Strengthening Adolescent-Adult Networks to Reduce Youth Violence

Protocol Number*: STUDY21030140

National Clinical Trial (NCT) Identified Number: NCT05185453

Principal Investigator*: Dr. Alison Culyba, MD PhD MPH

Sponsor: University of Pittsburgh

Grant Title: Strengthening Adolescent-Adult Networks to Reduce Youth Violence

Grant Number*: 1K23HD098277-01

- **Funded by: Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)**

Version Number: v.1.0

May 1, 2022

CONFIDENTIALITY STATEMENT

This document is confidential communication. Acceptance of this document constitutes agreement by the recipient that no unpublished information contained herein will be published or disclosed without prior approval of the Principal Investigator or other participating study leadership and as consistent with the NIH terms of award.

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STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signed:  Date: 6/1/2022

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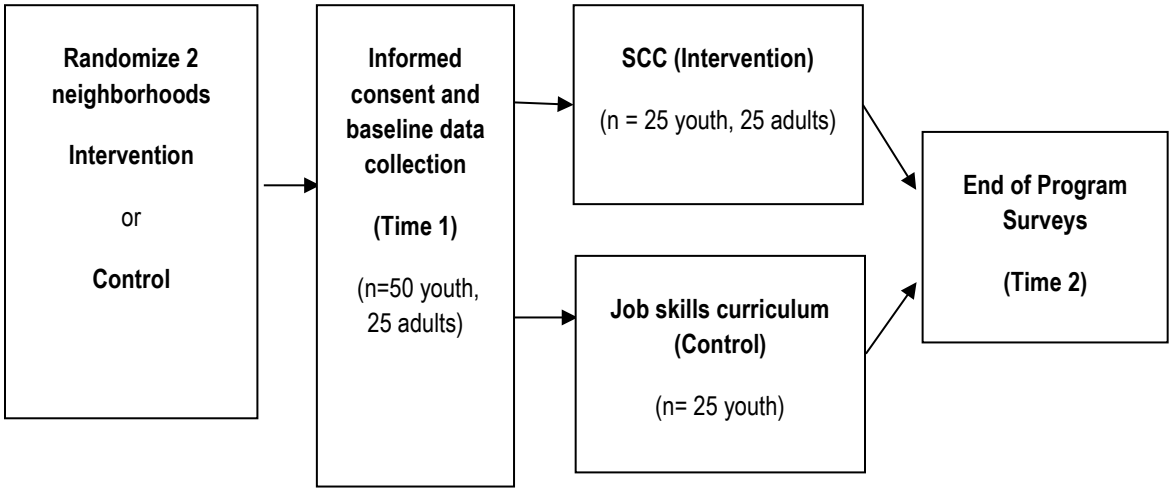
1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Strengthening Adolescent-Adult Networks to Reduce Youth Violence
Grant Number:	1K23HD098277-01
Study Description:	This community-partnered cluster-randomized trial will examine the feasibility and acceptability of a social network-based youth violence prevention program called Strengthening Connections for Change for youth ages 13-17 and their key adult supports. Set in four lower resource Pittsburgh, Pennsylvania neighborhoods, this study brings together youth ages 13-17 and their self-identified key adult supports to focus on leadership, strengthening intergenerational networks, community engagement, and violence prevention.
Objectives*:	The primary goal is to test the feasibility and acceptability of the adapted Youth Empowerment Solutions intervention (Strengthening Connections for Change, SCC) compared to a control intervention (Job Skills) delivered over 12 weekly sessions through a cluster-randomized community-based trial among adolescents, ages 13- 17 (n=50 youth, 25 in intervention group and 25 in control group) and their key adult supports (n=25 in intervention group) at four community-based sites (2 intervention and 2 control sites) in Pittsburgh, PA. As this is a feasibility trial, the primary end points are feasibility and acceptability.
Endpoints*:	Primary outcomes will include feasibility and acceptability. Feasibility is defined by participant attendance calculated as a proportion of total number of sessions attended (possible session attended #: 0-12 for youth participants and 0-9 for adult participants; possible proportion attended range: 0-1). Acceptability is defined as overall satisfaction with curriculum content and format among youth (intervention and control) and among adults (intervention) measured at the end of programming. Secondary outcome measures include assessment of participant satisfaction on weekly session feedback forms. Exploratory outcomes include changes between pre-and post-intervention assessments of social network-level measures (e.g., network size, network density, mean link strength), attitudes towards violence, conflict resolution and coping, future orientation, and violence experiences.
Study Population:	Youth between the ages of 13 and 17 who live or attend programming within randomized neighborhood boundaries and their self-identified key adult supports.
Phase* or Stage:	*N/A*

Description of Sites/Facilities Enrolling Participants:	The trial will be conducted in partnership with youth-serving community organizations in each neighborhood. Programming will be delivered in community settings and overseen by the Division of Adolescent Medicine research team.
Description of Study Intervention/Experimental Manipulation:	Strengthening Connections for Change is a 12-session curriculum adapted from the Youth Empowerment Solutions (YES) program and designed to strengthen adolescent-adult support networks, build leadership skills, foster community engagement, and challenge attitudes and behaviors that foster violence involvement. During the program, youth ages 13-17 years invite their self-identified key adult supports to jointly participate in programming including youth-focused, adult-focused and jointly focused activities. Towards the end of programming participants design a community project to strengthen intergenerational connections and promote community engagement.
Study Duration*:	15 months
Participant Duration:	12 weeks

1.2 SCHEMA



1.3 SCHEDULE OF ACTIVITIES

	Baseline	Session 1-12	EOP
Informed Consent	X		
Research Survey	X		X
Emotional Distress Checklist	X	X	X
Session Feedback Forms		X	
Session Activities		X	
Interview			X
Adverse Events Reporting	X	X	X

2 INTRODUCTION

2.1 STUDY RATIONALE

The overarching goal of this cluster randomized trial is to assess feasibility and acceptability of the Strengthening Connections for Change program. The first component of the study will involve iterative development of the Strengthening Connections for Change intervention with 5 adolescent-adult support dyads at a single community site. The goal of the first component is to identify gaps in the curriculum and obstacles to implementation that can be addressed prior to the RCT. In the pilot cluster-randomized trial, we will assess feasibility and acceptability by tracking recruitment, enrollment, attendance, and post-intervention surveys. We will also collect exploratory data on proposed outcomes to assess the feasibility of this data collection method and provide preliminary insights to guide a larger trial. Pre-intervention surveys will assess social support, social network structure, attitudes towards violence, conflict resolution and coping, future orientation, self-reported violence perpetration and victimization, ethnic identity, discrimination, and substance use. Post-intervention surveys will assess satisfaction and engagement and will reassess social networks, attitudes towards violence, conflict resolution and coping, future orientation, and violence experiences. We will also conduct semi-structured interviews with a subsample of adolescent-adult dyads in the intervention arm to further assess acceptability and guide refinements for a larger effectiveness trial.

