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Study Title: Social Mechanisms for Promoting Youth Physical Activity: Applying a Developmental Framework for Improving Youth Health-Based Interventions (**NIH R21 HD077357**)

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**University of South Carolina
Human Subjects Research Proposal**

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A. Abstract

Physical inactivity has been identified as a primary contributor of childhood obesity and related diseases, with underserved youth (minority and low-income status) at greatest risk of inactivity and its health consequences. However, physical activity (PA) interventions have attained limited-to-no sustained behavior change and thus, have rarely affected targeted physiological or anthropometric health outcomes. Despite substantial research noting the importance of social influences and goals (e.g., being with, and making friends) on PA motivation and participation, PA-based interventions have almost exclusively emphasized approaches centered on constructs related to physical ability (e.g., mastery, self-efficacy). To date, little research has focused on understanding the contributions that social goal orientations and need for connectedness make toward promoting sustained youth PA. We argue that during adolescence, when orientation towards social relationships is strongest, the desire for social connections is a primary goal of action underpinning youth PA behavior and thus, a key mechanism to target for sustained behavior change. Thus, the proposed study will address limitations in previous research by targeting the social mechanisms needed within afterschool programs (ASPs) to promote sustained increases in youth PA. Application of social development research, Achievement Goal Theory, and Self-Determination Theory provides the conceptual framework for addressing key social mechanisms: 1) Friendship (and the development of PA-based social skills); 2) Group Belonging (peer connection), and; 3) Connection with ASP Staff. Primary components of the study include “Get to know you” sessions aimed at providing youth guided social opportunities to foster friendship-building skills, and to promote acceptance, cooperation, contribution, and friendship affiliation, and infusing a novel socially-oriented PA curriculum within ASP free play sessions. A total of 8 afterschool programs that serve a primarily underserved population will be asked to participate in the program. During the spring of year 1, (phase 1), staff and youth interviews, youth surveys, and systematic observations of ASP sites were conducted to develop the program curriculum and staff training (previously approved by IRB – **Pro00031648**). During this upcoming Fall of year 1 we plan to test our curriculum during an 8-week pilot (1 intervention and 1 control ASP (N=60 youth). During year 2 (Fall, 2015), after addressing measurement and/or implementation challenges identified in our Y1 pilot, a randomized study (3 intervention and 3 control ASPs) will be implemented to test the feasibility of the intervention approach (N=200 youth). Feasibility of our intervention should demonstrate that intervention youth report greater perceived connectedness and affiliation goal orientation toward PA from baseline to post-intervention. Observations of ASPs will test changes in the social climate from pre- to post-intervention and process evaluation will assess dose and fidelity. It is hypothesized that: 1) youth in the intervention (vs. comparison) will demonstrate greater improvements in positive PA affect, cognitions, and behaviors, and BMI from baseline to post-intervention, and; 2) targeted social mechanisms will mediate the effects of the intervention on changes in PA outcomes.

B. Specific Aims

Physical inactivity has been identified as a primary contributor of childhood obesity and related diseases,¹⁻⁷ with underserved youth (minority and low-income) at greatest risk of inactivity and its health consequences.^{6,7} However, physical activity (PA) interventions have attained limited-to-no sustained behavior change and thus, have rarely affected targeted physiological or anthropometric health outcomes.⁸⁻¹² Extensive research on sport participation shows highly engaged youth report an affiliation orientation towards PA, identifying social reasons and goals (e.g., being with, and making friends) as their primary motivations for participation, and defining PA competence as achieving these social goals.¹³⁻¹⁵ Despite substantial research noting the importance of social goals on PA-based self-determined motivation¹⁶⁻¹⁸ and participation,¹⁹⁻²¹ PA-based interventions have almost exclusively emphasized approaches centered on constructs related to physical ability (e.g., mastery, self-efficacy).²² To date, little research has focused on understanding the contributions that affiliation orientations (social goals) make toward promoting sustained youth PA.^{23,24} We argue that adolescents' desire for social connections is a primary goal of action underpinning their PA behavior and thus, a key mechanism to target for sustained behavior change. The Active by Choice Today (ACT) program, conducted by our investigative team is one of the first afterschool programs (ASPs) to implement a climate-based intervention based on Self-Determination theory which shows significant improvements in PA in underserved youth.²⁵⁻²⁸ However, limited sustained effects found post-intervention, and data from interviews with ACT staff and youth²⁸ which indicated the presence of several interpersonal barriers (e.g., cliques, teasing) to program effectiveness, suggests additional social climate components still need to be addressed. Systematic observations of ASPs using an observational tool that the PI has developed and tested²⁹⁻³¹ and additional interviews conducted with ASP staff and youth further suggests that targeting youth social goals (e.g., building friendships through PA) and social competencies (e.g., friendship-building skills) may be particularly effective for increasing and *sustaining* the PA of underserved youth. Thus, the proposed study aims to test the feasibility of expanding on the social climate approach of ACT to include three key "PA affiliation orientation" elements for increased and sustained youth PA: 1) Friendships (conceptualizing PA success/competence in terms of having close, mutual relationships with other individuals); 2) Group Belonging (defining competence in terms of feeling liked and accepted by peers), and; 3) Staff Acceptance/Connection (viewing success as feeling connected to, supported, and encouraged by staff).¹³⁻¹⁵ These elements have not been explored in prior research and we believe by enhancing ACT to include them in the resultant ACT2-Connect intervention will lead to sustained positive PA affect, cognitions, and behaviors in underserved youth. Comparison of ASPs receiving the 8-week "Connect" intervention (N=3 ASPs) with ASPs randomized to receive the general ASP curriculum (control condition; N=3 ASPs) will yield preliminary data on the effectiveness of social mediators for improving moderate-to-vigorous (MV)PA and preventing obesity among at-risk youth that can inform future intervention design and youth programming policy. Results of this proposed project will provide the basis for conducting a large scale efficacy trial.

