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Title of the study: Social Influence Strategies during a Web-based Smoking Prevention Intervention for Adolescents: NIDA R00 Protocol

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Protocol

1. **Project Title:**

- Social Influence Strategies during a Web-based Smoking Prevention Intervention for Adolescents: NIDA R00 Protocol

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3. **Abstract:**

- **Problem:** Negative influence from peers and friends is a well-known potent predictor of adolescent smoking initiation. However, what is not known is how to design and implement an intervention that promotes positive social influence for adolescents (i.e., connection with and support from others who do not intent to use tobacco). One example of an intervention that lacks positive social influence is a Web-based, computer-tailored intervention called *A Smoking Prevention Interactive Experience* (ASPIRE).

- **Potential solution:** One innovative approach to fill the gap is to apply social influence strategies. First, game-based social activities (GSAs) can facilitate exploration of health information and drive social discussions against tobacco use. Second, social network analysis allows us to strategically group at-risk adolescents (i.e., those who use or intend to use tobacco) with close peers who do not intend to use tobacco (i.e., change agents), as they engage in ASPIRE. Change agents will positively influence at-risk adolescents for two reasons: (1) At-risk adolescents will be dominated in number by change agents, and (2) their interaction with change agents will be directed by the healthy content of ASPIRE and the GSAs.

- **Objective and central hypothesis:** The objective of the current research is to identify the effect of ASPIRE on key mechanisms underlying adolescents' intention to use tobacco products (cigarettes, cigars, hookah water pipes, and vaping products), when social influence strategies are added to the intervention. The central hypothesis is that the addition of social influence strategies to ASPIRE will boost ASPIRE's success in lowering intention to use tobacco.

- **What we will do:** Through focus group discussions, we will improve designed GSAs (Study 1). Then, through a group-randomized study (Study 2), we will compare the use of ASPIRE alone (ASPIRE) with the use of GSAs along with ASPIRE and social grouping using social network analysis (GSA-ASPIRE-Network). This study will be conducted with after-school or school programs (ASPs) in Florida.

- **The rationale:** The rationale is that new evidence will provide supportive data for the subsequent development and evaluation of a social influence intervention for tobacco prevention. Ultimately, the research plan for this project has the potential to inform the future development of a project to design and evaluate a comprehensive intervention for adolescents, with positive social influence as a driver of tobacco prevention.

4. **Background:**

- **Public Health Problem:** While overall rates of cigarette smoking in the U.S. have decreased during the past 20 years, adolescents have kept their cigarette initiation at about 5% and increased their use of new

and emerging nicotine and tobacco products (e.g., hookah [water pipes] and vaping products) to about 20%.[1,2] Such novel products have been found to lead to conventional cigarette use.[3] Ultimately, tobacco use in its many forms has been linked to several conditions among adolescents (e.g., nicotine dependence,[4] psychiatric disorders[5], and early signs of pulmonary[6] and cardiovascular disease[7]).

- **Social Influence:** Although reasons behind tobacco use at a young age are complex, prevention research has identified one potent predictor of adolescent smoking initiation: negative social influence. There is ample evidence that adolescents' smoking behavior is associated with their social group of school peers and friends.[8,9] Alternatively, adolescents' abstinence from smoking can be a socially learned behavior acquired by modeling peers who reject smoking (i.e., positive social influence).[10]

- **Gap in Knowledge:** Despite the empirical evidence and theoretical support of the role of social influence on smoking initiation, it is still not known how to design and implement an intervention that promotes positive social influence for adolescents (i.e., connection with and support from others who do not intent to use tobacco). First, the majority of school-based programs for smoking prevention have provided health messages about negative social influence (e.g., peer pressure to smoke), without the promotion of positive social influence.[11] Second, while some programs have provided social competence skills to refuse tobacco,[12] such skills were offered at the individual-level, without peer-to-peer interaction.

  One example is a Web-based interactive program called *A Smoking Prevention Interactive Experience* (ASPIRE). ASPIRE includes a series of videos and activities that teach about the consequences of smoking, social norms, and other smoking prevention issues. A randomized controlled trial (RCT) conducted in Houston (N=1,098) showed that by 18-month follow-up, fewer ASPIRE users initiated smoking, when compared to a standard-care booklet.[13] Still, ASPIRE can benefit from social influence strategies with peer-to-peer interaction for better outcomes.

- **Pilot Study – The Social Influence Factor:** My initial pilot study with ASPIRE (n=90), conducted at a previous institution, supported the need for peer-to-peer interaction. It indicated that adolescents who increased in intention to smoke had more friends who smoke ($p<0.001$), had tendency for more negative influence (i.e., likelihood of accepting a tobacco product from friends) ($p<0.001$), and less positive influence from friends (i.e., likelihood of agreeing with best friends when advised to avoid a tobacco product) ($p<0.05$). In-depth interviews indicated that adolescents need to interact with their peers in order to share what they learned and convince others to quit tobacco use.

