the site's university requirements, and may be done by such authorities as a University Human Resources Department, State Department of Public Safety, or Department of Justice.

All information collected by the program is considered confidential, and only numeric codes are used in identifying the source of data. Medically relevant information is available to health care providers only upon written request of the girl's parent or guardian. The Coordinating Center has developed specific guidelines for handling data to insure confidentiality.

Figure 15.1. Adverse Events Reporting in TAAG



16. ORGANIZATION AND ADMINISTRATION

TAAG is a collaborative study supported by a cooperative agreement from the National Heart, Lung, and Blood Institute (NHLBI). The study is divided into three phases. Phase I includes planning and protocol development and will last from September 1, 2000 through August 31, 2002. Phase II, the main trial, will last from September 1, 2002 through August 31, 2006. This trial will occur in six study centers with a total of 18 intervention schools and community catchment areas and 18 control schools and community catchment areas. Final data analyses, preparation of manuscripts, closeout activities, and archiving of data will take place during a one-year Phase III.

Six participating Study Centers, a Coordinating Center, and the NHLBI Project Office are carrying out TAAG. The Study Centers are as follows:

- University of Arizona, Tucson, AZ
- San Diego State University, San Diego, CA
- Tulane University, New Orleans, LA
- University of Maryland, College Park, MD
- University of Minnesota, Minneapolis, MN
- University of South Carolina, Columbia, SC

The Coordinating Center is located at the University of North Carolina, Chapel Hill, NC.

The NHLBI Project Office is located in the Division of Epidemiology and Clinical Applications (DECA), Bethesda, MD. Biostatisticians from the Biostatistics Research Branch of DECA are part of the Project Office and a Grants Management Specialist works closely with the Project Officer regarding policies and procedures related to fiscal matters. The NHLBI Project Officer serves as a link between TAAG investigators and the Director of NHLBI.

16.1. Steering Committee

The primary decision making structure of TAAG is the Steering Committee, consisting of the Principal Investigators of each of the six Study Centers, the Principal Investigator of the Coordinating Center, and the NHLBI Project Officer, each with one vote. If a member of the Steering Committee is not present at a meeting, that center's vote may be delegated to another investigator from that center. A motion or proposal can be passed by simple majority; in the case of a tie, the motion will be tabled for repeat consideration at the next meeting or conference call.

The Steering Committee met regularly during Phase I to review progress, direct the development of the study protocol, substudies, and Manuals of Operations, and review and approve all major intervention and measurement instruments of the study. The Steering Committee is the ultimate authority for deciding on the final study design, and has primary responsibility for facilitating the conduct of the study and reporting of the study results. The Committee can seek advice from the Data Safety and Monitoring Board (see below) or NHLBI regarding a Study Center or the Coordinating Center if they do not appear to be carrying out TAAG activities satisfactorily.

16.2. Subcommittees

The major subcommittees are: Design and Analysis; Intervention; Measurement; Formative and Process Evaluation; Recruitment, Retention, and Eligibility; and Publications and Presentations. The chair of each subcommittee is appointed by the NHLBI in consultation with the Principal Investigator of the Coordinating Center. At least one representative from each Study Center and the Coordination Center is a member of each subcommittee. The functions of these subcommittees are outlined briefly below:

Design and Analysis Subcommittee

- To develop a study design for the main trial and to insure adequate statistical power to quantify precisely specified intervention effects.
- To develop and implement appropriate analytical methods for testing relevant study hypotheses
- To review and advise on all proposed sub-studies and ancillary studies.

Intervention Subcommittee

- To develop theoretical models for study.
- To develop and standardize intervention programs in the areas of physical education and health education.
- To develop and implement a mechanism for involving schools and community partners to provide after-school physical activity for middle-school-age girls.
- To develop and implement methods to promote TAAG objectives and activities
- To develop appropriate training programs for TAAG staff, school personnel, and community partners

Specific tasks in developing interventions are assigned to the following Working Groups:

a) Physical Education Working Group
b) Health Education With Activity Challenges Working Group.
c) Programs to Physical Activity (After-School) Working Group
d) Promotions and Web-based Challenges Working Group
e) Action Planning Teams Working Group

Measurement Subcommittee

- To develop and standardize the measurement tools for the evaluation of each intervention and for assessing outcomes.
- To work with the Design and Analysis Subcommittee in designing, implementing, and analyzing results from sub-studies needed to develop and validate measurement instruments.

Specific tasks in developing measurement instruments are assigned to the following Working Groups:

a) Physical Activity Assessment Working Group
b) Physical Fitness Assessment Working Group
c) Mediators, Moderators, and Secondary Outcomes Working Group

Formative and Process Evaluation Subcommittee

- To generate preliminary information that can be used to improve and enhance program development and implementation.
- To develop and standardize measurement tools to monitor the progress of the intervention, fidelity to protocols, extent to which the target population was reached, and external factors that may compete with the program.

Recruitment, Retention, and Eligibility Subcommittee

- To develop standardized eligibility criteria for enrolling schools into TAAG.
- To develop standardized eligibility criteria for enrolling girls as participants in the TAAG trial
- To develop standardized eligibility criteria for enrolling community agency partners into the trial.

Publications, Presentations, and Ancillary Studies Subcommittee

The Publications, Presentations, and Ancillary Studies Subcommittee consists of eight members, one from each Study Center, one from the Coordinating Center, and one from the NHLBI Project Office. Guideline for publications and presentations are given in Section 18. The tasks of this subcommittee are as follows:

- To review and approve all publications and presentations proposed by investigators that relate to data collected through TAAG.
- To assure accurate and timely presentation of pertinent information from TAAG to the scientific community.
- To help ensure that all TAAG investigators have the opportunity to participate in presentation and publication of study-wide data.
- To review and approve all proposed ancillary studies to ensure that they do not adversely affect the main TAAG trial.

16.3. External oversight

A Data and Safety Monitoring Board (DSMB) will oversee the study in terms of safety, ethics, and science. This committee is advisory to NHLBI and is convened by NHLBI, independently of the TAAG investigation. This five to seven member committee will include persons with expertise in pediatrics, physical education, exercise physiology, health education, health behavior, epidemiology and biostatistics. The approval of the DSMB will be required for any significant changes in protocol recommended by the Steering Committee during the course of the study. The Coordinating Center will be responsible for preparing and presenting up-to-date statistical reports on the progress of the study for the DSMB. The DSMB will be convened by conference call or meeting at least twice per year. Presentations to the DSMB will be made by the Chair of the Steering Committee, the Director of the Coordinating Center, the NHLBI Project Officer, and other individuals proposed by the Project Office or requested by the DSMB. The NHLBI Project Officer, Steering Committee Chairman, and Coordinating Center Director are ex-officio members of the DSMB. An Executive Session (excluding all TAAG investigators) will be held at each meeting. An NHLBI staff member (not the Project Officer) serves as Executive Secretary to the DSMB.

17. HUMAN SUBJECTS

17.1. Consent process

Each Field Center participating in TAAG must file its own separate Federal wide Assurance of Protection of Human Subjects with the DHHS Office of Human Research Protection, providing written, informed consent using procedures reviewed and approved by each Field Center's local Institutional Review Board. These procedures must meet the requirements of 45 CFR 46, Protection of Human Subjects, including purpose of the study, guarantees of confidentiality and privacy, statement of possible risks, and resource for grievances. Protection is assured in accordance with the ethical principles of (a) respect for persons, (b) beneficence, and (c) justice. All provisions of the federal Privacy Act apply, as appropriate. TAAG qualifies under NIH FWA exemption number 1 and assurances are not required from the schools. Model consent forms for parent, child (assent), community agencies and schools (Memorandum of Understanding) are included in the appendix.