Specific Objectives:

Develop and test the feasibility of the "Connect" intervention for increasing PA affect, cognition, and MVPA of underserved youth within ASPs. The effects of the intervention on youth body mass index (BMI) trajectories will also be explored and will have implications for impacting BMI as the targeted outcome of a larger R01 trial.

Primary Aims (Program Development and Feasibility):

1. Through qualitative interviews with staff and youth at ASP sites serving at-risk youth assess:
a) conceptual constructs most relevant for facilitating and supporting youth PA social goals; b)

barriers present within ASPs for meeting PA social goals (addressed in Phase 1, previously approved by IRB: Pro00031648).

2. Explore the feasibility of the Connect program. The Connect program will be documented to be feasible as shown by: 1) youth's greater perceived connectedness and PA affiliation goal orientation from baseline to post-intervention; 2). changes in targeted social climate components from baseline to post-intervention as measured by systematic observations, 3) staff perceptions of feasibility and acceptability of program as measured by a baseline and follow-up readiness assessment, and; 4) adequate dose and fidelity of program implementation as indicated by weekly process evaluations.

Secondary Aims (Document the preliminary impact of the Connect program on PA outcomes):

1. Assess whether youth in the social climate program (vs. comparison) demonstrate greater increases in positive PA affect, cognitions, and MVPA from baseline to 12-weeks post-intervention.

2. Explore whether youth in the social climate program (vs. comparison) demonstrate healthier BMI trajectories (e.g., slight reduction) from baseline to 12-weeks post-intervention.

3. Assess whether changes in targeted social mechanisms will mediate the effects of the intervention on changes in PA affect, cognitions, and MVPA from baseline to post-intervention.

C. Background and Significance

Physical Activity for the Prevention of Obesity and Related Disease

Recognized as the primary health threat for young people, national reports indicate that 34% of youth (40% of African American adolescents) are now considered overweight or obese¹ with minority and low-income youth at greatest risk for obesity and related diseases.^{1,6-7} Sustained levels of moderate-to-vigorous (MV)PA, have been shown to have a strong effect on youth weight status, cardiorespiratory fitness, metabolic health, and body composition.¹⁻⁵ Despite the benefits of PA, 50 - 92% of youth still do not meet national guidelines of 60 minutes of daily PA and PA declines as much as 50% between the elementary and middle school years^{32,33} with greatest declines and lowest levels of PA observed among African American females.³⁴ Efforts to increase PA has become a national priority, however previous PA studies have been unable to sustain behavior change and thus, have rarely affected targeted physiological or anthropometric health outcomes.⁸⁻¹² This may be, in part, because youth intervention approaches have rarely considered youth social developmental needs. We argue that adolescents' desire for social connections is a primary goal of action underpinning their PA behavior and thus, a key mechanism to target for sustained behavior change. **The proposed study will expand on previous research by testing the feasibility of a social-climate intervention within under-resourced afterschool programs (ASPs) that promotes increases in youth daily MVPA through targeting three primary PA social affiliation goals: 1) Friendship, 2) Group Belonging, and 3) Staff Acceptance.**

Need for a Social Climate Approach for Promoting Youth PA

For decades, correlational research within PE and sport settings has shown youth report social reasons and goals (e.g., friendship opportunities, being part of a team, coach behaviors) for initial and continued engagement in PA.¹³⁻²¹ During early adolescence, orientation towards social connections, salience of social feedback, and need for self-preservation within social contexts is more prominent than during any other period of the lifespan.³⁵⁻³⁷ Despite the developmental needs of adolescents, and the theoretical and empirical evidence of the importance of social factors for promoting PA, these factors have been minimally incorporated within intervention design, less well-defined than mastery or autonomy supports, and rarely are

the targeted or primary mechanism for increasing PA. Rather, PA interventions have typically focused on education and behavior modification components (e.g., self-monitoring) as primary mechanisms for promoting sustained PA.³⁸⁻⁵⁰ Some studies have targeted contextual modifications within PA settings (e.g., teacher support, choice of “enjoyable” activities)^{42,48,50-57} however, with an emphasis on promoting PA self-efficacy and skill development rather than socially-relevant goals, they have contributed little to understanding whether these contextual changes affect key PA social mechanisms, and have shown minimal impact on sustained PA behavioral change.¹² Lastly, a small set of studies have been centered on addressing adolescents’ broader PA social experiences,^{52,56,57} with only a single study⁵⁶ linking PA to socially-relevant goals (exploring the importance of dance in African American culture) as a central aim. Although these studies have evidenced some effects on indicators of physical health they have exclusively targeted females and have included minimal measurement of changes in important social mechanisms.