- **Pilot Study – Social Influence Pathways:** Also at a previous institution, I conducted a retrospective study through the existing data of the original ASPIRE trial (N = 1,098),[13] highlighting the critical need to promote positive social influence for tobacco prevention. This study showed that adolescents who act as positive influencers (advice against smoking when their friends smoked) are less likely to initiate smoking by 18-months follow-up. ASPIRE effect is lost when controlling for social influence indicators (being a positive influencer and having friends who smoke). Results also showed that ASPIRE did not predict social influence indicators. This shows the limited ability of ASPIRE in preventing initiation, compared with the predictability of social influence factors.

- **Social Influence Strategies:** One innovative approach to fill this gap is the application of social influence strategies. First, game-based social activities (GSAs) applied in an entertaining environment can foster exploration of health information and drive social discussions against smoking.[14,15] Research indicates that adolescents' participation in organized activities contributes to peer-group formation.[21] In particular, activities serve to generate peer-group identity[16] and shared values and norms associated with the activity.[17] Complimenting ASPIRE with GSAs may drive social interactivity and ultimately give adolescents the opportunity to learn about tobacco effects through interpersonal discussions.[14,18] Social activities can also make use of game play in order to allow a successful learning process.[19] In addition to my own work, several researchers have shown the success of health games through RCTs.[20,21] Game play will moderate the discussions and allow group members to share information equally, without the domination of a leader. In addition, social network analysis will allow us to strategically group at-risk adolescents (i.e., those who intend to use tobacco), with close peers who do not intend to use tobacco (i.e., change agents), as they

engage in ASPIRE and the GSAs.[22,23] By exploring health information with change agents, at-risk adolescents may decrease in intention to smoke. Previous research has shown how interventions that make use to social network data can accelerate behavior change.[23] Change agents will influence at-risk adolescents for two reasons: (1) At-risk adolescents will be dominated in number by change agents, and (2) their interaction with change agents will be directed by healthy content in ASPIRE and the GSAs.

- **My central hypothesis** is that social influence can have an impact on ASPIRE's success in lowering adolescent tobacco use. My hypothesis has been formulated based on preliminary data, my pilot work, and theoretical frameworks.[24,25]

5. Specific Aims:

- **Specific Aim 1:** Conduct a qualitative study to improve the designed GSAs.
- **Specific Aim 2:** Conduct a study to compare the use of ASPIRE alone (ASPIRE) with the use of GSAs along with ASPIRE and social grouping using social network analysis (GSA-ASPIRE-Network).

- The rationale for the proposed aims is that new evidence will provide supportive data for the subsequent development and evaluation of a comprehensive social influence intervention for tobacco prevention among adolescents. The aims will be achieved by testing two main hypotheses and answering two research questions, under 2 studies; Study 1 (Specific Aim 1) and Study 2 (Specific Aim 2):
  - **Study 1:**
    RQ1: What are the design features that need improvement in the designed GSAs?

    Along with the aim to answer this research question, Study 1 will allow us to engage adolescents for participation in the Study 2 planning process and develop plans and materials for Study 2.
  - **Study 2:**
    H1: Adolescents in the GSA-ASPIRE-Network group will be more likely to increase in positive social influence, and decrease in intention to use tobacco, when compared with adolescents in the ASPIRE group.

    H2: Change in positive social influence over time mediates the relationship between GSA-ASPIRE-Network and change in intention to use tobacco over time.

    RQ2: How do adolescents in the intervention group describe their experience with GSA-ASPIRE-Network, compared with those who experience ASPIRE alone?

    Primary Outcome for Study 2:
    - **Intention to use tobacco** is defined as intention to use any tobacco product (cigarettes, cigars, hookah water pipes, and vaping products) in the near future.

    Secondary Outcome for Study 2:
    - **Positive social influence** is defined as connection with and support from others who do not intent to use tobacco.

6. Research Plan for Study 1:

- **Study Design.** Study 1 will address Specific Aim 1 and will involve a cross-sectional focus group design followed by a survey. Up to 80 participants can be recruited for study 1.

In addition to the cross-sectional focus groups, we will have a youth advisory board for the project. The youth advisory board will consist of adolescents ages 11-18 and college undergraduates. There will be up to 20 youth advisory board members.

Members of the youth advisory board would follow the development of the board game and would provide input from an adolescent's perspective during meetings and e-mails with the research staff. Colleagues of Dr. Khalil and the board game design company will not join meetings where youth advisory board members are present.