2.2 BACKGROUND

Youth violence is pervasive and increases morbidity and mortality. Each year over 500,000 youth seek care in U.S. emergency departments for assault-related injuries. Middle school-age youth in urban environments bear a disproportionate burden of witnessing and directly experiencing violence, with several studies demonstrating upwards of 97% of youth endorsing a lifetime history of community violence exposure, 5% being shot or stabbed, 19% witnessing a shooting or stabbing, and 13% having a weapon pulled on them in the past year. Exposure to pervasive violence can negatively impact physical and mental health and risk behaviors and increases risks for injury and incarceration. Strategies that leverage individual and relational assets to combat youth violence in urban environments during middle adolescence are urgently needed. Adult connection may play a significant role in violence prevention. Supportive adult connections are an important source of social support across adolescence, with the provision of both emotional support (things others do to make one feel loved and cared for) and instrumental support (tangible help that others provide) conferring protection against myriad health risk behaviors, including violence.

Building upon this evidence base, the CDC Center for Injury Prevention and Control recently put forth key prevention strategies for combating youth violence focusing on adolescent-adult connections: “foster safe, stable, nurturing relationships between young people and their parents and caregivers” and “build and maintain positive relationships between young people and caring adults in their community.” Research in low-resource urban populations suggests that families often struggle to protect youth in these contexts, and that the simple presence of an adult support may not universally confer protection from violence. Instead, interactions between youth and multiple social supports may be more important in

understanding risks. Additionally, grounded in social influence theory, researchers suggest that attitudes towards violence among youth's adult supports may play a mediating effect. Failure to fully account for interconnected positive and negative adult influences across contexts could explain previous mixed findings. Interventions that strengthen adolescent-adult support networks offer a novel approach to youth violence prevention.

Despite the importance of adolescent-adult connections, aside from intensive family-focused approaches for chronic offenders, few evidence-based violence prevention programs exist for middle adolescence that foster adolescent-adult relationships. The Youth Empowerment Solutions program (YES), an evidence-based violence prevention program, fosters interactions with adult volunteers and has been shown to reduce aggression and delinquency. In the YES 'building intergenerational partnerships' program component, youth interview and select adult volunteers without preexisting connections to join them in implementing community change projects. While youth report high satisfaction with the intergenerational partnership component, they have also identified challenges in fostering and maintaining meaningful adult connections in a short time span. Social network analysis can better elucidate how networks of adult supports may uniquely confer protection from violence in low-resource urban neighborhoods and identify novel leverage points for intervention.

The Strengthening Connections for Change intervention, an adaptation of YES, uses social network analysis methods to enhance the 'building intergenerational partnerships' component that leverages existing adolescent-adult relationship networks to increase social support and reduce violence perpetration and victimization among youth in urban neighborhoods.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

Since this study is a minimal risk study, there are few risks to participants who take part in the research study. The risks are a potential breach in confidentiality and the potential that some questions in the surveys may have sensitive question topics or be emotionally distressing.

2.3.2 KNOWN POTENTIAL BENEFITS

There is no direct benefit to individual subjects from takin part in the research.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

This study is of minimal risk to participants. It is possible that some youth may find some of the survey questions too sensitive or uncomfortable. Participation is voluntary; participants are reminded that they can stop participating at any point. Youth are provided with relevant resources at the end of each survey. The youth surveys are anonymous. That is, youth produce a self-generated personal code based on 8 nonidentifiable questions (e.g., first letter of mother's first name) to ensure responses will remain as anonymous as possible and can be matched across data collection points. No names or linking information will be connected to the surveys.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
The primary goal of the study is to pilot test the feasibility and acceptability of the adapted Youth Empowerment Solutions intervention (Strengthening Connections for Change) compared to a control intervention (Job Skills).	Primary outcomes will include feasibility and acceptability. Feasibility is defined by session attendance. Attendance will be recorded at the beginning and end of each session. Attendance will be calculated as a proportion of total number of sessions attended (possible session attended #: 0-12 for youth participants and 0-9 for adult participants; possible proportion attended range: 0-1). Feasibility is defined by participant satisfaction. Participant Overall Satisfaction with Curriculum Content and Format will be assessed by researcher-generated Likert-scale items. At the end of the program, participants will be asked about how satisfied they were overall with the topics discussed and format of the program using 5-point Likert scale items. Means score will be calculated across the items (possible range: 1-5; higher score means higher satisfaction).	Feasibility and acceptability are crucial to assess before planning a larger efficacy trial because if the program is not feasible or acceptable, changes will need to be made prior to a large-scale RCT. Moreover, satisfaction is an important indicator of overall interest in the intervention, and whether youth found this programming engaging and relevant. Operationalizing feasibility and acceptability came from stakeholder meetings about the amount of the curriculum that participants should receive to consider their participation as meaningful engagement.
Exploratory		
The exploratory objective is to assess the types of social networks and connections that youth make with the people around them, and to gather data on violence experiences and associated factors to inform a larger trial.	Exploratory outcomes include changes between pre-and post-intervention assessments of social network-level measures (e.g. network size, network density, mean link strength), attitudes towards violence, conflict resolution and coping, future orientation, and violence experiences.	The use of social network analysis techniques supports efforts to address critical gaps in our understanding of the networks of adults that youth in low-resource urban neighborhoods rely on for support across family, school, and community contexts and identifies targets for a network-based intervention to strengthen adult supports and reduce violence perpetration and victimization.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
		Additional exploratory measures will assess the feasibility of this data collection method and provide preliminary insights to guide a larger trial.