17.2. Elements of consent

Since TAAG is a study involving minors, parental consent is required. Consent (assent for minors) must include all of the elements listed below:

1. Participants must be advised that the study involves research. The following items must be addressed: purposes of the research; expected duration of the subject's participation; and a description of the procedures to be followed.
2. Anticipated benefits of the study must be explained to the participant (parent).
3. Attendant discomforts and risks reasonably to be expected must be described.
4. The extent, if any, to which confidentiality of records identifying the participant will be maintained must be described.
5. Prospective participants must be advised of the availability or non-availability of treatment or compensation for physical injuries incurred as a result of participation in the study, and, if available, what they consist of , or where further information can be obtained.
6. The informed consent must include the name of a contact person who can answer questions about the research, the participants rights, or information on what to do if a research related injury should occur.
7. Participants must be told that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which he or she is otherwise entitled.

17.3. Confidentiality

Participants at each Field Center in the TAAG study are protected by the customary constraints on confidentiality of participant data. Forms and electronic data are protected by reasonable security procedures including locked rooms and/or file cabinets for paper documents and coded security access for electronic data. Access to identifying information is limited to study personnel with a need for such access. Personnel involved in TAAG must agree not to disclose any information which might be protected by confidentiality policies to persons who do not work for the study or who do not have a need to know the information. No published data will include information which would permit readers to identify any individual participant in the study. When the study database is made available to the program office, it will not include actual identities

and contact information for participants. Such information will be retained under lock and key at the individual Field Centers and at the Coordinating Center for use in the event the future follow-up of the study participants is necessary. The Coordinating Center will also maintain confidentiality of participant data as explained in Section 13.6.

18. COMMUNICATION OF SCIENTIFIC RESULTS

18.1. Guidelines for publications and presentations

18.1.1. Overview

Guidelines were developed by the Publications and Presentations and Ancillary Subcommittee in order to insure that data generated by TAAG be reported in a consistent, accurate and timely fashion.

Specifically, these guidelines aim to:

1. Assure that results from the project be reported to the scientific community in an ethical, accurate and timely fashion.
2. Assure that communication of results to the public be done with accuracy and consistency, and without affecting the collaborative nature of the project or the acceptance of its results.
3. Develop mechanisms to share information from this project with the school and community agencies, while maintaining the originality of data required for peer reviewed scientific publications.
4. Maintain a complete up-to-date progress report of all publications and presentations.

18.1.2. Approval

All abstracts and manuscripts resulting from local studies, substudies, or ancillary studies must be approved by the Publications Subcommittee before being submitted to any organization or journal for presentation or publication. In addition, abstracts including tables and charts should be reproduced in complete sets so that copies are available to all centers. Approval shall be based on majority vote.

18.1.3. Authorship

It is anticipated that several initial TAAG publications will present the overall study design and methods and primary results of the study. In general, papers are initiated and writing teams designated according to the following guidelines:

1. The Steering Committee's scientific interests are announced in formal meetings and recorded in the minutes and through informal conversation.
2. Other proposals may be submitted to the Publications Subcommittee; they should include supporting literature, a clear statement of research hypotheses, a description of the data to be used, analytical methods, and any proposed collaborators or outside expertise.
3. The Publications Subcommittee can select authors for a particular area of study and appoint a paper writing committee. Other authors may be recommended by principal investigators for approval by the Publications Subcommittee.
4. First authorship is assigned by the Publications Subcommittee on the basis of effort contributed. The selection of writing committee members should be equitable and fair to all involved. Presenters are nominated by the writing committees and approved by the Publications Subcommittee.
5. Finished papers are reviewed by the Publication Subcommittee members and other designated reviewers.

6. Data being utilized for presentations or publications are obtained from the Coordinating Center (which maintains the final, corrected data sets). No final manuscripts are published on incomplete pooled data sets. Presentations on incomplete data sets can be made with prior approval of the Publications Subcommittee.
7. The Publications Subcommittee reserves the right to reassign first authorship if reasonable progress on completing an abstract or manuscript within a predesignated time frame has not been made.
8. All Ancillary Study Proposals must first be presented to the TAAG Publication Subcommittee for review and approval.

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20. APPENDICES

Appendix 1: Sample informed consent form for parents or guardians

<Letterhead>

INFORMED CONSENT FORM FOR PARENTS OR GUARDIANS

Dear Parent or Guardian:

Name of Middle School is involved in a research study with the Name of University. The name of the study is *Trial of Activity for Adolescent Girls (TAAG),* and it is funded by the National Institutes of Health. Only girls who are in 8th grade during the 2004-05 year can be involved in the TAAG measurement activities. We would like your daughter to take part in the TAAG measures. This consent form explains what is involved. Please read it closely and ask any questions that you have before you decide to let your daughter take part.

PURPOSE OF THE PROJECT:
The major purpose of the TAAG project is to study the physical activity levels of girls in middle school and other items that may relate to children's health. We will do this by asking students to complete the measures described in the next section. As part of the study, we will also look at whether girls who have physical activity opportunities located near their home are more physically active than girls with fewer opportunities.

WHAT IS INVOLVED?:
Your daughter will be asked to complete the measures listed below during the spring semester of her 8th grade year. She would complete these measures during three or four classes at her school. Should other times be needed before or after school, these details would be worked out to meet her schedule.

Students involved in the measures will:

1. Wear a small activity monitor all day for seven days in a row. The activity monitor will measure only your daughter's physical activity levels. A picture of the activity monitor is attached.

2. Fill out a survey to report what physical activities she did during the last three days.

3. Fill out surveys that will measure factors related to her physical activity or exercise.

4. Have height, weight, and body fat measured.

5. Ride a stationary bike for about 10 minutes**.** This may be scheduled to take place outside of school hours.

6. Respond to questions about any serious injuries that may have occurred during the last three months.

REASONS WHY YOUR CHILD MAY NOT BE ALLOWED TO BE INVOLVED:
Your child should not take part in the measures listed above if she:

- Cannot read and understand the questions on the survey, which will be written in English.

- Has a physical or medical condition that might cause health problems during the bike test. These conditions are listed on the last page of this consent form.

Also, some medications may conflict with the value of the bike test. Your child may not be allowed to take part in the bike test if she is taking any of these medications.

EXPECTED RISKS AND DISCOMFORTS:
The bike test involves moderate exercise and minimal risk for healthy girls (i.e., no greater than those that would occur during physical education classes). The activity monitor will be attached to an elastic belt and worn around the waist over your daughter's clothing (see attached picture). The small size of the activity monitor makes it highly unlikely that your child will feel any discomfort when wearing it. We will ask questions that deal with sensitive health issues, such as smoking. Some students may not feel at ease answering these types of questions. In the unlikely event that a medical emergency occurs during the measures, we will follow routine school procedures.

EXPECTED BENEFITS:
The results of the TAAG study will advance our knowledge of physical activity levels of middle school girls.

COMPENSATION:
Your daughter will receive a small gift for returning the consent form even if she decides not to take part in the measures. Each girl who participates in the measures will also receive a small gift valued at about $____.

VOLUNTARY PARTICIPATION:
Whether your daughter takes part in the measures is your choice. Also, your daughter may choose not to take part in any or all of the measures at any time or for any reason. If after giving your consent, you decide to withdraw your daughter from the study, this will not hurt your future relations with the Name of University or your daughter's school.

CONFIDENTIALITY:
During the study, all of your daughter's data, including address and phone number, will be kept private and will not be shared with others outside the TAAG study. All data will be stored safely in locked files. A number will be assigned to each child at the start of the study and this number will be used for record keeping and data analysis. Please note that we are required to inform you, in writing, if your daughter's height or body weight falls below the growth standards for girls her age. Also, if your daughter reports having a serious injury related to physical activity, a member of our research staff may call you if more information is needed. For these reasons, it is very important that you provide your mailing address and phone number on the last page of the consent form. After the study is completed, the data will be available to other researchers. However, we will never share any information that could be linked to your daughter. Your daughter's name will never appear in any reports or published papers.