INNOVATION

Expanding on Climate-based PA Interventions for Youth

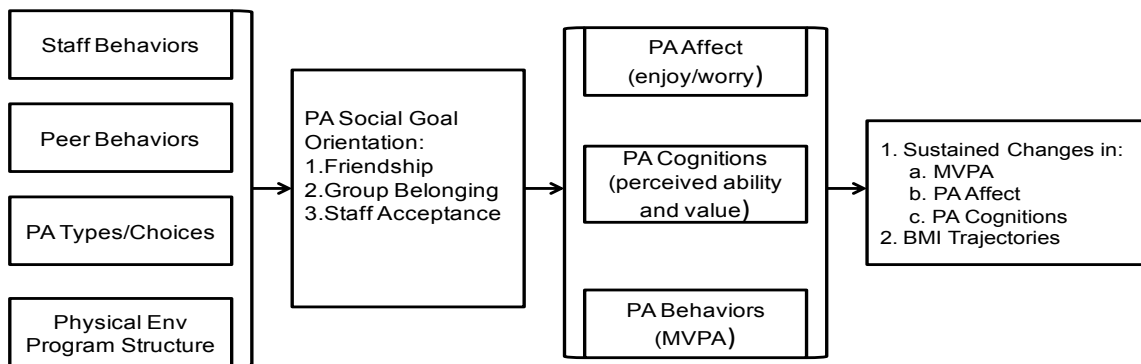
The climate-based approach for our feasibility trial is based on a novel theoretical framework (Figure 1) that expands on the social motivational constructs highlighted by SDT⁵⁸ and Achievement Goal Theory (AGT).⁵⁹ Along with the need for competence and autonomy, SDT highlights the need for positive social interactions for improving long-term life style changes. According to SDT, the basic human need for social connection and meaningful interpersonal relationships should stimulate goal-directed behaviors to satisfy it. However, the social-contextual features needed to meet youth relatedness needs have been less well-defined in previous PA interventions.^{23,60,61} AGT asserts that individuals want to and will strive to display competence in the way they define it,⁵⁹ and that adolescents commonly define PA competence in terms of different social relationships (e.g. peer acceptance, close friendships).¹⁵ However, facilitating and supporting PA orientations that define PA competence in terms of developing positive relationships with others is a key motivational component for sustained PA that has been missing from other PA interventions.

The proposed study addresses the limitations of previous youth PA interventions by targeting youth social goal orientations towards PA as the primary mechanism for promoting PA affect, cognitions, and behaviors in underserved youth. There are two distinct types of social goal orientations towards PA. The first orientation emphasizes affiliation experiences with the opportunity to socialize and develop relationships the primary goals for youth engagement in PA.^{23,24} The second orientation emphasizes social validation and stresses social status and approval from significant others as the primary goals for participating in PA.^{23,24} An affiliation orientation, which has been associated with help seeking, positive affect, and engagement at school, has been shown to be more favorable than a social validation orientation.^{62,63} Previous research has demonstrated three specific components of affiliation orientation that are particularly representative of the types of social relationships important to adolescents within physical domains: 1) Friendships (conceptualizing success/competence in terms of having close, mutual relationships with other individuals); 2) Group Belonging (similar to SDT’s relatedness component, represents youth tendencies to define competence in terms of feeling liked and accepted by a group of peers), and; 3) Staff Acceptance (which tailored to ASPs, can be defined as viewing success as feeling connected to, supported, and encouraged by staff).^{13-15,64} Extensive research on participation motivation in sport, physical education, and exercise shows highly engaged youth and adults report social reasons as their primary motivations for PA participation (viewing PA as an avenue for being with, and making friends, attaining peer acceptance/approval, and feeling connected to a group).^{16-23,65-67} Together, this research suggests that facilitating and supporting an affiliation orientation towards PA during adolescence

may function as a protective factor for sustaining PA throughout adulthood. However, no PA interventions to date have targeted social goal orientations as the key mechanism to promote sustained PA.

The goal of the proposed project is to test the feasibility of a social climate intervention that facilitates and supports PA affiliation goals as the primary mechanism through which youth will improve and sustain their PA affect, cognitions, and behaviors (see Figure 1). Youth focus groups and staff interviews, along with findings of previous research^{13-15,60,61,64} and systematic observations²⁹⁻³¹ were used in phase 1 to identify social climate features needed to facilitate and support youth's key PA affiliation goals: friendship, group belonging, and staff acceptance/connection.

Figure 1. Program Structure and Conceptual Model



D. Research Design and Methods

Preliminary Studies. Previous work by **Drs. Zarrett (PI)** and **Wilson (co-I)**²⁵⁻²⁸ on the ACT climate-based afterschool intervention (Wilson, PI) provide preliminary support for testing the feasibility of a social climate intervention for promoting MVPA in underserved youth. ACT, a novel program focused on increasing intrinsic motivation through involving students in the development and choice of physical activities offered (autonomy) and improving their sense of belonging (group cohesion) and PA mastery, is one of the first afterschool programs to implement a climate-based intervention based on Self-determination theory (SDT)⁵⁸ which shows significant improvements in PA in underserved youth.²⁵ Follow up data based on qualitative interviews also show significant staff changes that support a climate-based intervention approach.²⁸ However, limited sustained effects found post-intervention²⁵ indicated additional social climate components still need to be addressed. In particular, follow-up interviews with ACT youth and program staff conducted by the PI indicated there were key social barriers (self-consciousness, teasing, cliques) that undermined youth PA motivation and interfered with program effectiveness.²⁸ Although ACT addressed the social environment (e.g., belonging), findings suggest a need for more targeted approaches aimed at developing youth's intrapersonal assets (social skills for developing and maintaining friendships), enhancing youth's interpersonal PA supports, and reorienting youth PA attitudes so that they view social benefits (developing friendships, a sense of group belonging, staff connection) as the primary goal/purpose and achievement of PA. No PA intervention to date has been designed to test these specific social goals. The proposed study addresses the limitations of past work by identifying social mechanisms of the afterschool climate for targeting changes in PA social orientations (Friendship, Belonging, Staff Connection) using qualitative methods and an observation tool that the PI has developed and tested. Preliminary observational studies

assessing the PA social-motivational climate of summer camp^{29,30} and ASP³¹ settings conducted by the PI indicated ‘positive peer interactions’ was a primary predictor of youth higher rates of MVPA [F(1,329)=8.43, p<.01]. Moreover, findings indicated a clear deficit in observed instances of important social resources for PA (e.g., < 3% observed instances of staff verbal praise or PA promotion; 20% of activities were inclusive; 11% involved staff PA participation; 14% involved positive peer interactions).²⁹⁻³¹ The PI also conducted interviews and focus groups with 7 of the ASP sites (26 staff, 102 youth) to identify an initial set of social motivators and barriers for youth PA within each site and the program’s “readiness” for implementing the proposed intervention. Findings indicated the majority of staff (84%) view PA as a primary mission of their ASP (Freq=36; 24 staff; 6 programs), but also report several socially-based challenges to get youth active including “cliques, peer pressure, social norms” (freq=10; 7 staff; 4 programs) and youth “poor PA self-concept” (e.g., self-conscious, shy, afraid to mess up; Freq=9; 8 staff; 5 programs). Further, “finding better ways to motivate youth to participate with peers in PA” (5 staff; 4 programs) emerged as a common theme when staff were asked about ways to improve the program. These findings contribute to our understanding of the strengths and needs of ASPs, and the key mechanisms for inducing youth PA behavior change that will inform the proposed intervention design.