4 STUDY DESIGN

4.1 OVERALL DESIGN

This study design involves a two-arm cluster-randomized-controlled pilot feasibility trial conducted with adolescents ages 13-17 recruited from youth-serving community agencies in Pittsburgh, PA and their self-identified adult supports. Sites in four neighborhoods were randomly allocated to the intervention or control arm. Sites were selected based on participation as control sites in a previous cluster-randomized trial (NCT02427061). All neighborhoods in the study met criteria as socially or economically disadvantaged. Randomization was performed at the neighborhood level (i.e., cluster) to reduce risk for contamination. The randomization included 4 clusters that were assigned to experimental or control conditions. The study statistician performed this randomization such each site/neighborhood had a 50/50 chance of being assigned to intervention or control. Participants (anticipated n=50 youth, 25 adults) complete surveys prior to program implementation (baseline) and immediately following the program (end of program, EOP). Baseline surveys are completed in-person using tablets to complete the survey online. EOP surveys are also completed in-person on a tablet or remotely using survey links that are texted or emailed to participants using contact information provided with recruitment. We will also conduct semi-structured interviews with a subsample of adolescent-adult dyads in the intervention arm (n=5-8) to further assess acceptability and guide refinements for a larger effectiveness trial. Retention is facilitated by collecting detailed contact information and offering incentives for survey completion.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

The proposed study leverages existing data, research infrastructure, and community partnerships from Manhood 2.0, a large community-partnered sexual violence prevention cluster-randomized trial engaged with 866 male adolescents, ages 13-19, through youth-serving agencies in twenty disadvantaged neighborhoods in Pittsburgh (CDCU01CE002528; PI: Miller). The Strengthening Connections for Change intervention leverages existing adolescent-adult relationship networks to increase social support and reduce violence perpetration and victimization among youth in urban neighborhoods. The comparison intervention is a job readiness training program which focuses on skills needed to prepare youth for entering the workforce, including goal setting, accountability, resume building, and interview preparation. Both intervention and control programs involve a curriculum divided into 12 sessions delivered once or twice a week. The design builds on existing research infrastructure, community partnerships and focuses on prevention principles, youth engagement, and opportunity for prosocial relationship development. Randomization is designed at the neighborhood level to reduce the risk of contamination.

4.3 JUSTIFICATION FOR INTERVENTION

Youth violence is pervasive and increases morbidity and mortality. Middle school-age youth in urban environments bear a disproportionate burden of witnessing and directly experiencing violence. Exposure to pervasive violence can negatively impact physical and mental health and risk behaviors, and increases risks for injury and incarceration. Strategies that leverage individual and relational assets to combat youth violence in urban environments during middle adolescence are urgently needed.

Adult connection may play a significant role in violence prevention. Supportive adult connections are an important source of social support across adolescence, conferring protection against myriad health risk behaviors, including violence. Interventions that strengthen adolescent-adult support networks offer a novel approach to youth violence prevention. Despite the importance of adolescent-adult connections, few evidence-based violence prevention programs exist for middle adolescence that foster adolescent-adult relationships. The Youth Empowerment Solutions curriculum (YES), an evidence-based violence prevention program, fosters interactions with adult volunteers and has been shown to reduce aggression and delinquency. In the YES 'building intergenerational partnerships' program component, youth interview and select adult volunteers without preexisting connections to join them in implementing community change projects. While youth report high satisfaction with the intergenerational partnership component, they have also identified challenges in fostering and maintaining meaningful adult connections in a short time span. The current proposal will use social network analysis methods to inform an adaptation of the YES 'building intergenerational partnerships' component that leverages existing adolescent-adult relationship networks to increase social support and reduce violence perpetration and victimization among middle school age youth in urban neighborhoods.

Strengthening Connections for Change (SCC) is a 12-session curriculum that is adapted from the Youth Empowerment Solutions curriculum (YES). The Strengthening Connections for Change intervention uses social network analysis methods to enhance the YES 'building intergenerational partnerships' component that leverages existing adolescent-adult relationship networks to increase social support and reduce violence perpetration and victimization among youth in urban neighborhoods. The adaptation that developed into SCC was originally a 9-session intervention. Based on participant and facilitator feedback through the iterative development phases, SCC was expanded into 12 sessions to allow the groups to have more time to thoroughly cover all activities in each session of the curriculum.

4.4 END-OF-STUDY DEFINITION

A participant is considered to have completed the study if he or she (1) completes the baseline survey, (2) attends either the intervention program, a 12-session curriculum (youth and adults) or the control program, a 12-session evidence-based job skills curriculum (youth only), and (3) completes the end of program survey.

The end of the study is defined as completion of the end of program survey shown in the Schedule of Activities (SoA), **Section 1.3**.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

Neighborhood Eligibility: Neighborhoods were identified based on having participated in NCT02427061 and having been randomized to the control intervention in that trial. Neighborhoods were recruited from the previous 10 sites by identifying a potential community partner who could host the program and were willing to be randomized to receive the intervention or control programming. Neighborhoods had existing programs and were considered lower income communities based on census information and school district data.

In order for youth to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Ages 13-17
2. who speak English
3. are engaged with a community-based site
4. can provide contact information.

In order for adults to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Identified by the adolescent participant as a key support (family, school, or community-based)
2. speak English
3. can provide contact information.

5.2 EXCLUSION CRITERIA

Any youth who meet any of the following criteria will be excluded from participation in this study:

1. Current involvement in the juvenile justice system.

Any adult who meets any of the following criteria will be excluded from participation in this study:

1. Non-English speaking

5.3 LIFESTYLE CONSIDERATIONS

N/A

5.4 SCREEN FAILURES

Participants who assent in the program but do not meet eligibility criteria are invited to return when they meet criteria. Examples include interested youth who are currently involved in the juvenile justice system and youth who are not yet 13 years old.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

Youth Recruitment: In each of the participating neighborhoods, we have relationships with churches, libraries, youth serving agencies, and schools to assist with recruitment of eligible youth via flyers and word of mouth. We will draw on existing youth-serving agencies to assist with recruitment. As in previous studies, we will use 'respondent driven sampling' for youth to invite peers to participate. The type and effectiveness of strategies used for recruitment and retention will be tracked as part of the feasibility evaluation. The research assistant (RA) and the community liaisons will work with the community partners at each designated site to ensure that the parental information letter and assent forms are distributed to youth and families.

Adult recruitment: During program session #1, youth in the intervention group will be asked to identify a key adult support in his/her family, school, or community context to participate in the program. Youth will be asked to provide the identified adult with a letter from the study team that describes the research and get verbal permission to contact their key adult support. Once verbal permission is provided, the study team will reach out to the adult to facilitate enrollment using a preferred method of communication provided by the youth.