CONTACT PERSONS FOR QUESTIONS YOU MAY HAVE ABOUT THE RESEARCH STUDY:
You may ask questions about the study or anything you do not understand. If you do not have questions now, you may ask later. During the study, you will be told any new facts that could affect whether you want your child to stay in the study. For more information about the research, you may contact Name, Project/Measurement Coordinator, at Phone Number or E-mail; or Name, Principal Investigator, at Phone Number or E-mail.

Please complete and return this portion only.

Signing your name below means that you have read this consent form and have had a chance to ask any questions. Also, your daughter's signature on the attached *Child Assent Form* means that she has agreed to take part in the TAAG measures. If you agree to allow your daughter to be involved, you may change your mind and withdraw your consent at any time. As mentioned before, your daughter should not take part if she cannot read and understand the questions on the survey, which will be written in English.

1) **Will your child be able to read and understand questions written in English?** ☐ YES ☐ NO

Also, your daughter should not take part in the bike test if she has a physical or medical condition that might cause health problems during the test.

2) **Has a doctor told your daughter to avoid exercise for health reasons?** ☐ YES ☐ NO

3) **Does your child have any of the following conditions?** (We do not need to know which of these your child has.) ☐ YES ☐ NO

- Muscle, bone, or joint problems that limit her ability to ride a bike?
- Heart problem that requires a limit in physical activity?
- Fainting with exercise in the past 6 months?
- Uncontrolled asthma?
- Very high blood pressure that is not controlled on medication?
- Diabetes with frequent very low or very high blood glucose levels (sugars)?
- Thyroid problems not controlled on medication?
- Seizures not controlled on medication?
- Sickle cell disease, cystic fibrosis, anorexia nervosa, severe kidney problems, or severe liver problems?
- A blood condition that increases the risk of bleeding?

Finally, some medications may interfere with the value of the bike test. Your daughter may be excluded from the bike test if she is taking certain medications.

4) **Does your child take medication on a regular basis?** ☐ YES ☐ NO
If yes, please list medications here: _____

_____

Please mark one of the choices below:

____ **Yes**, I do consent to have my daughter to take part in ***all*** the measures.

____ **No**, I do not consent to have my daughter take part in *any* of the measures.

If you have selected 'Yes', please complete the information below:

Name of parent/guardian:

Last Name | First Name

Parent/Guardian Signature **Date** **Principal Investigator**

Name of child:

Last Name | First Name

Name of Child's Middle School:

Child's data of Birth:

Month-Day-Year

NOTE: We will NOT share your address or phone number with anyone outside of the TAAG studies.

Current address of child:

Street address | Apt. #

City | State | Zip -

Telephone - -

Permanent address of child (if different from the current address above):

Street address | Apt. #

City | State | Zip -

Who might know where you are should you move from your current address? Name of alternate contact person:

Last Name | | | | | | | | | | | | | | |

First Name | | | | | | | | | | | | | | |

Telephone | | | - | | | | - | | | | |

Relationship to Child | | | | | | | | | | | | | | |

Appendix 2: Sample child's assent form

Child's Assent Form

My parent or guardian has said it is okay for me to be in the project called Trial of Activity for Adolescent Girls (TAAG). This project will study the physical activity of girls in middle school. I understand that if I agree to take part in the measures, some people from Name of University will come to my school during the spring semester of 8th grade. They will ask me to take part in the measures listed below.

1. Wear an activity monitor all day for seven days in a row. (A picture of the activity monitor is shown on the last page.)

2. Write down the activities I did over the last three days.

3. Write down answers to questions that relate to being physically active.

4. Have my height, weight, and body fat measured.

5. Ride an exercise bike for about 10 minutes while my heart rate is being measured.

Being involved in the measures is up to me. I can choose to quit or ask to stop at any time. Also, if I do not like any of the questions, I do not have to answer them. No one will be upset if I don't want to be in the project. If I decide not to be in this project, it will not affect my schoolwork, grades, or what my teacher thinks of me.

Please mark one of the choices below to tell us what you want to do:

____ Yes, I want to be in this project.

____ No, I don't want to be in this project.

I understand that if my height or body weight is below that of other girls my age, my parent or guardian will receive a letter telling them that. Also, I understand that if I report a serious injury related to physical activity, a university person might call my parent or guardian for more information. Only the university people working on this project will see the rest of my information.

I understand that I will receive a gift worth about $____ for my taking part in the measures.

By signing my name below, I agree to be involved in the TAAG measures.

_____	_____	_____
Child's Signature	**Date**	**Project Coordinator or PI**

Please print your last name, first name, and name of your school below:

Last Name | First Name

School

Appendix 3: Sample Memorandum of Understanding

MEMORANDUM OF UNDERSTANDING (MOU)
BETWEEN
(Name of school partner and the University)
FOR THE TRIAL OF ACTIVITY FOR ADOLESCENT GIRLS (TAAG)

TAAG Objective: To test the effectiveness of a coordinated school- and community-based intervention to prevent the decline in physical activity of girls in middle school.

This Memorandum of Understanding (MOU) identifies elements of the TAAG partnership that will be important in completing this research project.

ELEMENTS OF THE PARTNERSHIP:

(Notice to TAAG Field Centers: This is a sample MOU that you can tailor to meet specific site requirements. ***The asterisks (*) below mark mandatory items, which must be included in each Field Center's school MOUs; however, you may reword them, as desired.*** *It is assumed that the details of each item would be discussed with the school prior to presenting the MOU and would, therefore, not be delineated herein. The specific formatting of the MOU is customizable. Please exclude this statement, as well as all remarks and asterisks, from your final MOUs.)*

I. The TAAG *University Partner* agrees to:

FOR ALL SCHOOLS:

1. Provide an annual gift of appreciation to the school during the academic years 2002-03, 2003-04, 2004-05 and 2005-06. *

2. Conduct all TAAG activities in a safe, professional, and sensitive manner. All university TAAG staff will be clearly identified and follow all established school protocols in a manner agreed upon by school administration. *

3. Provide a summary of the study findings after the TAAG main trial is completed and the data are analyzed. *

FOR CONTROL SCHOOLS ONLY:

4. Provide TAAG intervention training and materials to school staff after the main trial is completed. *

FOR INTERVENTION SCHOOLS ONLY:

5. Provide annual staff development-training programs for school and community personnel. Programs will be directed toward implementation of the TAAG intervention procedures. *

6. Provide substitute teacher and travel reimbursements for teachers involved in staff development sessions. *

7. Provide a stipend to teachers or other school staff who facilitate and supervise TAAG activities after school or during the summer.

8. Provide physical activity equipment and materials needed to implement the TAAG intervention. *

9. Provide start-up funds to facilitate the TAAG school-community agency-university partnership process.

10. Explore funding opportunities within the community to assist with physical activity program intervention costs and to maintain the TAAG intervention after the main trial has been completed.