Study Design of Proposed Connectedness Feasibility Trial

The proposed project will be a prospective, randomized controlled trial comparing a social climate program to a general ASP.

The proposed project will be implemented over a 2 year period (see Figure 2). A planning phase occurred during the first six months in order to conduct staff interviews, youth focus groups, and systematic observations of each ASP, hire staff, pilot survey measures, and revise intervention materials and evaluation tools based on observations, surveys, and interview and focus group feedback (addressed in phase 1 IRB application). During the fall of year 1, an 8-week pilot will be tested in 1 ASP (N=30) and compared to a general health curriculum school-based control (N=30). Results of the pilot study will be used to inform any necessary modifications of the intervention approach or measurement protocol for year 2. During year 2, a randomized study (3 intervention and 3 control ASPs) will be implemented to test the feasibility of the intervention approach (N=200 youth). A 12-week follow-up, will test the sustained effects of the social climate intervention on ASP PA climate, youth PA affect, cognitions, behaviors, and BMI

Figure 2. Project Timeline

YEAR 1	YEAR 2
<p>April-Sept 2014</p> <ul style="list-style-type: none"> - Interviews/Focus Groups - Observations - Intervention development - ASP program recruitment - Hire and Train Staff 	<p>Aug-Oct 2015</p> <ul style="list-style-type: none"> - Intervention/Measurement Staff Training - Baseline Data Collection (2 ASPs) - Intervention Implement cohort 1
<p>Sept-Dec 2014</p> <ul style="list-style-type: none"> - Pilot Baseline Data Collection - Pilot Intervention (1 ASP vs. 1 control) 	<p>Oct-Dec 2015</p> <ul style="list-style-type: none"> - Baseline Data Collection for cohort 2 (2 more ASPs) - Intervention Implement (cohort 2)
<p>Feb-Apr 2015</p> <ul style="list-style-type: none"> - Post-measures in Pilot ASPs - Data cleaning - Hire Project Staff for Y2 	<p>Jan-March 2016</p> <ul style="list-style-type: none"> - Post-measures for cohorts 1 and 2 - Baseline data collection for cohort 3 (2 ASPs) - Intervention implement (Cohort 3)
<p>April-July 2015</p> <ul style="list-style-type: none"> -Data analysis - Revisions to intervention and measurement - ASP Recruitment for Y2 	<p>April-May 2016</p> <ul style="list-style-type: none"> - Post-measures cohort 3 - Data Management/ Analysis -Manuscript Preparation

Primary Aim 1 (COMPLETED PHASE 1): Interviews/Focus Groups and Youth Survey

Measures. During year 1, we conducted staff interviews (SIs) and youth focus groups (FGs; youth ages 9-14) in ASP sites to assess 1) key physical (e.g., equipment allocation), structural (e.g., PA preferences, activities offered), interpersonal (e.g., peer behaviors), and intrapersonal supports (e.g., social skills) needed to promote and support a social affiliation orientation towards PA (friendship, group belonging, and staff connection goals), 2) program barriers impeding the development and achievement of these social goals, and 3) input on the design and feasibility of initially- developed program components. Through content analysis (NVivo) we identified key themes related to improving social affiliation that were used to inform the development and implementation of the social climate intervention.

Targeted Population, Recruitment, and Retention. We aim to recruit 8 middle-school ASPs located within a 70 mile radius of Columbia that serve a primarily underserved population of middle school youth (6th–8th grade) youth. All ASP sites will need to include 1 hour of daily PA/freeplay as one component of the curriculum and be similar in size, percentage of youth per site on free or reduced lunch, race, and gender. One ASP will be asked to participate in the pilot during year 1 and will be compared to a school-based control (youth in the control will receive our general health curriculum administered in their health class during the school day). During year 2, six ASPs will be randomized to the treatment or control (general health curriculum) conditions after baseline data collection. ASP staff and all youth enrolled in the program will be asked to participate in the study. To be eligible, youth must 1) be enrolled in the ASP, 2) have parental consent and assent to participate, and 3) be available for baseline and post-intervention measurement. Youth will be excluded from participation only if they have a medical condition that would interfere with the program’s prescribed PA.

Overview of Intervention.

Drawing from theory and previous correlational^{13-21,64-72} and qualitative research,^{60,61} along with our preliminary studies in ASPs²⁵⁻³¹ we have identified key components for establishing a positive PA social climate that will inform the initial development of the intervention (**see Appendix A**). The intervention will target multiple levels of the ASP setting including staff- and peer- behaviors, program structure (e.g., activities), and the physical environment. Initial essential elements were derived from common themes identified across these levels including: 1) moral, emotional, and social goal-oriented support and skill development (e.g., friendship-building skills) 2) collaborative, cooperative play centered on friendship and informal-fun; 3) equal treatment and access, and; 4) inclusive and engaging for both youth and staff. The primary components of the study include: 1) “Get to know you” sessions aimed specifically at providing youth guided social opportunities to foster friendship building skills, and to promote acceptance, cooperation, contribution (to self and others), and friendship affiliation, and; 2) infusing a novel socially-oriented PA curriculum within ASPs’ free play sessions (**see Appendix B**). The intervention will take place during ASPs’ 1.5 hour “free play” component 2 times per week for 8 weeks. **Dr. Thom McKenzie (Consultant), Dr. Dawn Wilson (co-I)**, and a staff of **Physical Educators** will assist the **PI** in designing all program activities to meet the criteria of the essential elements.