Members of the advisory board will receive compensation for their time:

- A $10-gift-card by end of August
- A $10-gift-card by end of September
- A $10-gift-card by end of October
- A $10-gift-card by end of November
- Two $10-gift cards by end of December
- A $5 gift card by end of January
- A $5 gift card by end of February
- A $5 gift card by end of March
- A $5 gift card by end of April
- A $5 gift card by end of May

Members of the advisory board will not have access to research files and will not be eligible to participate in study 2 of this project.

- **Eligibility.** Adolescents will be eligible if (1) they are of ages 11-18 years and (2) they are English-speaking. Adolescents with developmental disability, mental or physical, are not excluded from the study. However, they will only be able to participate if (1) they understand the information presented to them in the consent document, and (2) they believe they are capable to engage in the board game, use the internet, and answer survey questions. Pregnant adolescents will be eligible to participate in the research study as requested by the NIH based on the following 2 principles:
  1) *Consideration of risks of exclusion as well as risks of inclusion.* Pregnant adolescents are a group for whom tobacco use poses particular risk and preventing tobacco use in this group is beneficial. There is therefore concern for excluding this population from the potential benefit of the prevention intervention. There is also potential risk in listing pregnancy as the only exclusion criterion, in that pregnant adolescents may not desire to self-identify to the researchers or to other members of the youth group. The exclusion criterion may create pressure to self-identify or create an assumption that non-participating individuals in these after school groups are pregnant.
  2) *The equitable distribution of the burdens and benefits of research, which is central to the Common Rule.* The potential burdens that you identify for the intervention may apply to many people, not exclusively pregnant persons, and potential participants could evaluate for themselves whether they are willing to meet the research requirements during the informed consent process. You might also consider the degree to which some burdens (e.g., sitting for extended periods) could be addressed through intervention re-design or reasonable accommodations to make participation more inclusive.

Eligibility Criteria during COVID-19:
Considering COVID-19, we will require that the adolescent have access to a webcam, a computer, and internet should they complete the study tasks in the privacy of their homes.

- **Methods for Study 1.**
  - **Connection with after-school and school program sites:** At first, as many as a minimum of 4 after-school programs or schools (ASPs) from the Boys and Girls Clubs and the YMCA in Florida will be approached for this study. The PI and/or study staff will attend ASP sites. In order to present the study to program directors and describe to them the study procedure. We expect to obtain interest from at least 1 ASP.

Once an ASP is recruited, we will obtain a letter of support (Sample in Appendix 0) or a signed Contract for Services (Sample in Appendix 15). Signed letter of support or Contract for Services will be submitted to IRB. We will not move forward with data collection from adolescents unless a signed letter of support is obtained or Contract for Services from the ASP. Due to COVID-19, the PI and/or study staff will connect with ASP sites via phone call or Zoom.

In addition, considering COVID-19, recruitment will also occur by connecting with parents of adolescents through the HealthStreet Program at UF, by connecting with parents of adolescents through ResearchMatch, and via advertisement on Facebook with the assistance of the clinical and translational science institute recruitment center.

Connection with HealthStreet Members: Study staff will recruit participants by connecting with members of HealthStreet. Parents of adolescents will be sent an announcement (appendix 1c) from HealthStreet via e-mail. The parents will contact HealthStreet to discuss the study and the eligibility requirements using a pre-screener (Appendix 8).

Adolescents who are 18 years old and are members of HealthStreet will be sent an announcement (appendix 1h) from HealthStreet via e-mail. The adolescents will contact HealthStreet to discuss the study and the eligibility requirements using a pre-screener (appendix 8).

Connection with Members of Facebook Groups & Pages: Study staff will recruit participants by connecting with parents of adolescents in groups and pages on Facebook (appendix 9). Study staff will post in the Facebook group/pages and will direct parents to contact study staff. Once they have connected with study staff, the parents and study staff will discuss the study and the eligibility requirements.

18-year-old adolescents that are members of the Facebook groups/pages will be directed to contact study staff if they are interested in participating in the study. Once they have connected with study staff, the adolescents and study staff will discuss the study and the eligibility requirements.

Connection with Members of ResearchMatch: Study staff will recruit participants by connecting with parents of adolescents who are members of ResearchMatch where they will be sent a message through the website (appendix 10). The parents of adolescents will be instructed to contact study staff. Once connected with study staff, study staff will discuss the study and eligibility requirements.

18-year-old adolescents that are members of ResearchMatch will be directed to contact study staff if they are interested in participating in the study. Once they have connected with the study staff, the adolescents will discuss the study and the eligibility requirements.