11. Appoint a staff member to serve as a member of the school-community agency-university partnership. This representative will attend collaborative partnership meetings to develop and implement the TAAG physical activity intervention for middle school girls. *

12. Conduct yearly evaluations of the TAAG intervention.

II. The *School Partner* agrees to:

FOR ALL SCHOOLS:

1. Accept that the school will be equally likely, by random allocation, to be assigned to either the control (delayed intervention) or the intervention group. *

2. Support student recruitment and measurement activities, which will take place at the school during the spring of 2003, 2005, and 2006. *

3. Identify a school staff member who will serve as the liaison for coordinating TAAG activities at their school. This school representative will assist university research staff in scheduling the recruitment and measurement activities at the school. *

4. Provide a classroom or other adequate physical space for TAAG measurement activities to take place during the spring of 2003, 2005, and 2006. *

5. Participate in an interview to provide information on school policies and practices related to physical activity. This interview will be conducted once or twice each year and involve a school administrator, a PE representative, and a health education teacher. *

6. Have routine school procedures for responding to acute injuries and medical emergencies that may occur on school grounds or during student participation in school-sponsored activities. *

7. Have a procedure for reporting to study personnel acute injuries or emergencies, related to physical activity, that may occur on school grounds or during student participation in school-sponsored activities. If routine procedures do not already exist, the *University Partner* will assist in their development. *

INTERVENTION SCHOOLS ONLY:

8. Identify a school staff member who is willing to serve as the intervention liaison and who will work with TAAG university staff and other community partners to implement all TAAG activities both during school and outside of school. *

9. Provide physical space, when feasible, for TAAG activities occurring at the school.

10. Allow school staff (e.g., all physical education instructors and health educators) to attend annual staff development training to learn about the TAAG intervention methods and materials. The planned training is as follows: *

    a. Physical Education: 1 full day + two 4-hr booster sessions each year (2003-04 and 2004-05)

    b. Health Education: 1 full day session + 1 half-day booster session each year (2003-04 and 2004-05)

11. Implement TAAG health education lessons and physical education program throughout the 2003-04 and 2004-05 school years. *

12. Allow other school staff members, who are willing, to work with TAAG university staff and community partners with the purpose of developing physical activity programming outside of school time.

13. Allow a TAAG project staff member to observe occasional physical education classes, health education classes, and other TAAG activities at the school. *

14. Allow school personnel to complete confidential, written evaluations of the TAAG activities intermittently during the intervention period. *

15. Allow TAAG promotional materials to be posted and distributed within the school. *

16. Allow University staff to provide on-site assistance during the intervention to include feedback to teachers, technical support, model lesson segments, and answer questions. *

The terms of this MOU will be _____ through _____.
(mo/day/yr) *(mo/day/yr)*

This MOU shall be reviewed annually to ensure that it is fulfilling its purpose and to make any necessary revisions.

On behalf of the organization I represent, I am signing this MOU to be a partner in the TAAG intervention.

_____	_____	_____	_____
School partner representative	**Date**	**University representative**	**Date**
_____		_____	
Title		**Title**	

Cc: School, University (TBN)

Appendix 4: Data Analysis

A.4.1. Statistical model

For the primary analysis of MET-weighted minutes of MVPA, the data are analyzed in two stages and as though there is no overlap among girls measured in the 6th and 8th grade cross-sectional samples. This two-stage approach serves two useful functions. First, it avoids many of the complexities inherent in a single-stage mixed-model regression analysis of data from a multi-center group-randomized trial (Murray, 1998b). Second, it mimics an analysis of covariance performed on 8th grade data, with regression adjustment for 6th grade values on the primary endpoint.

In the first stage, we regress the girl's MET-weighted minutes of MVPA on school, time (baseline or follow-up), their interaction, ethnicity and week of data collection; study condition is not included in that model:

$$\text{MVPA} = \text{school} + \text{time} + \text{time} \times \text{school} + \text{ethnicity} + \text{week} + \text{error} \qquad (1)$$

Here, all terms are modeled as fixed effects, except for week and residual error. Of interest in this first stage is the estimation of ethnicity-adjusted school means for MET-weighted minutes of MVPA, estimated for each school at 6th grade and at 8th grade. We include ethnicity in Eq. 1 because we observed a substantial reduction in the school-level intraclass correlation (ICC) in the variance components substudy when we adjusted for ethnicity. We include week as a random effect because we observed a substantial reduction in the same ICC in the baseline survey when we included week as a random effect. Given that the intraclass correlation is so strongly related to power, we want to take every opportunity to make it as small as possible. We adjust for ethnicity in a pooled analysis of 6th and 8th grade data, rather than in separate analyses, so as to standardize the results for the two surveys against the same reference distribution, here the average ethnicity distribution over time.

The second stage analysis is conducted on the 72 ethnicity-adjusted time x school means from the first stage. In a preliminary analysis, we look for evidence of a differential effect of the intervention among the six Field Centers by testing for an interaction between Field Center and condition, as detailed below in the section on tests of assumptions. If there is a significant interaction between Field Center and condition, we cannot pool across Field Centers and instead must report results separately for each Field Center. However, we do not anticipate any evidence of such heterogeneity, so that we can remove the interaction term and proceed with a main-effects model.

In this main-effects model, we regress the follow-up school mean MET-weighted minutes of MVPA on study condition, adjusting for the baseline school mean and stratifying on site (i.e., Field Center):

$$\text{MVPA}_{\text{follow-up}} = \text{condition} + \text{MVPA}_{\text{baseline}} + \text{site} + \text{school} \qquad (2)$$

Here, condition and baseline MVPA are fixed effects while site and school are random effects; in this model, there is no residual error beyond school, and we use the term school instead of residual error to avoid confusion between Eq. 1 and Eq. 2. This model provides an unbiased test of the intervention effect given a proper randomization and a well-executed study. It also provides the statistical basis for inferences to sites and schools like those included in TAAG.

Eq. 3 expresses Eq. 2 using the notational scheme of Murray (Murray, 1998b). In adapting that notation for the stage-two models, we omit all references to Member $\mathbf{M}_i$ (i=1…m), here girl, and to Week $\mathbf{W}_q$ (q=1…w) because the second-stage analysis involves only the 72 adjusted time x school means. In that scheme, Group, $\mathbf{G}_k$ (k=1...g), identifies the unit of assignment, here the school. Condition, C_l (l=1...c), identifies the study conditions, here treatment and control. Stratum, $\mathbf{S}_p$ (p=1...s), identifies site, which is the stratification factor in the primary analysis. The regression adjustment for the baseline school mean on the dependent variable is identified as $\beta_x\left(X_{xk} - \overline{X}_{x\cdot}\right)$. All random effects are in bold type and all fixed effects are in plain type.

$$Y_{k:lp} = \mu + C_l + \beta_x\left(X_{x:k:lp} - \overline{X}_{x\cdots}\right) + \mathbf{S}_p + \mathbf{G}_{k:lp} \qquad (3)$$

The degrees of freedom (df) and expected mean squares are shown below, assuming balanced data. There are c=2 conditions, s=6 sites, and there is 1 covariate. The number of districts per site and the number of girls per school play no role in this second-stage analysis. The (c-1)(s-1) degrees of freedom not used for the condition x site interaction fall to the school-level error term (Murray, 1994). With an unlimited number of schools, the degrees of freedom for school would be cs(g-1)+(c-1)(s-1); however, when the total degrees of freedom are limited to 36, and we use 8 degrees of freedom for the intercept, condition, strata and the covariate, we have only 28 left for school, and so the result of that formula must be reduced by 1. Note that in Eq. 3 and in the EMS table below, we do not include the usual ε, σ_e^2, or MS_e and instead use $\mathbf{G}_{k:lq}$, $\sigma_{g:cs}^2$, and $MS_{g:cs}$ to represent the error term in the second-stage analysis, because that error term is the school-level error.

Source		df		E(MS)	MS	
Generic	TAAG					
Intercept			$=1$			
Condition	Condition	$c-1$	$=1$	$\sigma_{g:cs}^2 + gs\sigma_c^2$	MS_c	
Strata	Site	$s-1$	$=5$	$\sigma_{g:cs}^2 + gc\sigma_s^2$	MS_s	(4)
Covariate	$\text{Activity}_{\text{baseline}}$		$=1$			
G:CS	School	$cs(g-1)$ $+(c-1)(s-1)-1$	$=28$	$\sigma_{g:cs}^2$	$MS_{g:cs}$	
Total			$=36$			

The test of the intervention effect is given by $MS_c/MS_{g:cs}$ and has 1 and 28 degrees of freedom.