The “Get to Know You” small group sessions (30 minutes) will be designed to specifically increase friendship building skills, and a value and efficacy for contributing to the health and well-being of oneself and others. It will involve interactive student-led discussions and activities that are designed to foster the intra- and interpersonal assets needed to build and support friendships, group cohesion, and staff connections through PA. For example, in small (staff-assigned) groups, staff will challenge youth with fun team building activities and icebreakers, youth will be encouraged to share ideas (e.g., brainstorm sessions on best methods for teaching friends new activities; how to be a good friend, active listener), personal stories, preferences,

and goals (e.g., their happiest/scariest memory, favorite PA to do with a friend), and activities (e.g., they will each be asked to bring in a favorite activity to teach their peers). They will also collaborate each program day to develop a campaign to encourage others to be active (e.g., family members, friends, teachers). This will include developing fliers/posters, and logos, performing and recording an entertaining media/video clip, and designing their own choreography for a dance or martial arts routine that they will teach and then perform with their targeted group (families, friends, teachers) at a ‘family and friends’ night, to further empower youth to exercise their newly developed PA-based social skills and goals, build social connections through PA outside of ASP time, and help sustain PA behaviors post-intervention. (See Appendix C for “Get-To-Know You” curriculum)

The PA component (60 minutes). Youth will participate in one of three socially-oriented physical activities that will be offered based on student preference ratings obtained the week prior. Studies by our group²⁵⁻²⁸ show that student motivation is increased by allowing students to vote for their PA preferences among a list of activities. To promote a PA affiliation orientation, available games to choose from will be novel, inclusive, emphasize teamwork, and centered on social goals that involve components of the “get to know you” sessions. (See Appendix D for PA curriculum)

The Comprehensive (general) Health Comparison Program (60minutes). (See Appendix E for comprehensive health curriculum). The comparison programs (ie., during health class for year 1 pilot; 3 ASP in year 2) will receive a comprehensive health curriculum within their programs that is designed to increase youth knowledge and skills across a wide variety of health-based behaviors. The curriculum includes interactive components addressing stress management and reduction (yoga and breathing exercises), media literacy and cyber safety, self-discipline (achievement and goal setting, martial arts), risk prevention, and building a positive self-esteem and positive thinking.

Zarrett (PI) and Wilson (co-I) will oversee the intervention team which will consist of a program coordinator, 2 certified PA activity leaders, and, at minimum, 10 trained intervention staff. Program staff of each participating ASP will also be involved in all aspects of the intervention. The PI and the program coordinator will monitor the daily activities of the intervention and comparison programs. All intervention staff will be required to attend a 3-day training course on implementing one of the two programs (intervention or comprehensive comparison) and a 1-day booster session at midpoint. To ensure sustainability of the program’s climate and activities post-intervention, ASP staff will also play a primary role in implementing program components. All ASP staff will be provided a program manual, two 2-hour trainings prior to program implementation in which the **intervention team** and **physical educators** will teach ASP staff the program’s essential elements and the associated PA games and leadership strategies, and a 1 hour booster at midpoint. Three 15-minute youth “training” sessions conducted by the intervention team will help guide youth in deriving ground rules for promoting teamwork, respect, and a sense of social responsibility.

Potential Challenges and Alternative Strategies. Given all study components occur in ASPs (where all study participants typically attend daily), and previous work with these same ASP partners resulted in over 95% youth/staff participation, recruitment and retention difficulties are not anticipated. However, we will partner with the program directors to assist in recruitment (e.g., getting parent consent). A follow-up mechanism in which we place “check-in” phone calls to study participants, and the provision of small incentives for completing baseline and post-intervention measures, will be employed as strategies to ensure retention. To ensure adherence

to intervention protocol an internal process evaluation will be implemented each week for corrective feedback and adjustment as needed, and a booster training session for all staff will be implemented at mid-point. There is little-to-no communication across ASP sites (each site has their own staff and serve youth from distinctly separate schools), however to limit cross-contamination between study sites we will enlist the help of the program directors who have previous experience with other RCTs and possess a strong understanding of the importance of having distinct intervention and control conditions. These strategies have been highly successful in our previous studies.²⁵⁻²⁷

Study Measures

All study measures will be collected by trained and certified staff blind to group assignment. The PI will hire a Program Coordinator to assist with oversight and training of measurement staff. Measurement certification entails reviewing protocols and demonstrating agreement with the Coordinator on anthropometrics, systematic observations, survey protocols, and PA assessments. Our team has experience developing and using these protocols in large scale studies.²⁵ **See Appendices for all measures.**

Primary Aim 2. Feasibility

To test the feasibility of intervention implementation, **process evaluations** that monitor dose and fidelity will be conducted within both the intervention and control conditions once a week by an independent process evaluator for the duration of the program (**see Appendix B**). Through observation and use of a quantitative checklist and rating scales, the process evaluator will assess whether there are any changes in the structure, delivery, or climate of the control condition (e.g., whether youth are consistently provided at least 1 hour of daily free play), and whether the social climate of intervention ASPs achieve the program's essential elements.