Participant Retention:

An advantage of conducting this study in Pittsburgh is that the turnover of youth in neighborhoods and schools is relatively low (except for youth who are juvenile justice involved, who will be excluded from the proposed study) and few students move out of the Pittsburgh area. As a stakeholder-engaged community-based study with strong buy-in from community agencies, stakeholders will assist with identifying and locating participants who need to complete post-intervention surveys and facilitating survey administration in community-based settings to improve retention.

The intervention will be evaluated utilizing all available data from participating youth and adults receiving the SCC curriculum or the control curriculum and completing pre-intervention and/or post-intervention surveys. We recognize retention can be a challenge; our team has experience with maintaining high retention in community intervention studies through a detailed contact sheet collected at baseline, scheduled follow up calls and emails, and working with community partners to help find youth. A system of escalating incentives for youth and adult participants will be employed. Youth will receive $15 for completing the baseline survey, $5 for completing each of the 12 feedback sessions, and $20 for completing the survey after program completion (total $95). Adults will receive $15 for completing the baseline survey, $5 for completing each of the 10 feedback sessions, and $20 for completing the survey after program completion (total $85). Even participants who may have missed portions of the sessions will still be asked to complete the post-intervention survey, utilizing an 'intent to treat' design.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION.

This pilot community-partnered cluster-randomized trial will examine the feasibility and acceptability of a social network-based youth violence prevention program called Strengthening Connections for Change for youth ages 13-17 and their self-identified key adult supports to focus on leadership, strengthening intergenerational networks, community engagement, and violence prevention. The study will be located in four lower resource Pittsburgh, Pennsylvania neighborhoods ('clusters') randomized to receive either the Strengthening Connections for Change program (i.e. intervention neighborhoods) or to a job skills training program (i.e. control neighborhoods). Randomization will occur 1:1 at the site level (2 intervention and 2 control sites). The study team will then work with each community-based site to recruit youth already engaged with the respective community site into the program to which each site has been randomized. The Strengthening Connections for Change intervention will be delivered weekly by research staff in twelve 2-hour sessions at community sites. The first 2 sessions will include youth-specific programming. For session 3-12, youth and adults will participate in separate programming for the first hour, then participate in a joint session.

Strengthening Connections for Change uses a group discussion format with activities that explore identity, adolescent-adult relationships, social networks, and community engagement. Youth invite their self-identified key adult supports to jointly participate in programming and curriculum includes youth-focused, adult-focused and jointly focused activities designed to build leadership skills, enhance intergenerational networks, challenge attitudes towards violence and retaliation, and reduce violence involvement. Strengthening Connections offers leadership development coupled with strengths-based youth violence prevention programming. The Strengthening Connections for Change curriculum will include: 1) a social network mapping session for youth to define and reflect upon existing sources of support, as well as leadership and community engagement training; 2) a curriculum for key adult supports focused on the protective effects of adult supports, key barriers/facilitators to helping youth build their support networks, and developing action steps; 3) joint sessions to address attitudes towards violence, strategies to promote network expansion and cohesion, interview and photovoice methods, and a youth-led change project. *The 12-session curriculum will be delivered over 6-12 weeks.*

The control intervention (Job Skills) uses a group discussion format to learn specific skills to prepare for employment including developing goals, seeking jobs, preparing for interviews, adapted from the widely used program called "Jump Start Success Work Readiness and Career Exploration Training" (*http://www.youthworksinc.org/jumpstart_success/index.html*). Discussions include a wide range of topics related to career exploration and job readiness. The Job Skills curriculum focuses on the skills needed to prepare youth for entering the workforce, including goal setting, accountability, resume building, and interview preparation. *The 12-session curriculum will be delivered over 6-12 weeks.*

All youth and adult participants will complete pre- and post-intervention surveys. Participants will be sent a text or email (based on preference) with a link to the survey, session reminders, and follow-up reminders to complete surveys before or after each group session. Participants who miss a session will also be sent a follow-up message. Dyads from the iterative testing and a subsample of 5-8 dyads from the pilot feasibility trial will also be invited to participate in a semi-structured dyadic interview, expected to last 45 minutes, following program completion.

Surveys: Youth and adult participants will be asked to complete pre- and postintervention surveys that cover a range of topics on social networks, adolescent-adult connections, attitudes towards violence, and violence involvement. A subsample of 5-8 adolescent-adult dyads will also be invited to complete a semi structured interview following program completion. Interviews will be audio-recorded. Surveys will

be offered in English using REDCAP. Paper surveys will be available as back-up in case of computer malfunction. Study staff will provide participants with instructions on using the web-based survey tool and will be available to guide participants through survey completion as needed. Participants enter their responses directly onto the tablet computer. Surveys take approximately 30-45 minutes to complete. Analogous to study procedures for Manhood 2.0, adolescent participants will produce a self-generated personal code based on eight nonidentifiable questions (e.g., "Please enter the first letter of your mother's first name or select N/A if you don't know or this is not relevant to you.") to ensure responses will remain as anonymous as possible. A similar personal code will be created for adult participants that will allow linking of adult participant data to the corresponding youth's data.

6.1.2 ADMINISTRATION AND/OR DOSING

Tracking Dosage: Attendance forms are completed at each site for each round. As surveys are anonymous, tracking number of sessions for each individual will require linking feedback surveys using participants' secret code. Should secret codes not be possible to match across session, dosage will be calculated for each round based on % overall attendance.

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

Facilitators at the community-partner sites will be trained on the intervention curriculum by study personnel prior to launch of the study. Pilot testing before the start of the study will allow study staff to finalize the curriculum and training necessary to begin the intervention. The facilitators that are chosen for this study have experience being facilitators in similar research studies. Research personnel will attend every session and complete fidelity feedback forms on the structure and completion of the session. Surveys will also be given to the facilitators to review their participation and program leading for the intervention. Sessions will be tracked in an online database and on the research database with session updates, upload of fidelity forms, and study tracking. Survey tracking from REDCap will be completed through the database and on REDCap.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

Assignment of Interventions: Randomization was performed at the neighborhood level. The initial randomization included 4 community-based sites. The study statistician performed this randomization as a one-to-one randomization between control and intervention arms.

Randomization was performed after approval for the study was obtained for a site in a new neighborhood so that the randomization assignment would not influence a site's willingness to participate. Sites chosen for the program have participated in other studies and interventions prior to the implementation of SCC, so many of the sites and facilitators were familiar with the content and programming guidelines. Due to the study design, investigators, research staff, participants, facilitators, and community partners could not be blinded to intervention assignment.