A.4.2. Evaluation of model assumptions

A.4.2.1. Sources of variation

This plan assumes that there are four sources of random variation in our data (girls, week, schools, sites); if there are additional sources, the model is misspecified and the Type I and II error rates are unknown. One possible additional source is school district; however, as noted below, the Type I error rate is the same for analyses that attend to or that ignore any stratification on school district, so that ignoring it does not lead to a misspecification error. There are no other likely sources of random variation.

A.4.2.2. Error distributions

Under the General Linear Mixed Model, the two random effects in Eq 1 are assumed to be independent and distributed as $W_{q:k:lp} : N\left(0,\sigma_w^2\right)$ and $\varepsilon_{i:q:k:lp} \sim N\left(0,\sigma_e^2\right)$; these random effects allow for random variation among observations taken on girls in the same school and for correlation among observations taken on girls measured in the same week. The two random effects in Eq 3 are assumed to be independent and distributed as $\mathbf{G}_{k:lp} \sim N\left(0,\sigma_{g:cs}^2\right)$ and $\mathbf{S}_p \sim N\left(0,\sigma_s^2\right)$; these random effects allow for correlation among observations taken on girls in the same school and for correlation among observations taken on girls in the same site. These independence assumptions are reasonable, as the major sources of dependence expected in the data are modeled explicitly in the form of the terms representing week, school and Field Center. The model is robust to violations of normality at the level of the residual error so long as there are at least four schools per condition and 20 observations per school (Hannan, 1996), a requirement that is easily exceeded in TAAG. The model is robust to violations of normality at the level of the school so long as the number of schools in each condition is the same (de Moor, 1999), a requirement that is also easily met in TAAG, so long as none of the TAAG schools drop out of the study before the trial is over. Similarly, the model is robust to violations of normality at the level of the week so long as the number of weeks is the same in each school; that requirement is easily met either by constraining the number of weeks to be three or by collapsing later weeks into the third week.

A.4.2.3. Regression adjustment

The model makes the usual assumptions regarding the covariate (linear relationship to the endpoint, homogenous regression slopes across conditions and schools, independent of condition). These assumptions are also reasonable given that the covariate in the first stage is precisely measured (dummy-coded indicators for ethnicity) and that the covariate in the second stage is the baseline school mean for activity. Even so, we plan to test for linearity and homogeneity of regression slopes to ensure that these assumptions are met.

A.4.2.4. Homogeneity of the intervention effect across Field Centers

Eq. 3 assumes homogeneity of the intervention effect across Field Centers. The test for a condition x site interaction requires adding that interaction to Eq. 3; that term uses 5 degrees of freedom, reducing the school-level error degrees of freedom from 28 to 23. Because site is a random effect, the condition x site interaction is also a random effect. To evaluate the significance of random effects (Self, 1987), suggest fitting maximum likelihood models with and without the random effect of interest, then testing the difference in the -2 log-likelihoods via a likelihood ratio chi-square test (Self, 1987). Dividing the usual p-value in half provides a one-tailed test.

A.4.2.5. Errors in measurement

Eq. 3 includes the baseline school mean of MET-weighted minutes of MVPA as a covariate. A possible concern is that mismeasurement of the baseline mean level might bias the estimates of intervention effect and its standard error. The issue was addressed by a Monte Carlo simulation study. The Monte Carlo study was conducted on unweighted minutes of MVPA, not MET-weighted minutes of MVPA, but we do not think that weighting is pertinent to the issue of errors-in-measurement.

Using prior estimates of means, variance, and intraclass correlation for schools taken from

the calibration substudy, a Monte Carlo process generated a perturbed baseline school mean MVPA, and a follow-up school mean correlated 0.2 with the true baseline mean, but also perturbed by error. The hypothesized effect of intervention was set at 2.29 minutes for unweighted minutes of MVPA, equivalent to 10% of the mean, in keeping with our proposed intervention effect. Two investigators independently implemented this model, one using SAS PROC REG, the other using SAS PROC IML. Sample sizes were varied from 120 down to 20 in steps of 20; the number of Monte Carlo runs was generally 12,000 or more, but for the smaller sample sizes only 6,000 runs were made.

The results indicated that the estimates of the intervention effect were always unbiased. Down to 60 girls sampled per school, the error-in-measurement of the covariate degraded expected power by less than 0.3%. For sample sizes 40 or 20 the degradation was less than 1.5%, but the expected power at those sample sizes is unacceptably low in any event.

We feel confident that, at the average sample size of 120 per school at posttest to be used in the TAAG study, the use of the baseline school mean MVPA as a covariate in a two-stage analysis introduces only a very small increase in variance, even if that baseline mean is computed on 40-60 girls per school. MET-weighting minutes of MVPA does not have much impact as long as 1) the coefficient of variation of MET-weighted minutes of MVPA is similar to that for unweighted minutes of MVPA, and 2) the intraclass correlation is similar or greater.

A.4.2.6 Equal weighting

We do not propose to weight the school means in the second stage of the analysis. While we recognize that there will be some variation in the number of girls measured in each school across the six field centers, our selection criteria will limit this variation so that the ratio of the largest and smallest number of measurements per school is no more than 2:1. Under these circumstances, weighting would have little effect and so is not required.

A.4.3. Attrition, refusals, and other missing data

Attrition is a common problem in health promotion and disease prevention studies because most rely upon a cohort design in which the same participants are followed over time to assess the impact of the intervention. The TAAG design relies upon two independent cross-sectional surveys, one of 6th graders and a second of 8th graders two years later. Because those data are analyzed as though there was no overlap between the two samples, attrition does not pose the same kind of threat to the primary analysis plan proposed for TAAG as it does with the more traditional cohort design and cohort analysis. Even so, attrition is a potential problem in TAAG for other reasons. Certainly, if there is substantial in and out-migration in the participating schools, the average level of exposure of students measured in the 8th grade is less than if the in- and out-migration rates were lower, with adverse consequences in terms of any expected intervention effect. For this reason, TAAG has established eligibility and exclusion criteria to limit the degree of in- and out-migration (cf., Section 5). We have also made conservative projections about the partial-dose effect of the intervention for girls measured in 8th grade who were not enrolled in the intervention school in 6th or 7th grade.

Differential attrition remains a concern for the primary analysis for TAAG, even though it is not a cohort analysis. If more low-activity girls leave the intervention schools or more high-activity girls to leave the control schools, an analysis ignoring that pattern might suggest an

intervention effect even if the intervention was completely ineffective. The opposite pattern could mask an intervention effect. As noted above, we plan a cohort design for some of our analyses, particularly for analyses involving mediation. The first step is to identify as 8th graders all of the girls who completed the 6th grade survey and who remain in the participating schools. All of those girls are recruited to participate in the 8th grade survey, even if not otherwise selected as part of the independent cross-sectional sample of 8th graders. This allows us to determine with good precision which girls remained in their original school and which girls did not. We can compare those two groups of girls, using their 6th grade data, to look for any evidence of differential attrition. In particular, we propose a mixed-model logistic regression analysis to perform a propensity score analysis (Rosenbaum, 1995) in which we predict status (still enrolled in original school vs other) given a variety of variables measured at baseline, including the girl's activity level. We can examine the results to evaluate the manner in which the girls who remain differ from those who left and save the predicted values, which indicate the propensity to leave the original school. This allows us to repeat the mediation and moderation cohort analyses, adjusting for the propensity score, and compare the results of those analyses to the original results. The analyses that include the propensity scores estimate effects as though the two study conditions were balanced in terms of propensity to leave. Adjustment for such a propensity score does not eliminate differential attrition, but it can help reduce the threat to internal validity that would exist if the propensity to leave were different across the conditions.