Systematic observations will be conducted using the System for Observing Children's Activity and Relationships during Play (SOCARP; **see Appendix F**)^{73,74} and a modified version of the System for Observing Fitness Instruction Time (SOFIT) that includes a social climate observation tool that has been developed and tested by the PI (MCOT-PA).²⁹⁻³¹ Teams of two coders will make continuous observations of daily activities throughout 5 program days at each ASP. Observations will be used to assess changes in key social climate features for promoting youth affiliation goals. Staff structured interviews (**Readiness Assessment**) will assess staff perceptions of the feasibility and acceptability of the intervention program components conducted at baseline, mid-point, and post-intervention. This readiness assessment is developed to correspond with a multi-component theory of organizational readiness that addresses both program motivations and capacities⁷⁵ including motivation for implementing the CONNECT intervention, innovation-specific capacity for CONNECT, and general capacity, and has been previously piloted with principals, teachers, and technology specialists for a school-based technology intervention. We have adapted the assessment to fit within the afterschool program structure and PA goals of our intervention (**see Appendix H**).

The Social Motivational Orientations Scale for Sport (SMOSS)²³ will be used to assess changes in participants' degree of social affiliation orientation (7 items) and social validation orientation (8 items) toward PA (5-point scale, $M=2.44$; $SD=1.04$). The SMOSS is well-validated,^{23,76} correlated with PA value, enjoyment, and perceived ability, and has adequate internal consistency (reliability coefficients range from .77 to .87). **The Motivation for Physical Activities Measure (MPAM)** assesses five motives for participating in PA: Fitness, Appearance, Competence/Challenge, Social, Enjoyment. The scale has been used to predict various behavioral outcomes, such as attendance, persistence, or maintained participation in some sport or exercise activity, and to predict mental health and well-being and has demonstrated strong internal consistency (alphas above .87 for each of the subscales)⁷⁷ **The**

Task and Ego Orientation in Sport Questionnaire (TEOSQ) assesses youth task (mastery) or ego (performance) orientations towards PA and is predictive of value, intrinsic interest and enjoyment in PA (reliability coefficients range from .71 to .87)⁷⁸. **The Need for Relatedness Scale**⁷⁹ will assess feelings of social connections to others within the ASP setting and has been previously validated using other SDT constructs⁸⁰⁻⁸² (reliability coefficients range from .86 to .92; 5-pt scale, $M=3.74$; $SD=.75$). The **Perceived teacher support scale**⁸³⁻⁸⁵ (reliability coefficient = .84; 5-pt scale, $M=3.22$; $SD=1.05$) and **The Peer Motivational Climate in Youth Sport Questionnaire**⁸⁶ (reliability coefficients range from .69 to .82; 7-pt scale, $M=3.18$, $SD=1.32$) will be used to measure youth perceptions of staff and peer connections. Validity of both measures has been supported in previous work and shown to correlate with PA enjoyment, effort, and prosocial and social responsibility goals.⁸³⁻⁸⁶ **The Social Support and Exercise Survey** will measure changes in youth family and friend social support for youth PA.⁸⁷ (See Appendix G for Youth Survey Measures).

Secondary Aims 1, 2, and 3: Youth MVPA, Cognitions, Affect, and BMI

Youth Physical Activity (Accelerometer). Objective assessments of PA will be obtained on youth with omni-directional accelerometers (Acticals; Mini-Mitter, Bend, OR).⁸⁸ Actical has demonstrated correlations between activity counts and energy expenditure of individuals measured concurrently with accelerometers (e.g., MTI Actigraph, Caltrac, Tritrac) in several studies.⁸⁹ Youth will wear an accelerometer over 7 consecutive days to calculate PA at baseline, endpoint, and post-intervention. Data will be recorded in 30-s epochs to best capture short bouts of vigorous activity,^{90,91} and raw activity data will be converted into time spent in moderate (3-5.9 METS), vigorous (6-8.9 METS), and MVPA (3-8.9 METS) based on activity count thresholds for children identified by Puyau et al.⁸⁸ Dr. Zarrett (PI) and Dr. Wilson (Co-I) have been involved in multiple trials using accelerometer to measure PA in youth.²⁵⁻²⁷

PA Cognitions will be measured by **youth perceptions of their physical ability** (5-pt scale, $M=3.68$; $SD=.97$) and **value of PA** (5-pt scale, $M=3.81$; $SD=1.18$) using four items derived from the expectancy-value model that have been well-validated in youth minority populations⁹²⁻⁹⁴ (reliability coefficients range from .76 to .94). PA Affect will be measured by the extent to which adolescents engaged and enjoyed PA activities using **The Intrinsic Interest Scale**⁹⁵ (reliability coefficients from .83 to .94; 5-pt scale, $M=3.7$, $SD=1.0$) and the degree to which youth are concerned about performing well during PA using the worry subscale of **The Sport-Anxiety Scale-2** (reliability coefficient = .89; test-retest = .90; sum score range 4 to 20; $M= 12.12$; $SD= 3.85$).⁹⁶ All PA cognition and affect measures have been shown to be correlated with the SMOSS and other measures of interest to the study (e.g., PA effort, ability).^{23,76,96} **Body Mass Index.** Height and weight will be measured at baseline and post intervention using a Shorr Height Measuring Board and a SECA 880 digital scale. Sex- and age-standardized BMI (zBMI) will be calculated for youth using CDC 2000 reference curves. (See Appendix G for Youth Survey measures).

Covariates. Demographic data will be collected on adolescents at baseline including self-report age (date of birth), race/ethnicity, and gender. Free /reduced lunch status will be derived from school/program records. The Positive Youth Development Scale (PYD-VSF; reliability coefficients from .72 to .90)⁹⁷ and The Strengths and Difficulties Questionnaire (SDQ; test-retest reliability=.80)^{98,99} will be used to measure indicators of positive development (e.g., connection, competence) and the presence of depressive symptoms because of previous research indicating an association between well-being/depression and youth PA and obesity. Lastly, the Self-Regulation Questionnaire- Prosocial (SRQ-Prosocial) assesses individual differences in prosocial behaviors, friendship, interpersonal skills, and exercise (reliability coefficients from .61-.85).¹⁰⁰

E. Analysis Plan

This proposal is a feasibility test of the social climate intervention and will gauge a plausible effect size of the program for a larger R01 application. To that end, we will examine several subjective and objective markers of program success such as changes in targeted social mechanisms within youth and the ASP climate, and explicit PA outcomes. We will also explore the potential effects of the intervention on youth BMI. Although only minimal change in BMI would be plausible given the length of the current proposal, our findings will have implications for impacting BMI as the targeted outcome of a larger R01 trial.