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

Session participation will be monitored through sign in sheets at each session as well as survey completion at baseline and end of programming. Completion of the sessions and the surveys will be monitored through REDcap. Retention is facilitated by collecting detailed contact information and offering incentives for survey completion.

6.5 CONCOMITANT THERAPY

N/A

6.5.1 RESCUE THERAPY

N/A

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

A participant may stop participating and withdraw from the study at any time. If a subject discontinues from either arm but not from the study, remaining study procedures will be completed as indicated by the study protocol.

The data to be collected at the time of study intervention discontinuation may include the reason(s) for discontinuing from the intervention, and methods for determining the need to discontinue.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.
An investigator may discontinue a participant from the study for the following reasons:

- Request from youth to discontinue their participation
- Lost-to-follow up; unable to contact subject (see **Section 7.3, Lost to Follow-Up**)
- Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

The reason for participant discontinuation or withdrawal from the study will be recorded. Subjects who withdraw from the study, before any data collection is completed, such as survey responses, documentation of consent/assent will be kept in the database.

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if they fail to respond to at least 10 contact attempts for follow-up surveys and the 3 months window for follow-up survey completion has passed.

Missing sessions (not participating in the program) will not be considered a reason for loss to follow up. We will make every attempt to reach participants who are missing sessions including using all contact information provided as well as through the community facilitators in their neighborhood.

Before a participant is deemed lost to follow-up, the investigator or research team member will make every effort to regain contact with the participant. These contact attempts will be documented in the participant's study file. Should the participant continue to be unreachable, they will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Assent and Consent
Youth ages 13-17 receive a description about the research study and parental letter about the study from the community sites. The parent letter includes an option for parents/caregiver to decline their child's participation. We received a waiver of parental permission and waiver of signed consent from the University of Pittsburgh Human Subjects Research Protection Office. Research assistants review the verbal consent form with youth at the beginning of the first session and answer any questions pertaining to confidentiality, the program flow, and survey time points. The consent form covers all research surveys over the course of the program. An additional consent is used for the optional interview portion at the end of the project.

Data Collection
There are several points of data collection throughout the study including baseline surveys, feedback forms, End of Program (EOP) survey, and interview. The surveys are all anonymous, linked by a personal secret code that youth create by answering a series of questions that only they know the answer to at the beginning of each survey. This method of using a personal study code was selected to ensure anonymity and increase the likelihood of honest responses. In addition to survey data, other sources of data for this study (primarily for process evaluation and assessing intervention fidelity) include: 1) feedback forms completed by youth after the end of each session; 2) fidelity forms completed by research assistants at each session; 3) interviews with site leads and facilitators; 4) interviews with youth.

Main Study Phase

Baseline survey: Youth are asked to complete the baseline survey the first time they attend a session (can enter study at Sessions 1 – 3; if participant is interested in joining after session 3, they are asked to return for the next round). All sites conduct web-based surveys (back up paper surveys are used as needed) on tablets using REDCap, an online data management and survey system. Responses to the anonymous web-based secure survey are entered by the youth participants themselves on an electronic tablet; no data are stored on the computers themselves. Only research staff who have been added to the project can access this online database. Data are downloaded and stored on a password-protected share drive that can only be accessed by users with the appropriate permissions. No names are connected to the survey data as each participant creates their own secret code as described above.

End of program survey: At the end of the program, youth are asked to complete an end of program survey that asks about which sessions they attended, their impressions of the program, and reassesses measures collected on the baseline survey. Surveys are self- administered on electronic tablets provided by the research staff (back up paper surveys will be used if tablets are not available or fail). All participants, regardless of the amount of curricular content completed, are eligible to take this survey; participants are asked to complete the end of program survey later if they miss the last session.

Emailed/text survey option: Participants who cannot attend the study site or other community site (e.g., due to lack of transportation, neighborhood barriers) for EOP survey administration will be offered the option to take the survey via email or a texted link on an internet-capable device (e.g., computer, smartphone). The RA will confirm via phone that the participant is OK to take the survey. The link will be specific to the email address that the young person provides and will only allow the survey to be taken once. Using REDCap's anonymous survey feature, we can create an individualized link to be sent to each participant's email or phone, and confirm if their survey was completed, but we cannot determine which survey data corresponds to that participant (i.e., remains anonymous). Phone call option: participants can also opt to complete the survey during a phone call with a research assistant, who reads aloud the questions and the participant responds; the research assistant enters the answers directly into the online survey tool.

Alternate contact information: We will also use the alternate contact information provided by youth upon study enrollment to reach them for follow-up surveys. This may include, but is not limited to, phone numbers or email addresses for parents, caregivers, other family members, and close friends. We then ask these contacts to facilitate us reaching the participant. Community site partners from the program are also contacted to ask for retention assistance.

Interviews: At or after the EOP survey, some youth will be invited to participate in a confidential interview about their experiences receiving the control or intervention, their feedback about the relevance of the program, and additional input about the impact of the program on themselves and their peers. The interviews will be digitally recorded, transcribed, and the audio files destroyed once the transcription has been checked for accuracy and all identifying information removed.

Data Management

Baseline and follow-up survey participation coincide with the beginning of the intervention and end of the program (EOP). All sites conduct web-based surveys (back up paper surveys are used as needed) on tablets using REDCap, an online data management and survey system. Youth provide detailed contact information at baseline to facilitate follow up. Contact information is confirmed again at sessions following the baseline survey. Responses to the anonymous web-based secure survey are entered by the youth participants themselves on an electronic tablet; no data are stored on the computers themselves.

Only research staff who have been added to the project can access this online database. Data are downloaded and stored on a password-protected share drive that can only be accessed by users with the appropriate permissions. No names are connected to the survey data as each participant creates their own secret code as described above. The only study documents that contain unique personal identifiers are contact forms and the contact list of participants (youth and prevention educators) that are kept to assist with re-contacting participants for follow up surveys. Contact forms are stored in a secure file drawer inside the locked office of the PI whenever not in use. Contact forms are stored separately from any survey data collected in this study (the survey data are collected via computer and immediately housed in a password-protected secure database). The names of participants are kept in encrypted files on a password-protected server behind the UPMC firewall.