- **Consent procedure:** If the ASP director agrees to have their program site participate in Study 1, they will complete and sign a letter of support or Contract for Services.

Then, the PI and/or study staff will verbally announce the study to adolescents in a private classroom setting, in the presence of ASP staff (it is expected that the announcement will reach approximately 60 adolescents). Interested adolescents will be presented with all information concerning the study (study purpose, requirements, risks, and benefits of participation) and will be given a form to share with their parents (Appendix 1a).

Research staff may announce the study to parents at an ASP parent orientation in the presence of ASP staff. In this case, research staff will approach parents after the orientation to review and sign the informed consent form.

If parents/legal guardian arrive to pick up their adolescents at the ASP, they will be approached concerning the study and all informed consent information will be presented to them verbally and on

iPad screen. After obtaining parental permission, the interested adolescent will be presented with the assent form to sign in the presence of a witness (a staff from the ASP).

Emancipated adolescents (age 18) will not be asked for parental permission. They will be asked to sign a complete consent form. All such procedures will occur in a private room at the ASP.

Parents will use the iPad to review the consent and provide an electronic consent. Adolescent will also assent on the iPad. However, paper consent forms will be available in case parents or adolescents prefer a paper-based form. Both parents and adolescents will receive a copy of the consent document for their own records. Also, these documents include the contact information of the PI and the University of Florida's Institutional Review Board (IRB).

A separate consent form has been created for 18-year-old adolescents. Following our announcement at the ASP, if an adolescent who is 18 years of age expresses interest in the study, we will approach this individual during breaks at the ASP to go in detail over the consent form.

The tablets have touch screen ability so the e-consent can be signed and saved. The paper versions will form copies that participants can keep to read the consent document at any time. Also, if adolescents or parents prefer to use a paper version, it will be available to them for use. We want to make sure that we offer both options to potential participants and their parents. From an administrative perspective, the use of tablets will allow us to efficiently store and organize consent documents.

It is expected that 63 adolescents and their parent/legal guardian will be interested and eligible. Parental permission and child assent forms will be presented in-person, and in details by a study staff or the PI. A staff member of the ASP will act as witness during consent.

After identifying interested adolescents and receiving signed child assent and parental permission forms, we will schedule dates with the ASP in order to conduct the study with 45 adolescents.

Consent procedure for study 1 during COVID-19:
Due to COVID-19, we will be reviewing the study information and assents/consent forms with adolescents and parents remotely via phone call or Zoom if the ASP is not allowing adolescents and parents to be inside the facility.

If PI and/or research staff, adolescents and parents are allowed inside the ASP facility, research staff may go over the consent form with adolescents and parents remotely or in person and will provide the option of signing a paper consent form.

If parents and adolescents need to be contacted for research purposes, the research staff will contact them using Cisco Jabber or Zoom.

If the ASP director agrees to have their program site participate in Study 1, they will complete and sign a letter of support or contract for services that can be available electronically.

Through ASP recruitment, the ASP will distribute an announcement (Appendix 1a) to parents via e-mail. ASP staff may also announce the study to adolescents in need of parent permission via email using the informational form (Appendix 1b). On the other hand, through HealthStreet, ResearchMatch, and Facebook, parents will be approached directly by study staff with the study announcement.

If PI and/or research staff cannot be at the ASP in person with adolescents due to ASP guidelines for COVID-19, research staff will announce the study to the adolescents in a private classroom setting using Zoom in the presence of ASP staff. After the announcement, ASP staff will provide interested adolescents with an informational form to give to their parent about the study (Appendix 1a). The parent may contact research staff using the contact information on the form. During the phone or Zoom call,

interested adolescents and parent/legal guardian will be given a link to the online consent form to review and sign with the guidance of the PI and/or study staff. Research staff will contact participants using Cisco Jabber or Zoom.

If parents and adolescents are allowed to be at the ASP facility, research staff will review the consent form with parents and adolescents in person. Parents and adolescents will be given the option of signing a paper consent form to review and sign with the guidance of PI and/or study staff.

Adolescents of age 18 will be sent an announcement (Appendix 1d) by ASP or study staff via HealthStreet, ResearchMatch, and Facebook. If the 18-year-old adolescent expresses interest to PI and/or study staff, he/she will be invited to a phone call or Zoom meeting to discuss the research study. They will be sent a complete online consent form to review and sign with the guidance of the PI and/or study staff. Research staff will contact participants using Cisco Jabber.

The parents and adolescents will be given the option to download an electronic copy of the signed online informed consent form for their own records. If the parents and adolescents sign a paper consent form, research staff will email the scanned signed consent form to the parent and adolescent for their records.