Primary Aim 1. (ADDRESSED). The first aim of the study is to conduct qualitative interviews with program staff and youth to identify conceptual constructs most relevant for fostering youth PA affiliation orientation. Interviews and focus groups will be transcribed, coded, and analyzed (QSR NVivo) to identify common themes for these study goals. A coding scheme composed of “levels” of categorization or manageable “themes,” will be developed to guide the manner in which the qualitative data will be analyzed. Ultimately, these themes will be used to summarize the data. Data will be coded by two coders and inter-rater reliability estimates will be assessed. Prior to analysis, raters will meet to discuss each coding disagreement until consensus is met regarding final codes. The PI has extensive experience in using QSR NVivo to conduct content analysis of themes (see our previous work).²⁸

Primary Aim 2. The second primary aim of the study is to assess whether youth in the intervention demonstrate greater change in the 3 PA social affiliation mechanisms from baseline to post-intervention. Gains in these social mechanisms will be assessed with repeated measures ANCOVA models in which time (baseline to end of program and baseline to post-intervention) is a within subject factor and treatment is a between subjects factor for social mechanism variables measured in both conditions. Analyses will control for demographics, baseline BMI, and any other variables for which there are baseline differences between treatment and control groups (e.g., PYD, depression). To examine overall changes in social mechanisms within the intervention alone, similar repeated measures ANCOVAs will be used, with the between subjects treatment factor dropped. The test of interest will be the within subjects factor of time, with affiliation goals expected to improve over time. Process Evaluation, used to assess the quantity (dose) and quality (fidelity) of program implementation, will also serve as feasibility assessments. Our group has extensive experience with “dose-response” analyses.²⁷ Weekly observational assessments of program facilitation, using standardized ratings developed for other studies,¹⁰¹⁻¹⁰³ will be reduced to a total score, indicating overall fidelity to the activity observed.

Secondary Aims. Secondary Aims 1 and 2 tests the a-priori hypothesis that youth in the intervention (vs. comparison) will have greater improvements in PA affect, cognitions, and MVPA and healthier BMI (z-score) trajectories (e.g., slight reduction; less increase) from baseline to post-intervention. This study will also provide us with information on the effect size that might be expected to power an efficacy trial after completion of the R21 project. Greater improvements will be assessed with several repeated measures ANCOVA models in which time (baseline to post-) is a within subject factor and treatment is a between subjects factor for PA variables measured in both conditions. Analyses will control for demographics (and BMI for PA outcomes) and other variables for which there are baseline differences between treatment and control groups. Multiple imputation protocols^{104,105} will be used to address missing accelerometer data (see our previous work).²⁵

Secondary Aim 3 explores whether changes in youth PA social orientations mediate the effect of the intervention on changes in adolescent PA outcomes. This hypothesis will be tested with a

multiple mediator model (estimated path model) where the indirect effect of the program on PA through social mechanisms will be examined. Bootstrapped estimates of the mediated effect will be examined in line with recommendations from methodological research.^{106,107} Both the total indirect effect of all variables together and specific mediated effects of each variable will be examined.

F. Human Subjects

Protection of Human Subjects

Risks to the Subjects

Human Subjects involvement and Characteristics. Subjects will be healthy male and female adolescents and adults. To be eligible, adolescents must 1) be currently enrolled in the afterschool program, 2) have parental consent to participate, and 3) agree to study participation and random assignment, and 4) be available for baseline and post-intervention measurement. Adolescents will be excluded from participation if 1) have a medical condition that would interfere with the prescribed physical activity intervention plan, 2) are developmentally delayed such that the intervention materials will not be appropriate or, 3) are in treatment for a psychiatric disorder. To be eligible, adults must 1) be part of the afterschool staff, 2) have no medical condition or disorder that would limit participation, 3) be available and able to participate in the interviews and/or the intervention phase for the study period.

Sources of Material. All data will be obtained for research purposes only. Data collected for adolescents will be demographic (age, race, date of birth), anthropometrics (height and weight), behavioral (physical activity as measured by accelerometer estimates), and psychosocial surveys related to changes in physical activity affect, cognitions, behaviors, and general well-being. Data collected for adults will include demographics (age, race, etc.), and structured interviews to ask about their views on the best methods for engaging staff in program goals and for adopting the intervention into their pre-existing program and assess what supports are needed to increase the quality of implementation and sustainability of the program post-intervention. Distinct program dimensions measured include motivation for implementing the CONNECT intervention, innovation-specific capacity for CONNECT, and general capacity (**see Appendix H**). The interview protocol also includes measurement of staff motivation, value, and perceived efficacy for implementing the intervention curriculum and PA more generally. Interviews will be tape recorded and transcribed and names will not be included with the participants' recorded responses.

Potential Risks. There is little risk involved in participating in this study. Typical to any Physical Education class (PE) subjects who participate in the intervention may experience some discomfort such as minor physical strains and sprains associated with engaging in physical activities during the intervention. Activities offered in both the health class and the afterschool program are similar in risk to the typical activities offered in the class/afterschool program. There is little risk associated with wearing the accelerometers in the study. Adolescents will be monitored to determine if they are experiencing any discomfort as a result of wearing the devices. There is also little risk to filling out the questionnaires – the majority of questions are centered on PA (social) preferences and perceptions about their experiences in the program, and are not anticipated to trigger negative emotional states. Adolescents will be encouraged to skip a question or stop filling out the questionnaire if they feel any discomfort with questions asked. Numbers will be provided to each adolescent so that their questionnaire cannot be identified, and the names-to-numbers list will be kept separate from participants' recorded responses. The data collected from youth will be kept confidential in all circumstances unless information acquired about a child's wellbeing indicates the child may be at harm. In such a case, we would privately contact the parent and refer the child to the school counselor for further assessment. This breach of confidentiality is articulated in the consent form.