8.2 SAFETY ASSESSMENTS

Data Security: Responses to the anonymous web-based secure survey are entered by the youth participants themselves through a computer-based system; the data are automatically entered into a password protected database accessible only to the investigative team. No names are connected to the survey data as each participant creates their own secret code as described above. Contact forms will be stored in a secure file drawer inside the locked office of the PI's research lab whenever not in use. Contact forms will be stored separately from any survey data collected in this study (the survey data are collected via computer and immediately housed in a password-protected secure database). The names of participants will be kept in an encrypted file on a password protected secure on-line server (available to the research team through the University of Pittsburgh), and accessed only when needed to arrange the follow up data collection with each community site. Please note that there are three layers of protection for the contact information: password protection to enter the University of Pittsburgh system, a username that has been granted access to the secure drive, and another password to decode the encrypted file. This information will be accessed only when needed to arrange follow-up contact with participants and scheduling data collection.

Internal Data and Safety Monitoring Plan: Given the sensitivity of the questions being asked regarding violence perpetration, we are taking extra precautionary measures with an internal data safety and monitoring plan in place. The senior research coordinator is responsible for daily monitoring of data and safety. They will work with research assistants to ensure that all data are collected and stored securely. The research team consisting of the PI (Dr. Culyba), senior research coordinator, research assistants, data analysts, and other research staff as appropriate, will meet weekly to review study progress and status of data collection and safety of participants. Each neighborhood/site has a designated point RA, who along with the research coordinator, is connected to the community site leads and can identify concerns about data collection or participant safety.

Extra precautionary measures were taken to protect the data, including the use of a personally created ID code to maintain anonymity of the survey data and an internal data safety and monitoring plan, which included the following:

a) Systematically review assessment materials to ensure that assessment is conducted appropriately and that participants disclosing abuse or violence during the course of taking the survey receive appropriate connection to violence-related services and that mandated reports are made by site personnel when appropriate.

b) Systematically review notes from research assistants to ensure that participants experiencing distress are being connected directly with the site directors and youth workers, receiving educational materials, and being referred appropriately; this includes ensuring that all research assistants document asking each participant about emotional distress after completion of the survey.

c) Monitor staff performance with regard to protection of privacy, confidentiality, maintenance of secure databases, and study procedures designed to reduce the risk of distress and potential breaches of confidentiality.

d) Ensure that the PI (Dr. Culyba), or a designated qualified individual, will be available in case research staff needs to confer regarding participants' behaviors or comments made during a survey or other research activities.

e) Ensure that the PI (Dr. Culyba), or a designated qualified individual, will be available in case educators needs to confer regarding participants' or youth workers' behaviors or comments made during study implementation (i.e., during training, survey administration, or follow up contact with site administrators, youth workers and facilitators).

f) Review and report any adverse events associated with the study.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS

This study is of minimal risk to participants because there is low likelihood of any risk or adverse events to occur during administration of anonymous surveys and confidential interviews. Precautions will be implemented to protect participating subjects' privacy and confidentiality. The primary risks are risk for breach of confidentiality and potential for emotional distress related to answering survey questions, both highly unlikely events.

Should a participant disclose safety concerns during the course of programming, the site RA follows the emotional distress protocol and immediately notifies Dr. Culyba (PI), a plan for safety and any reporting requirements are addressed, and the RA completes a report. Such events are reported to the IRB.

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS

We follow the definition of serious adverse events as outlined by the University of Pittsburgh Human Subjects Research Protection Office, and any questions we have about specific events, we review with a representative from this office.

While we do not anticipate any serious adverse events, we will promptly report to the IRB any unintended or unanticipated consequences from participating in this study. If any serious adverse event occurs (death, life threatening, new, serious, or permanent disability), it will be reported within 72 hours to the IRB. Specific information that will be recorded on the adverse event form will include details of the adverse event, treatment required for the event, the participant's condition after the event, an estimate of the extent of injury, and ways to prevent similar events from occurring in the future. Dr. Culyba will classify the relationship of the study protocol to the event on a scale from not related to highly probably

related as outlined by the IRB, and severity of the event from mild to severe based on a degree of intensity outlined by the IRB, which will be reviewed by the IRB.

All adverse events will be reported to the National Institutes of Health in addition to the University of Pittsburgh Human Research Protection Office.

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

Mild – Events require minimal or no treatment and do not interfere with the participant's daily activities.
Moderate – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
Severe – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by an appropriately trained clinician based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

Related – The AE is known to occur with the study procedures, there is a reasonable possibility that the study procedures caused the AE, or there is a temporal relationship between the study procedures and the event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study procedures and the AE.
Not Related – There is not a reasonable possibility that the study procedures caused the event, there is no temporal relationship between the study procedures and event onset, or an alternate etiology has been established.

8.3.3.3 EXPECTEDNESS

Given the sensitivity of the questions being asked regarding violence perpetration, we are taking extra precautionary measures with an internal data safety and monitoring plan in place, described above. All research personnel are trained on the emotional distress protocol and complete training on child abuse reporting requirements. Each neighborhood/site has a designated point RA, who along with the research coordinator, is connected to the community site leads and can identify concerns about data collection or participant safety.

A Summary Report of the Data and Safety Monitoring Plan will be submitted with the annual IRB renewal.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study participant.

Should a participant disclose safety concerns during the course of programming or study procedures, the site RA follows the emotional distress protocol and immediately notifies Dr. Culyba (PI), a plan for safety and any reporting requirements are addressed, and the RA completes a report. Such events are reported to the IRB.

All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

8.3.5 ADVERSE EVENT REPORTING

Review and report any adverse events associated with the study to the IRB.

8.3.6 SERIOUS ADVERSE EVENT REPORTING

In consultation with the PI, a trained member of the study team will be responsible for conducting an evaluation of a serious adverse event and shall report the results of such evaluation to the NIH and the reviewing Institutional Review Board (IRB) as soon as possible, but in no event later than 10 working days after the investigator first learns of the event.

8.3.7 REPORTING EVENTS TO PARTICIPANTS

N/A

8.3.8 EVENTS OF SPECIAL INTEREST

N/A

8.3.9 REPORTING OF PREGNANCY

N/A

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.4.2 UNANTICIPATED PROBLEMS REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB) and to the Data Coordinating Center (DCC)/lead principal investigator (PI). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB and to the DCC/study sponsor/funding agency within 2 days of the investigator becoming aware of the event
- Any other UP will be reported to the IRB and to the DCC/study sponsor/funding agency within 10 days of the investigator becoming aware of the problem
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) within 10 days of the IRB's receipt of the report of the problem from the investigator

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

N/A

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

Aim 3: To pilot test the feasibility and acceptability of the adapted YES intervention compared to a control intervention (Job Skills) among adolescents and their key adult supports at four community-based sites.