Some girls may be expected to refuse to participate in the data collection activities, both at 6th grade and at 8th grade. Because the 6th grade data are collected prior to randomization, we need not be concerned about differential refusal rates as a threat to internal validity. However, differential refusal at 8th grade is a threat, just as described above for differential attrition. Unfortunately, we cannot use the same propensity score analysis to address the problem of refusals, because we won't have 6th grade data on all the girls who refuse to participate in the 8th grade data collection. We can use such data for girls measured at baseline who are selected for the follow-up survey and plan to explore those data for evidence of differential refusals, as noted above. If we find such evidence, we plan to perform a secondary analysis using multiple imputation methods to impute an activity score using school- and individual-level predictor variables for girls who refuse measurement at follow-up.

We anticipate other important types of missing data as well. In particular, we recognize from our experience in Phase I that there are occasional missing CSA data for many girls who otherwise fully cooperate in the 6th or 8th grade data collection activities. We have seen, for example, considerable variability in the degree to which girls comply with the protocol for wearing their CSA monitor. This can result in a substantial imbalance in the amount of physical activity data collected from each girl, not only in terms of total hours, but also in terms of the timing of the observations. Some girls may be missing data at times when we know girls are active, while others are missing data at times when we know girls tend to be inactive. We propose methods based on the expectation maximization (EM) algorithm to replace occasional missing data within a CSA record provided by an otherwise compliant girl. We have adapted this methodology to the unique features of TAAG in a methodological investigation to be published as a separate paper. We divided each day into five intervals, allowing the beginning and ending of the intervals to vary according to whether the day is a weekday or a weekend. We then had *a priori* criteria for

the amount of data that must be available (in minutes) in order to accept the observed data. Where a girl did not meet the criteria for a given interval, data were imputed using the EM algorithm, using information from that girl as well as from the other girls who were not missing data during the same time period on the same day. We evaluated our method using the data from the variance components substudy. After creating non-ignorable missing data by hiding selected periods for selected girls, we applied the imputation method and compared the results to the observed complete data set. Average discrepancies were quite small for MET-weighted minutes of MVPA, and the correlation between the imputed value and the observed value was quite high, indicating that the methodology was working as intended.

A.4.4. Alternative analytic plans

A.4.4.1. Variations on the primary analysis as proposed

We considered stratification on school district as part of the primary analysis. As is true in the case of matching (Diehr, 1995; Proschan, 1996), the Type I error rate is the same for analyses that attend to or that ignore any stratification on school district. In other words, we are not required to include the stratification factor in the analysis in order to avoid bias. As a result, we can make this decision based on power or other considerations. One consideration is that the pattern of schools and school districts is likely to vary across Field Centers. Some Field Centers may have a single school from each of six districts, while others may have six schools from a single school district. Still other Field Centers may have multiple schools in some districts, but the number of districts and the number of replicate schools in each district varies across Field Centers. Given the heterogeneity expected in the pattern of schools and districts across centers, it is not likely that it is even possible to stratify on school district within each Field Center, though it may be possible in some Field Centers. A second consideration involves power. Power in TAAG is closely related to the degrees of available for the error term in the primary analysis. Error degrees of freedom necessarily is smaller in any analysis that stratifies on school district compared to an analysis that ignores such stratification. If each Field Center has two schools per school district, we have a paired design and the error degrees of freedom are only 16, compared to the 28 available ignoring district. Given the limited number of error degrees of freedom available for TAAG, this also argues strongly against stratification on district in the analysis.

We also considered modeling Field Center as a fixed effect rather than as a random effect. However, the expected mean squares for the test of condition are the same for the primary analysis whether site is modeled as a fixed or as a random effect. As such, there is no downside either in terms of loss of degrees of freedom or variance inflation for modeling Field Center as a random effect. The major benefit is that it provides a statistical basis for generalizing any findings to other schools like the TAAG schools. For these reasons, we rejected the idea of modeling Field Center as a fixed effect.

A.4.4.2. Alternative design and analytic models

As noted in Section 4, we considered several alternative designs for TAAG. The design suggested in the RFA was a traditional cohort design, with baseline data from 6th graders and follow-up measurements on the same girls through 8th and 9th grades. Analysis would have been via mixed-model analysis of covariance, regressing 8th or 9th grade physical activity measures on condition and the baseline activity measure, with site and school included as random effects in a one-stage analysis. While the traditional cohort design

and analytic plan have much to offer, a serial cross-sectional design is conceptually more consistent with the purpose of the intervention, which is to create a school-community environment conducive to promoting physical activity. This concept leads to a focus on schools rather than on individual girls. In addition, we were concerned about attrition, about the need to impute data for girls lost to follow-up in a cohort design under the intention to treat principle, and about the effect of such imputation on power. Our projections indicated that the effect would have been substantial, so that given a 30% attrition rate over two years, power would have been very adversely affected for a study involving 36 schools and approximately 120 girls per school at follow-up. Indeed, it was that analysis that led us to consider a number of other design and analytic models, and ultimately, to the design and analytic model described in this protocol.

We considered several hybrid designs, involving both cohort and cross-sectional components. For example, we considered collecting data from two independent cross-sections, but taking advantage of the adventitious cohort created by the expected overlap in the two samples, so that we would analyze the overlapping students as a cohort and the others as a serial cross-section, then pool the intervention effect estimates. We considered expanding the basic cohort design by adding additional girls at 8th grade, selected at random to represent their schools; here too, we would analyze the cohort data and cross-sectional data separately, then pool the intervention effect estimates. None of these hybrid designs proved satisfactory, based on costs and power, and indeed, the proposed design emerged from these considerations as the strongest candidate, both from the perspective of internal validity and from the perspective of power and cost.

A.4.5. Effect Modification

Effect modification in TAAG can involve an individual-level variable or a school-level variable. The former requires an adaptation of the primary analysis to accommodate post-hoc stratification at the level of the girl in the first stage of the analysis. The latter requires an adaptation of the primary analysis to accommodate post hoc stratification at the level of the school in the second stage of the analysis. These modifications are slightly different, and so we discuss them separately.

At the same time, effect modification is the same thing, at least conceptually, whether it involves an individual-level or a school-level variable. So significant effect modification means that the stratum-specific effects of the intervention are different from one stratum to another. If we stratify girls on baseline BMI ($\leq$the median vs >the median), significant effect modification means that the intervention effect was greater in one half of the girls than in the other. And if we stratify schools on % free and reduced lunch ($\leq$the median vs >the median), significant effect modification means that the intervention effect was greater in one half of the schools than in the other.

To guide our examination of the analytic and power issues, we must anticipate the magnitude of any effect modification that we judge important to detect. Given that the overall intervention effect is expected to be 10%, we assume that one stratum had an effect twice as large as, or more, than the other stratum. With an average of 10%, that means stratum specific effects of 6.67% and 13.34%, respectively, to define a minimum interaction effect of 6.67% (=13.34%-6.67%).

We know that power is reduced in any interaction analysis compared to the primary analysis, which is a main effect analysis. We also know that it is worse for school-level effect interaction than for girl-level interaction. The reasons are serial:

- The intervention effect for the interaction model is smaller, by about one-third, than we posited for the main effect. We could change that, but larger effects are more difficult to achieve.
- For two levels of the stratification factor, the intervention effect is defined as the net difference upper(I-C)-lower(I-C), where upper and lower refer to those above and below the study-wide median on the stratification factor. This intervention effect involves twice as many means as were involved in the intervention effect in the primary analysis, thereby increasing the standard error of the intervention effect, other factors constant. The situation only grows worse with more than two levels of the stratification factor.
- With girl-level stratification in the main nested cross-sectional design, the number of schools per condition x stratum x Field Center is 3, as it was per condition x Field Center in the primary analysis; however, the number of girls per condition x stratum x Field Center is only half what it was per condition x Field Center in the primary analysis.
- With school-level stratification in the main cross-sectional design, the number of schools per condition x stratum x Field Center is reduced by half compared to the number per condition x Field Center in the primary analysis; however, the number of girls per condition x stratum x Field Center remains at the same level as it was per condition x Field Center in the primary analysis.