Once parents have provided consent for their adolescent to participate, the participant will be asked to provide demographic information (appendix 2c) and contact information (appendix 2d) via REDCap survey. The contact information will be used to coordinate with participants to schedule a time for the focus groups to take place and to provide compensation. In addition to collecting the participant's contact information, we will also collect the contact information of the participant's legal guardian to provide compensation.

Parents and adolescents will use their computers to sign the e-consent and to complete the contact information & demographic information REDCap survey. If the ASP allows adolescents and parents inside the facility, research staff will provide the option of signing a paper consent form and the option of filling out contact information and demographic information on a paper form.

For parents that are hard to reach, ASP staff will send the adolescent home with an informed consent form with a summary of the consent form attached (Appendix 14a) for the parent to review and sign should they decide to provide their permission for their child to participate. Once parental permission is obtained, research staff will review the child assent with the adolescent and obtain their assent should they decide to participate in the study.

For sites that require parent permission for 18-year-old adolescents to participate in extracurricular activities, ASP staff will send the adolescent home with a summary of the research project for the parent to review and give permission by signing the bottom of the form (Appendix 14c). Once the parental permission is obtained, research staff will review the informed consent form specific to 18-year-old adolescents with the 18-year-old adolescent.

If research staff are to work with parents, adolescents, and ASP staff inside the ASP facility, research staff will follow COVID-19 guidelines put in place by the ASP. Research staff will wear masks, use hand sanitizer, and will distance themselves from others by at least 6 feet. If someone at the facility were to test positive for COVID-19, all who were in contact with the person who tested positive will be required to quarantine for at least 2 weeks.

It is expected that 63 adolescents and their parent/legal guardian will be interested and eligible. Parental permission and child assent forms will be presented online, and in detail by a study staff or the PI.

Assessment: First, during the focus group sessions, qualitative semi-structured questions and messages (Appendix 2a) will address adolescents' most and least favorite elements in the intervention, and ways to improve the design of the GSAs. The questions listed in appendix 2a will not all be asked during each focus group session, but however many can be discussed until the time limit of the focus group session has been reached. Adolescents' answers are interpreted by using concepts from the social learning theory (i.e., learning from observation), experiential learning (i.e., learning from experience[26]), and gamification (i.e., making activities playful[15]). Adolescents will be asked about (1) their thoughts about the activities, (2) their experience with teamwork, and (3) ways to improve the activities.

Following the focus group session, in a classroom setting, participating adolescents will be invited to complete a 20-minute psychosocial survey named Post-Discussion Survey (Measures in Appendix 2b). The survey will include questions about demographic characteristics, tobacco use status[27] and intention to use tobacco,[28] psychosocial determinants of smoking and factors that may affect an online experience, social influence, social activity engagement, and game play.[29-31]

The survey results will be de-identified after receiving each survey and focus group data. As we collect surveys, we will link survey responses with focus group comments and then de-identify the data by replacing names with code numbers.

This Post-Discussion Survey will be employed in order to pilot-test the instruments and the survey implementation in the ASP setting.

- **Assessment for Study 1 during the COVID-19 quarantine:** Due to the current COVID-19 quarantine, the setting of the phase 1 of study 1 will change from a classroom setting to a remote setting. The PI and/or study staff will remind participants of the focus group session one day prior to the session, and 3 hours prior to the session. The PI and/or study staff will facilitate the focus group via Zoom.

  The setting of phase 2 of study 1 will take place at the ASP with research staff facilitating remotely. Research staff will visit the ASP to set up webcams and laptops prior to playtesting. Research staff will abide by COVID-19 guidelines set by the ASP. Once webcams and laptops are set up, research staff will facilitate playtesting via Zoom. Research staff will remind participants of the playtesting session one day prior to the session, and 1 hour prior to the session.

  During study 1, PI and/or staff will invite participating adolescents to the Zoom meeting via e-mail and phone call should they participate in the privacy of their home. Research staff will contact participants via phone using Cisco Jabber.