Approach: Participant tracking and post-intervention surveys will assess feasibility and acceptability.. Exploratory outcomes will include changes between pre-and post-intervention assessments of social network structure, relationship quality, social support (emotional and instrumental), attitudes towards violence, and violence involvement.

Primary Outcome Measure:

1. Participant Attendance: Attendance is recorded at the beginning and end of each session. Calculated as a proportion of total number of sessions attended (possible session attended #: 0-12 for youth participants and 0-10 for adult participants; possible proportion attended range: 0-1). [Time Frame: through intervention completion, 12 weeks]

2. Participant Satisfaction: At the end of the program, participants will be asked about how satisfied they were overall with the topics discussed and format of the program using 5-point Likert scale items. Means score will be calculated across the items (possible range: 1-5; higher score means higher satisfaction). [Time Frame: end of program (12 weeks)]

Secondary Outcome Measure:

3. Participant Satisfaction: At the end of each weekly session, participants will be asked about how satisfied they were with the topics discussed for that session using 5-point Likert scale items. Means score will be calculated (possible range: 1-5; higher score means higher satisfaction). [Time Frame: weekly for 12 weeks]

Other Pre-specified Outcome Measures:

4. Change in social network composition: Participants will complete an abbreviated social network survey that asks them to identify key sources of emotional and instrumental support, and to characterize the nature of these relationships (network size, network density, mean link strength). [Time Frame: Baseline, end of program (12 weeks)]

5. Change in violence perpetration: Summary score of past 30-day youth violence perpetration adapted from the Aggressive Behavior-SAGE Baseline survey (9 items, each measured on a 5-point frequency scale from 0 times to 7 or more times). Violence perpetration items will be added to create a summary violence perpetration score with 1 point for each response of at least 1 time (possible range: 0-9; lower score indicates better outcome). [Time Frame: Baseline, end of program (12 weeks)]

6. Change in violence victimization: Summary score of past 30-day youth violence victimization adapted from the Victimization-Problem Behavior Frequency Scale (9 items, each measured on a 5-point frequency scale from 0 times to 7 or more times). Violence victimization items will be added to create a summary violence victimization score with 1 point for each response of at least 1 time (possible range: 0-9; lower score indicates better outcome). [Time Frame: Baseline, end of program (12 weeks)]

7. Change in attitudes towards violence: Modified from the Children's Perception of Environmental Violence Scale, 6 items assessed on 5-point Likert scale, calculated as a mean score (possible range 1-5; lower score indicates better outcome). [Time Frame: Baseline, end of program (12 weeks)]

8. Change in coping: Modified from the Healthy Pathways Child-Report Scales: Active Coping Scale, 7 items assessed on 5-point Likert scale, calculated as a mean score (possible range 1-5; higher score indicates better outcome). [Time Frame: Baseline, end of program (12 weeks)]

9. Change in future orientation: Modified from the California Healthy Kids Survey, 7 items assessed on 5-point Likert scale, calculated as a mean score (possible range 1-5; higher score indicates better outcome). [Time Frame: Baseline, end of program (12 weeks)]

9.2 SAMPLE SIZE DETERMINATION

As previously described, the primary endpoints for this cluster-randomized feasibility trial are feasibility and acceptability among a sample of 50 adolescents and 25 adult participants. As such, point and interval estimation will be utilized for parameter estimation. Assuming 25 adolescents with complete data in each arm and a 5% type I error rate, we will have the ability to estimate within-arm 95% confidence interval margin-of-errors of no more than 0.20 for the proportion of participants achieving these feasibility and acceptability outcomes. We will additionally examine intraclass correlation coefficients (ICC) for all youth across 4 sites and for all adults at 2 sites; these ICCs will inform power and sample size calculations for a future R01 cluster-randomized intervention trial.

9.3 POPULATIONS FOR ANALYSES

All analyses will use an intention to treat approach and include all participants with available data. Primary outcomes will be estimated within each study arm using point estimates and 95% confidence intervals.

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

Descriptive statistics will characterize participants' demographics and baseline survey responses. T tests, Wilcoxon rank sum tests, and chi square tests will assess for differences in baseline characteristics and baseline survey responses among intervention versus control participants, after accounting for clustering. Feasibility and acceptability will be the primary outcomes of the pilot trial. Both feasibility/acceptability

and exploratory outcomes will be estimated within each study arm using point estimates and 95% confidence intervals. We will examine these endpoints separately for youth and adults. As an exploratory measure, we will assess outcomes on the difference between pre- and post-intervention measures of social network metrics, relationship quality and communication, attitudes towards violence, conflict resolution and coping, and future orientation between intervention and control participants. We will utilize generalized linear mixed models to account for site-level clustering. Missing data will be managed with multiple imputation if the mechanism of missingness is ignorable. Interview transcripts will be coded and analyzed by two independent reviewers through content analysis to identify themes related to intervention acceptability and satisfaction.

9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

The primary outcome measures for this study are participant attendance (feasibility) and participant satisfaction (acceptability). Both feasibility and acceptability and exploratory outcomes will be estimated within each study arm using point estimates and 95% confidence intervals. We will examine these endpoints separately for youth and adults.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

Secondary assessments using similar measures will be administered at the end of each session to assess satisfaction with the content of each session (7 items, each measured on a 5-point Likert scale, where 1= Strongly disagree, 2= Disagree, 3= Neutral, 4= Agree, 5= Strongly agree; e.g. “I felt I could trust my group leaders”). We will calculate the mean scores for each sessions for youth and adults. The percentage of youth participants with mean score ≥4 and the percentage of adult participants with mean score ≥4 will be calculated (range 0-100%).

9.4.4 SAFETY ANALYSES

N/A

9.4.5 BASELINE DESCRIPTIVE STATISTICS

Summary statistics, including frequency tables, percentages, and proportions, will be used to describe participant demographic data and social network characteristics. Histograms, boxplots, quantile-quantile plots, and quantile-normal plots will be generated to visualize distribution functions and assess normality of quantitative data. Moreover, measures of center (mean, median) and measures of spread (standard deviation, range, interquartile range) will be calculated and presented. To assess differences at baseline between the youth in the experimental and control groups, demographics such as grade-level, race, and parental education will be compared while accounting for within-neighborhood clustering. Demographic variables resulting in between-arm imbalances will be considered as covariates in the primary and secondary analyses.