Adequacy of Protection Against Risks

Recruitment and Informed Consent. All program staff from each of the 7 afterschool programs (the health program control administered during the school day in y1 will be excluded) will be asked to participate in the interview component of the study (N=21). Informed consent will be sought from each adult for participation in this project.

A total of 298 students in the select afterschool programs will be recruited to participate in the study (Y1 Pilot study = 98 students; Y2 Intervention = 200 students). Adolescents will be excluded from participation if they 1) have a medical condition that would interfere with the prescribed physical activity intervention plan, 2) are developmentally delayed such that the intervention materials will not be appropriate or, 3) are in treatment for a psychiatric disorder. Informed consent will be sought from each child's parent/guardian for participation in this project. Assent forms will also be completed by all students prior to participating in the study. Parents and children will be encouraged to ask any questions they might have regarding the procedures. There will be no coercion to participate or prejudice against those who choose not to take part in the study. We will submit an application to the University of South Carolina Institutional Review Board for approval of study procedures and the informed consent protocol. No data collection will take place prior to IRB approval.

Protection Against Risk. There is little risk associated with wearing the physical activity monitors in this study. Adolescents will be monitored to determine if they are experiencing any discomfort as a result of wearing the devices. Safety and prevention of injury while wearing the monitors will be considered. Likewise, there is little risk associated with participating in the physical activities. Risks are parallel to a typical PE class and are similar to the risk of the typical activities offered in the class/afterschool program. Staff from the University of South Carolina will be available to assist with any minor injuries as a result of participating in the physical activities during the program. All school-based ASP staff are trained in CPR and intervention staff will be trained by PA leaders (hired PE teachers) on injury prevention during the pilot study and randomized intervention study. The majority of staff interview questions and youth questionnaires will be centered on PA (social) preferences and perceptions about their experiences in the program and the proposed intervention, and are not anticipated to trigger negative emotional states (see above for details). Participants will be encouraged to skip a question or dismiss themselves from the interviews or questionnaires if they feel any discomfort with questions asked. Data will be kept completely confidential unless a child provided information that indicates he/she may be at harm (e.g., depression). In such a case, we will privately contact the school counselor and caregiver. Numbers will be provided to each participant so that they are not addressed by name in the recorded interview, and the names-to-numbers list will be kept separate from participants' recorded responses. Similarly, youth names will be kept separate from their questionnaires, and the names-to-numbers list will be stored in locked file cabinets. Data collected in this study will be accessed only by the investigators and designated staff persons. Staff that collect study measurements will be trained and supervised by the PI and program coordinator on the proposed project. Data will be stored in locked file cabinets that only study staff can access. Additionally, electronic participant databases will be password protected and stored at the University of South Carolina. Afterschool program personnel will not have access to the data. We have used these procedures on several research studies to successfully protect against risk.

Potential Benefits of the Proposed Research to the Subjects and Others. The goal of the proposed study is to assess the feasibility of developing an afterschool program climate that increases and sustains youth moderate-to-vigorous physical activity and improves youth body mass index (BMI) trajectories through meeting youth social developmental needs. The findings from this study will provide the information necessary to conduct a large scale efficacy trial that

could have important implications for increasing the potential impact of afterschool-based health interventions for preventing obesity.

Adult participants in this study will learn valuable information about how to improve the afterschool climate to support student engagement in physical activity, and will be provided valuable strategies and tools that they can implement within their programs. Psychosocial benefits for both students and adults include improved relationships within the program (including between staff, between students, and between staff and students), improved afterschool program supports for health initiatives, and valuable opportunities and strategies for improved physical activity. Physical benefits of the proposed research for youth (and, indirectly, adults) will include weight control, building muscle mass, reducing fat, lowering blood pressure, and reducing psychosocial symptoms of depression and anxiety. Thus, increasing physical activity in adolescents (and, indirectly adults through intervention implementation) may have important public health implications for reducing chronic disease and increasing longevity and quality of life in this population. The benefits of the proposed research to the adult and adolescent participants outweigh the potential risks.

Importance of the Knowledge to be Gained. Results will fill knowledge gaps and provide feasibility for a larger afterschool-based efficacy trial that will implement a social climate that 1) facilitates youth perceived connectedness and affiliation goal orientations during PA; 2) improves youth PA-related affect, cognitions and behaviors to reduce youth body mass index (BMI), and 3) sustains behavior changes post intervention for continued improvements in BMI trajectories. The results from this study will have important implications for increasing the effectiveness of afterschool interventions/programs for obesity prevention among underserved youth.

Data Safety Monitoring Board and Plan. A data and safety monitoring committee (DSMB) consisting of a variety of experts in conducting large-scale PA interventions and measuring the quality of afterschool programs for youth will be convened at the beginning of the study to provide input and guidance on the study evaluation and intervention procedures including quality assurance and safety issues related to the study design. Robert Brustad, PhD., Professor of Sport and Exercise Science at the University of Northern Colorado, has agreed to serve on the committee as Chair. He will help elect two additional members, who will also be independent to the University. The committee members will provide input and feedback through email and regularly scheduled conference calls during implementation of the intervention twice per year. Adverse event information will be recorded at all assessments points and during the intervention on standard forms and will be reported to the DSMB. Consistent with NIH and USC IRB policy, adverse events will be promptly reported in writing to the NIH and IRB.

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