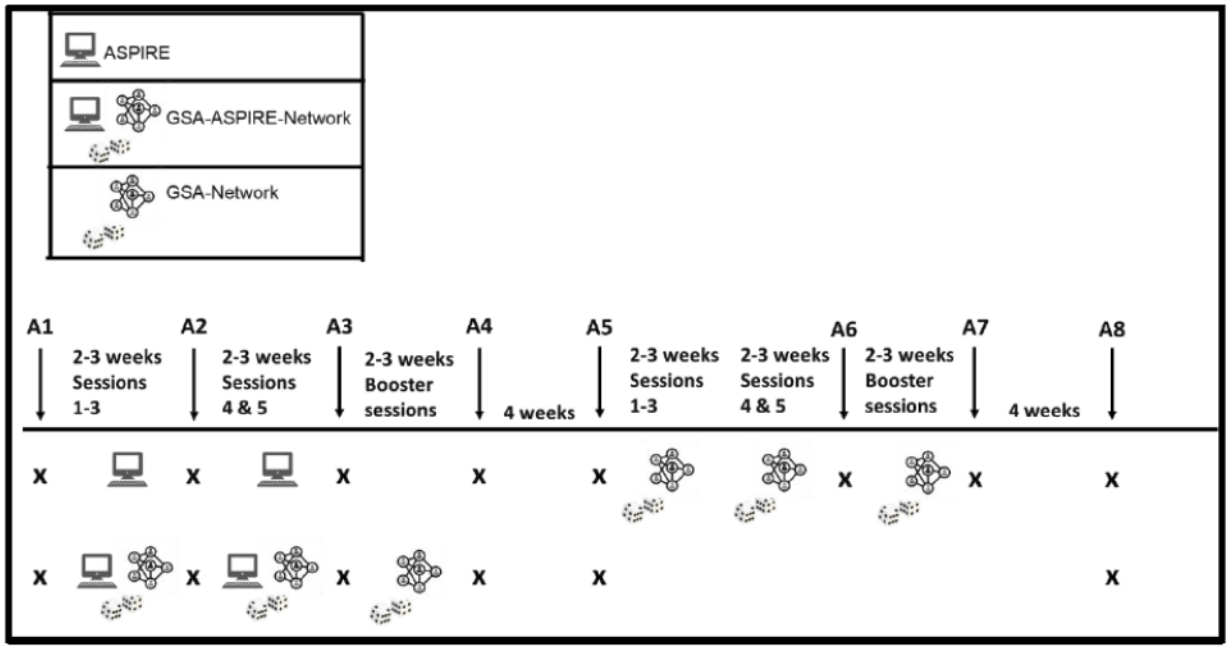
Sample Size Considerations for Study 1. Prior qualitative research has indicated that thematic saturation is on average attained with 15 participants. The organization of participants in groups of 5 participants is recommended by previous research for qualitative data analysis of focus group discussions. This study will be separated into two phases with the first phase separated in two sets. The first set of focus groups will have participants discuss and playtest the board game content and design. The second phase of focus groups will have participants discuss tobacco and the environment. We plan to have 3 focus groups of 5 participants for each set, but we may facilitate more focus groups in order to reach thematic saturation for each set. The first phase of focus groups will have up to 40 participants (20 for each set) with hope to retain 38 participants. The second phase will have up to 60 adolescents, with hope to retain 25 participants. As a result, a total of **one hundred** may be enrolled with hope to retain **63** participants. The expected retention rate of participants is 62% due to COVID-19.

- **Qualitative Data Analysis for Study 1.** Qualitative data analysis for study 1 will be conducted to answer RQ1. The audio-recordings of the focus group discussions will be transcribed verbatim by the study staff or by a professional transcription service. Then, the data will be analyzed using techniques described by Stewart and Shamdasani.[32] The transcripts will be read independently by two study team members and major emerging themes will be identified. The sessions will allow for the exploration of relevant adolescents' experience with the intervention, thoughts about the activities, their experience with

teamwork, and ways to improve the activities. Themes will be defined as intervention issues or ideas that are repeated and common to several participants in a group, and common between groups.

7. **Research Plan for Study 2:**

- **Study Design.** Study 2 will address Specific Aim 2 and will involve a nested, group-randomized controlled design, recruiting adolescents from ASPs, such as the Boys and Girls Clubs in Florida. In a 2 (condition) by 4 (time) design, 4 clubs minimum will be randomly assigned to one of two conditions named "ASPIRE" and "GSA-ASPIRE-Network". Additional ASPs may be recruited in case sample size is not reached.
- Similar to a "wait-list" group, participants in the "ASPIRE" group will receive the GSAs and Network (GSA-Network) portions of the program about 4 weeks following Survey Assessment 4 (A4), between Assessments 5 and 7, in 5 to 7 sessions (5 regular sessions and up to 2 booster sessions). This will include 4 additional assessment points following Assessment 4. With 4 additional assessment points following Assessment 4, we will get to examine improvement over time following participants' engagement in the social features of the program. Participants in the ASPIRE-only group did not have the opportunity to engage with these social features of the program during the Fall.
- To assess long term success among participants in the "GSA-ASPIRE-Network" group, 2 assessment points will be added to this group (A5 and A8 only).
- Survey assessments A5 through A8 will be the same as the network assessment survey (Appendix 4).