9.4.6 PLANNED INTERIM ANALYSES

N/A

9.4.7 SUB-GROUP ANALYSES

N/A

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

N/A

9.4.9 EXPLORATORY ANALYSES

As an exploratory measure, we will assess outcomes on the difference between pre- and post-intervention measures of social network metrics, including network size, density, and mean link strength, as well as violence perpetration, violence victimization, attitudes towards violence/retaliation, coping, and future orientation. We will utilize generalized linear mixed models to account for site-level clustering and include selected covariates. Missing data will be managed with multiple imputation if the mechanism of missingness is ignorable. Given the small sample and exploratory nature of the additional analyses, each exploratory test will utilize $\alpha=0.1$ for the threshold of significance, and no corrections will be made for multiple tests.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Research assistants will provide an overview of what the research involves with youth who express interest during the initial conversation. Adults identified by youth will be given an overview of what the research involves during an initial conversation. Verbal informed consent from adults and informed assent from youth 13-17 will be obtained prior to the initial survey.

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

A waiver to document informed consent and a waiver for parental permission were granted by the IRB.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor/funding

agency and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance of study staff to the protocol (ie, significant protocol violations)
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, sponsor, IRB, Food and Drug Administration (FDA), or other relevant regulatory or oversight bodies (OHRP, DSMB).

10.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the safety and oversight monitor(s), and the sponsor(s) and funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally-identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

All research activities will be conducted in as private a setting as possible.

The study monitor, other authorized representatives of the sponsor or funding agency, representatives of the Institutional Review Board (IRB), regulatory agencies or representatives from companies or organizations supplying the product, may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor/funding agency requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored in the research team's secure, password protected electronic database. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number (using the secret code generated by participants).

Measures Taken to Ensure Confidentiality of Data Shared per the NIH Data Sharing Policies
It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see *https://grants.nih.gov/policy/sharing.htm*). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and

security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

Certificate of Confidentiality
To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (see *https://humansubjects.nih.gov/coc/index*). As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

Data collected for this study will be analyzed and stored at the University of Pittsburgh in Dr. Culyba (PI) research office, on a password protected secure drive. The research team will not make individual participant data (IPD) available to other researchers.

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator	**Study Statistician**
Alison Culyba, MD PhD MPH	*Kaleab Abebe, PhD*
UPMC Children's Hospital of Pittsburgh	*University of Pittsburgh*
120 Lytton Ave, Pittsburgh, PA 15213	*200 Meyran Ave., Suite 300, Pittsburgh, PA 15213*
Alison.culyba@chp.edu	*Kza3@pitt.edu*

10.1.6 SAFETY OVERSIGHT

As a minimal risk study, safety oversight is under the direction of the PI and an internal safety monitoring group including the study coordinator and study statistician.

10.1.7 CLINICAL MONITORING

Extra precautionary measures are taken to protect the data, including the use of a personally created ID code to maintain anonymity of the survey data and an internal data safety and monitoring plan, which includes the following:

- Systematically review assessment materials to ensure that assessment is conducted appropriately and that participants disclosing abuse or violence during the course of taking the survey receive appropriate connection to violence-related services and that mandated reports are made by site personnel when appropriate.
- Systematically review notes from research assistants to ensure that participants experiencing distress are being connected directly with the site directors and youth workers, receiving educational materials, and being referred appropriately; this includes ensuring that all research assistants document asking each participant about emotional distress after completion of the survey.
- Monitor staff performance with regard to protection of privacy, confidentiality, maintenance of secure databases, and study procedures designed to reduce the risk of distress and potential breaches of confidentiality.
- Ensure that the PI, or a designated qualified individual, will be available in the case the research staff needs to report behaviors or comments made during a survey or other research activities.
- Review and report any adverse events associated with the study.

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

Quality control (QC) procedures will be implemented as follows:

Informed consent --- Study staff will review both the documentation of the consenting process as well as a percentage of the completed consent documents. This review will evaluate compliance with GCP, accuracy, and completeness. Feedback will be provided to the study team to ensure proper consenting procedures are followed.

Source documents and the electronic data --- Data will be initially captured on source documents will ultimately be entered into the study database. To ensure accuracy site staff will compare a representative sample of source data against the database, targeting key data points in that review.

Intervention Fidelity — Consistent delivery of the study interventions will be monitored throughout the intervention phase of the study and documented on RA-completed session fidelity forms.

Protocol Deviations – The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection will be the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data.

Hardcopies of the contact sheets, attendance sheets, and fidelity forms will be provided for use as source document worksheets for recording data. Data recorded in the electronic database derived from source documents will be consistent with the data recorded on the source documents.

The main survey data are entered directly by study participants via an electronic notepad displaying an online survey. Those data are transmitted directly into the secure database.

10.1.9.2 STUDY RECORDS RETENTION

Study documents will be retained for a minimum of 10 years following guidance from the University of Pittsburgh Human Research Protections Office. No records will be destroyed without the written consent of the sponsor/funding agency, if applicable. It is the responsibility of the sponsor/funding agency to inform the investigator when these documents no longer need to be retained.

10.1.10 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1, and 5.20.2.

It will be the responsibility of the site investigator to use continuous vigilance to identify and report deviations within 2 working days of identification of the protocol deviation. Protocol deviations will be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator will be responsible for knowing and adhering to the reviewing IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

10.1.11 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers 10 years after the completion of the primary endpoint by contacting the PI. Considerations for ensuring confidentiality of these shared data are described in Section 10.1.3.

10.1.12 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the University of Pittsburgh has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

10.2 ADDITIONAL CONSIDERATIONS

N/A

10.3 ABBREVIATIONS AND SPECIAL TERMS

AE	Adverse Event
CDC	Centers for Disease Control and Prevention
CMP	Clinical Monitoring Plan
COC	Certificate of Confidentiality
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DHHS	Department of Health and Human Services
DSMB	Data Safety Monitoring Board
FFR	Federal Financial Report
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Council on Harmonisation
IRB	Institutional Review Board
MOP	Manual of Procedures
NCT	National Clinical Trial
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SCC	Strengthening Connections for Change
SOA	Schedule of Activities
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

10.4 PROTOCOL AMENDMENT HISTORY

Version	Date	Description of Change	Brief Rationale

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