A.4.5.1. Post hoc stratification for individual-level moderators

For individual-level moderators, we distinguish between moderators that are immutable and those that can change over time.

A.4.5.1.1. Immutable moderators

For immutable factors, such as age or ethnicity, we look at moderation in the main cross-sectional design by adapting our primary analysis to include post hoc stratification on the moderator. In the first stage of the analysis, we stratify girls based on a median split on age, using the grade-specific study-wide median for the baseline and follow-up data, respectively; as a result, stratum is crossed with time and school. We then regress the girl's MET-weighted MVPA on school, time (baseline or follow-up), stratum (hi or lo), their interactions, ethnicity and week of data collection; study condition is not included in the model:

$$\begin{aligned} \text{MVPA} = \ & \text{school} + \text{time} + \text{stratum} + \text{ethnicity} \\ & + \text{time} \times \text{school} + \text{time} \times \text{stratum} + \text{school} \times \text{stratum} \\ & + \text{time} \times \text{school} \times \text{stratum} + \text{week} + \text{error} \end{aligned} \qquad (5)$$

Here, all terms except for week and residual error are modeled as fixed effects. Of interest in this first stage is the estimation of ethnicity-adjusted school means for MVPA, estimated for each school at each combination of time x stratum.

Given c=2 conditions, f=6 Field Centers, s=2 strata, t=2 time points, and g=3 schools per Field Center per condition, we have 144 ethnicity-adjusted time x stratum x school means from the first stage. The 72 follow-up means provide the values for the dependent variable in the second stage, while the 72 baseline means are used as values for the covariate $\text{MVPA}_{\text{baseline}}$. The full model for the second stage analysis is:

$$\begin{aligned} MVPA = {} & \text{condition} + MVPA_{\text{baseline}} + \text{fieldcenter} \\ & + \text{condition} \times \text{fieldcenter} + \text{school}(\text{condition} \times \text{fieldcenter}) \\ & + \text{stratum} + \text{stratum} \times \text{condition} + \text{stratum} \times \text{fieldcenter} \\ & + \text{stratum} \times \text{condition} \times \text{fieldcenter} + \text{stratum} \times \text{school}(\text{condition} \times \text{fieldcenter}) \end{aligned} \quad (6)$$

Condition, baseline MVPA and stratum are fixed effects while Field Center and school are random effects; in this model, there is no residual error beyond school, and we use the term school instead of residual error to avoid confusion.

In a preliminary step, we evaluate several interaction terms, which we expect to be zero. As in the primary analysis, we evaluate the condition x center interaction; in addition, we evaluate the stratum x center and condition x stratum x center interactions. If any of those interactions are significant, we interpret the results based on the full model. However, if those interactions are not significant, we delete those terms from the second-stage analysis and pursue a reduced second-stage model:

$$\begin{aligned} MVPA = {} & \text{condition} + MVPA_{\text{baseline}} + \text{fieldcenter} + \text{school}(\text{condition} \times \text{fieldcenter}) \\ & + \text{stratum} + \text{stratum} \times \text{condition} + \text{stratum} \times \text{school}(\text{condition} \times \text{fieldcenter}) \end{aligned} \quad (7)$$

The expected mean squares for this model are shown below:

The degrees of freedom total 72 because there are 72 follow-up school x stratum means. The degrees of freedom that are otherwise used by the condition x Field Center interaction fall to the school term, bringing the total for that term to 29. The degrees of freedom that are otherwise used by the stratum x Field Center and condition x stratum x Field Center interactions fall to the stratum x school term, bringing the total for that term to 33.

In this analysis, the term of interest is the stratum x condition interaction, as it reflects any differential intervention effect between the strata. It is tested against the stratum x school interaction, with 1 and 33 degrees of freedom. The intervention effect is estimated as the net difference among four adjusted posttest means: upper(I-C)-lower(I-C), where upper and lower refer to the two strata.

Source	df		E(MS)	MS
Intercept		$=1$		
Condition	$c-1$	$=1$	$s\sigma^2_{g:cf} + fsg\sigma^2_c$	MS_c
$MVPA_{baseline}$		$=1$		
FieldCenter	$f-1$	$=5$	$s\sigma^2_{g:cf} + sgc\sigma^2_f$	MS_f
School	$cf(g-1)=24$		$s\sigma^2_{g:cf}$	$MS_{g:cf}$
	$+(c-1)(f-1)=5$		from condition x field center	
		$=29$		
Stratum	$s-1$	$=1$	$\sigma^2_{sg:cf} + fgc\sigma^2_s$	MS_s
Condition × Stratum	$(s-1)(c-1)$	$=1$	$\sigma^2_{sg:cf} + fg\sigma^2_{sc}$	MS_{sc}
Stratum × School	$(s-1)cf(g-1)=24$		$\sigma^2_{sg:cf}$	$MS_{sg:cf}$
	$+(s-1)(f-1)=5$		from stratum x field center	
	$+(s-1)(c-1)(f-1)=5$		from condition x stratum x field center	
	-1	$=33$	correction for school - level covariate	
Total		$=72$		

(8)

Given the same assumptions as for the primary analysis, and with the additional assumption that stratification reduces the girl and school-level variances by 10%, we calculate the power for the interaction effect in this stratified version of the primary analysis applied to the nested cross-sectional design. Table 1 presents power for an interaction effect of 6.67% in an analysis of girl-level effect modification.

Table 1. Power projected for girl-level effect modification					
ICC	Girls/School Invited to Participate at Follow-up				
	90	105	120	135	150
0.010	30%	32%	34%	36%	37%
0.003	40%	44%	48%	52%	55%
0.000	47%	53%	59%	64%	69%

A.4.5.1.2. Moderators that could change over time

There are also moderators that could change over time at the individual level, such as BMI. Evaluation of moderation for such variables is complicated in the main nested cross-sectional design because we have different girls at baseline and follow-up. It is not at all clear that a median split of the sample at follow-up necessarily divides the girls in the same way they would have been divided at baseline, even if the same median were used for both samples. Girls change over time on variables like BMI, and some girls who might have been below the median if measured at baseline might be above the median if measured at follow-up. Application of the analysis described above for an immutable moderator would require the assumption that change in BMI over time did not affect the

allocation of girls into the strata. It would also require the assumption that the intervention did not affect BMI. If those assumptions are not acceptable, and they likely are not, then it would be better to restrict evaluation of effect modification by such changeable moderators to the cohort analysis, where girls can be stratified according to their baseline level. Power for interactions in those models is improved to the extent that the cohort analysis is stronger, but is harmed to the extent that the cohort sample is appreciably smaller.

A.4.5.2. Post hoc stratification for school-level moderators (e.g., % free and reduced lunch)

It is not possible to stratify girls within a school on a school-level moderator, because all girls in the same school have the same value on that moderator. As a result, stratification for school-level moderators must occur at the second stage; the first stage of this analysis is identical to that proposed for the primary analysis. We regress the girl's MET-weighted MVPA on school, time (baseline or follow-up), their interaction, ethnicity and week of data collection; study condition is not included in that model:

$$\text{MVPA} = \text{school} + \text{time} + \text{time} \times \text{school} + \text{ethnicity} + \text{week} + \text{error} \qquad (9)$$

Here, all terms are modeled as fixed effects, except for week and residual error. Of interest in this first stage is the estimation of ethnicity-adjusted school means for MVPA, estimated for each school at 6th grade and at 8th grade.