- **Eligibility.** An ASP is eligible if it provides internet connection at its club and houses at least 10 adolescents. Adolescents will be eligible if (1) they are of ages 11-18 years, (2) they are members of ASP, (3) they are English-speaking, and (4) have not participated in an educational program about tobacco in the last year. Adolescents with developmental disability, mental or physical, are not excluded from the study. However, they will only be able to participate if (1) they understand the information presented to them in the consent document, and (2) they believe they are capable to engage in the board game, use the internet, and answer survey questions.

- **Methods for Study 2.** The following section describes the methods being used and step-by-step procedures to conduct the study.
    - **Final design of the GSAs:** First, the game-based social activities (GSAs) will be developed and printed by working closely with the development company, expert in social action and education. The development company is called Toolbox for Education and Social Action (TESA). There is no connection with them other than through this research project. Based on 3 focus group discussions conducted in Houston, Texas through a previous institution, adolescents reported preference for

social interaction through cooperation, a narrative guiding their advancement through activities, and the use of strategy for education. As a result, the GSAs will be developed in the form of a cooperative tabletop board game, which will include a set of cards with GSAs and a series of challenges to overcome on a game board. The learning process occurs through 4 sets of cards and activities: trivia (answer multiple-choice questions, fill in the blank, and reorder words), discussions (discuss difficult situations), and interactive activities during and outside of the board game sessions (charades, drawing, miming, role playing to understand tobacco scenarios, arts and crafts projects, journal entries, practicing stress reducing techniques). Some activities will be completed outside of the session (appendix 13). The cards and activities have 3 teaching goals: friendship building, tobacco prevention, effects on the environment, and advocacy. Any changes in the kinds of GSA activities uncovered by Study 1 (e.g., adding a physical activity) will be described in a revision to the study before implementing.

- **Final design of the GSAs during COVID-19:** In case ASPs are not allowing their adolescent members meet in person at their sites, we plan to use a web-based version of the GSAs that we will develop with a team of computer scientists. The computer science team will create the web-based GSAs to incorporate all aspects of the GSAs created by TESA. While overseen by the Integrated Risk Management (IRM) team at the University of Florida, the computer science team will develop the web-based version while complying with UF security and privacy guidelines and policies. The web-based GSAs will have a secure built-in video-conferencing system to ensure that participants can communicate with one another as well as the research team. The web-based GSA will also have the ability to record sessions, administer questionnaires, and collect activity entries for the purpose of data collection. Appendix 12 shows a mock picture of what is envisioned for the web-based GSAs. Any changes in the web-based GSAs based on the recommendations of IRM and the computer science team will be described in a revision to the study before implementing. In addition to the web-based GSA, the TESA team may make the boardgame playable online by creating the boardgame in an online portal for virtual boardgames known as Tabletopia. The use of Tabletopia will not be done without a risk assessment completed by Integrated Risk Management (IRM).

- **Connection with ASP sites:** At first, as many as a minimum of 20 ASPs such as the Boys and Girls Clubs in Florida and schools such as PK Yonge school will be approached for this study. The PI and/or study staff will attend ASP sites, in order to present the study to program directors and describe to them the study procedure.

  Once ASPs are recruited, we will obtain letters of support (Sample in Appendix 0) or a Contract for Services (Sample in Appendix 15) from these ASPs. Signed letters of support or Contract for Services will be submitted to IRB. We will not move forward with data collection from adolescents unless signed letters of support are obtained from the ASPs.

- **Consent procedure:** If the ASP directors agree to have their program site participate in Study 2, they will complete and sign a letter of support or Contract for Services. Then, the PI and/or study staff will verbally announce the study to adolescents in a private classroom setting, in the presence of ASP staff. Interested adolescents will be presented with all information concerning the study (study purpose, requirements, risks, and benefits of participation) and will be given a form to share with their parents (Appendix 1e). When parents register their child for the ASP Summer Camp, research staff will attend the ASP Summer camp registration in-person, virtually, or over the phone to discuss the project and review the consent form with parents.
- If the location has ended their Summer registration before research staff could be present, ASP staff will contact parents with eligible adolescents to discuss the project. If parents are interested, ASP staff will send research staff contact information of the parent. ASP staff will use a script to discuss the project with parents (Appendix 16). ASP staff will share contact information in an encrypted excel spreadsheet.
- When parents/legal guardian arrive to pick up or drop off their adolescents at the ASP, they will be approached concerning the study and all informed consent information will be presented to them verbally and on iPad screen.