Given c=2 conditions, f=6 Field Centers, t=2 time points, and 3 schools per Field Center per condition, we have 72 ethnicity-adjusted time x school means from the first stage. The 36 follow-up means provide the values for the dependent variable in the second stage, while the 36 baseline means are used as values for the covariate $\text{MVPA}_{\text{baseline}}$. We stratify the schools based on a median split of the baseline school-level % free and reduced lunch, using the study-wide median. Stratification at the school level results in an uneven distribution of schools among the condition x stratum x Field Center cells, with an average of g=1.5 schools per cell, but school remains balanced for all main effects. We then conduct a second-stage analysis on those stratified means. The full model for the second stage analysis is:

$$\begin{aligned}\text{MVPA} = {} & \text{condition} + \text{MVPA}_{\text{baseline}} + \text{fieldcenter} + \text{stratum} \\ & + \text{condition} \times \text{fieldcenter} + \text{condition} \times \text{stratum} + \text{stratum} \times \text{fieldcenter} \\ & + \text{stratum} \times \text{fieldcenter} \times \text{condition} \\ & + \text{school}(\text{condition} \times \text{stratum} \times \text{fieldcenter})\end{aligned} \qquad (10)$$

Condition, baseline MVPA and stratum are fixed effects while Field Center and school are random effects; in this model, there is no residual error beyond school, and we use the term school instead of residual error to avoid confusion.

In a preliminary analysis, we evaluate several interaction terms, which we expect to be zero. As in the primary analysis, we evaluate the condition x center interaction; in addition, we evaluate stratum x center and stratum x center x condition interactions. If any of those interactions are significant, we interpret the results based on the full model. However, if those interactions are not significant, we delete those terms from the second-stage analysis and pursue a reduced second-stage model:

$$\begin{aligned}\text{MVPA} = {} & \text{condition} + \text{MVPA}_{\text{baseline}} + \text{fieldcenter} + \text{stratum} \\ & + \text{condition} \times \text{stratum} + \text{school}(\text{condition} \times \text{stratum} \times \text{fieldcenter})\end{aligned} \qquad (11)$$

The expected mean squares for this model are shown below:

Source	df		E(MS)	MS
Intercept		$=1$		
Condition	$c-1$	$=1$	$\sigma^2_{g:csf} + fsg\sigma^2_c$	MS_c
$MVPA_{baseline}$		$=1$		
FieldCenter	$f-1$	$=5$	$\sigma^2_{g:csf} + sgc\sigma^2_f$	MS_f
Stratum	$s-1$	$=1$	$\sigma^2_{g:csf} + gcf\sigma^2_s$	MS_s
Condition × Stratum	$(c-1)(s-1)$	$=1$	$\sigma^2_{g:csf} + gf\sigma^2_{cs}$	MS_{cs}
School	$cfs(g-1)=12$		$\sigma^2_{g:csf}$	$MS_{g:csf}$
	$+(c-1)(f-1)=5$		from condition x field center	
	$+(s-1)(f-1)=5$		from stratum x field center	
	$+(s-1)(c-1)(f-1)=5$		from condition x stratum x field center	
	-1	$=26$	correction for school - level covariate	
Total		$=36$		

(12)

The degrees of freedom total 36 because there are 36 follow-up school means. The degrees of freedom that otherwise are used by the condition x Field Center, stratum x Field Center, and condition x stratum x Field Center interactions fall to the school term, bringing the total for that term to 26.

In this analysis, the term of interest is the condition x stratum interaction, as it reflects any differential intervention effect between the strata. It is tested against the school term, with 1 and 26 degrees of freedom. The intervention effect is estimated as the net difference among four adjusted posttest means: upper(I-C)-lower(I-C), where upper and lower refer to the two strata.

Given the same assumptions as for the primary analysis, and with the additional assumption that stratification reduces the girl and school-level variances by 10%, we calculate the power for the interaction effect in this stratified analysis. Table 2 presents power for an interaction effect of 6.67% in an analysis of school-level effect modification.

Table 2. Power projected for school-level effect

ICC	Girls/School Invited to Participate at Follow-up				
	90	105	120	135	150
0.010	16%	17%	18%	19%	20%
0.003	21%	24%	26%	28%	30%
0.000	25%	29%	32%	36%	39%

A.4.6. Reduced Sample Size at Baseline

We propose to invite 60 girls per school to participate in the CSA measurements at baseline and 120 girls per school at follow-up. We make this proposal after careful consideration of the implications of this plan for the design and analytic plans described in this Chapter.

A.4.6.1. Implications for the Primary Analysis

The primary analysis requires 72 time x school means from the first stage, to be used in a second stage analysis for intervention effects. This is unaffected by changing the size of the baseline sample, except that the baseline means are estimated with fewer observations than the follow-up means. The role of the baseline mean in the primary analysis is as a covariate, and to the extent that we increase variation in those means by reducing the number of observations contributing to each mean, we may reduce the over time correlation at the school level, and so reduce power. However, that reduction in power cannot be large: even if the over time correlation were reduced to zero, the loss of power is minimal, so that given 120 girls per school invited to participate and an intraclass correlation of 0.01, the power drops from 90% with 120 girls per school invited at baseline to 89% with 60 girls per school invited at baseline. This is reflected in the power analysis presented for the primary analysis in Section 14.

A.4.6.2. Implications for Secondary Analyses

Any secondary analysis employing the same analysis plan as proposed for the primary analysis is negligibly affected by reducing the size of the baseline survey sample, for the reasons noted above. The two secondary analyses that are proposed that employ a different analysis plan are those involving cohort analyses for mediation and for effect modification. Those analyses are adversely affected by reducing the size of the baseline sample, as that necessarily reduces the size of the cohort available for those analyses.

Under the original plan, we expected to have 49 girls per school available in the cohort if we selected 120 girls per school at baseline given a two-year attrition rate of 36% and annual refusal rates of 20%. That figure is reduced to 25 girls per school given only 60 girls per school at baseline. With 36 schools, that still provides 900 girls in the cohort, and the degrees of freedom for those analyses are unchanged, as they are still based on 36 schools. Power calculations for an intervention effect on a hypothesized mediator indicate that there is 80% power for an effect of 0.21 sd units and 90% power available for an effect of 0.25 sd units. An effect size of 0.25 sd units is widely considered to be small (Cohen, 1988). In contrast, our hypothesized intervention effect on MET-weighted minutes of MVPA of 10% represents an effect size of 14.5/86=0.17 sd units, which is quite small. This is why, the power for the mediation analysis is reasonable even with a reduced baseline sample.

Power for moderation is diminished by reducing the size of the baseline sample, but is already poor, so we don't do too much harm by reducing it further.

A.4.7. Power Calculations for PWC_{170}

Cardiovascular fitness will be assessed by the Physical Work Capacity 170 (PWC_{170}) cycle ergometer test. For the PWC_{170} test, the outcome measure will be the predicted power output based on a two-stage required to elicit a heart rate of 170 beats/min. We will express, PWC_{170} as kilogram-meters per minute per kilogram lean body weight (kg-m/min/kg). The estimates used in the power calculations below were from studies that controlled for total weight, rather than more precise measures of lean body weight that we will use. Therefore, the estimates shown here may be conservative.

Using a cross-sectional design, we will model the 36 school-level fitness means at the end of 8th grade as a function of treatment condition, site, and school. Power calculations were performed for a 2-sided type I error rate of 0.05. We assumed a mean and standard deviation for PWC_{170} of 11 $\pm$ 2.7, an ICC estimate of 0.01. The following table shows the power to detect a 5% or 6% difference in fitness at 8th grade as a function of the number of girls invited to participate in the fitness measure in each school, with the expectation that 80% will participate.

POWER FOR PWC_{170} - 36 Schools		
Girls Invited Per School	Intervention effect	
	5%	6%
60	0.88	0.96
50	0.84	0.94
40	0.78	0.91
30	0.68	0.83
20	0.53	0.69