- Research staff may also announce the study to parents at a parent orientation hosted by the ASP. In this case, parents will be approached to review and sign the informed consent form after the parent orientation.
- After obtaining parental permission, the interested adolescent will be presented with the assent form to sign in the presence of a witness (a staff from the ASP). An adolescent may sign a one-page assent form in place of the assent portion of the informed consent form.
- Emancipated adolescents (age 18) will be asked for parental permission in cases where ASPs ask for parental permission from adolescents of the age 18. Emancipated adolescents will be asked to sign a complete consent form or a one-page consent form in its place. All such procedures will occur in a private room at the ASP.
- Parents will use the iPad to review the consent and provide an electronic consent. Adolescent will also assent on the iPad. However, paper consent forms will be available in case parents or adolescents prefer a paper-based form. Both parents and adolescents will receive a copy of the consent document for their own records.
- For parents that are hard to reach, ASP staff will send the adolescent home with a one-page parent permission consent form for the parent to review and sign. Once parental permission is obtained, research staff will review the child assent with the adolescent and obtain their assent.
- Adolescents ages 11-17 will review and sign the child assent with study staff either in-person or remotely.

  For sites that require parent permission for 18-year-old adolescents to participate in extracurricular activities, ASP staff will send the adolescent home with an informed consent form or a one-page parent permission form for the parent to sign. Once the parental permission is obtained, research staff will review the informed consent form or the one-page consent form specific to 18-year-old adolescents with the 18-year-old adolescent.

  A separate consent form has been created for 18-year-old adolescents. Following our announcement at the ASP, if an adolescent who is 18 years of age expresses interest in the study, we will approach this individual during breaks at the ASP to go in detail over the consent form.

- It is expected that 800 adolescents and their parent/legal guardian from about 15 ASPs will be interested and eligible. Parental permission and child assent forms will be presented in-person, and in details by a study staff or the PI. A staff member of the ASP will act as witness during consent.

- After recruitment, we will schedule dates with the ASP in order to conduct the study.

- **Consent procedure for study 2 during COVID-19:**
  Due to COVID-19, we will be reviewing the study information and assents/consent forms with adolescents and parents remotely via phone call or Zoom should the ASP not allow research staff, adolescents, or their parents inside the facility. Research staff will contact participants using Cisco Jabber.

  If parents and adolescents are allowed to be at the ASP facility, research staff will review the consent form with parents and adolescents in person. Parents and adolescents will be given the option of signing a paper consent form to review and sign with the guidance of PI and/or study staff.

  If the ASP director agrees to have their program site participate in Study 2, they will complete and sign a letter of support or Contract for Services that can be available electronically.

  Through ASP recruitment, the ASP will distribute an announcement (Appendix 1e) to parents via e-mail. ASP staff may also announce the study to adolescents in need of parent permission via email using the informational form (Appendix 1f). On the other hand, through HealthStreet, ResearchMatch, and Facebook, parents will be approached directly by study staff with the study announcement.

If PI and/or research staff cannot be at the ASP in person with adolescents, research staff will announce the study to the adolescents in a private classroom setting using Zoom in the presence of ASP staff. After the announcement, ASP staff will provide interested adolescents with an informational form to give to their parent about the study (Appendix 1e). The parent may contact research staff using the contact information on the form. During the phone or Zoom call, interested adolescents and parent/legal guardian will be given a link to the online consent form to review and sign with the guidance of the PI and/or study staff. Research staff will contact participants using Cisco Jabber or Zoom.

Adolescents of age 18 will be sent an announcement (Appendix 1g) by ASP. If the 18-year-old adolescent expresses interest to PI and/or study staff, he/she will be invited to a phone call or Zoom meeting to discuss the research study. They will be sent a complete online consent form to review and sign with the guidance of the PI and/or study staff. Research staff will contact participants using Cisco Jabber.

For parents that are hard to reach, ASP staff will send the adolescent home with a one-page parent permission consent form for the parent to review and sign. Once parental permission is obtained, research staff will review the child assent with the adolescent and obtain their assent.

For sites that require parent permission for 18-year-old adolescents to participate in extracurricular activities, ASP staff will send the adolescent home with an informed consent form or a one-page parent permission form for the parent to sign. Once the parental permission is obtained, research staff will review the informed consent form specific to 18-year-old adolescents with the 18-year-old adolescent.

The parents and adolescents will be given the option to download an electronic copy of the signed online informed consent form for their own records or a copy of the one-page parent permission consent form that they reviewed.

Parents and adolescents may use their computers to sign the e-consent.

If research staff are to work with parents, adolescents, and ASP staff inside the ASP facility, research staff will follow COVID-19 guidelines put in place by the ASP. Research staff will wear masks, use hand sanitizer, and will distance themselves from others by at least 6 feet. If someone at the facility were to test positive for COVID-19, all who were in contact with the positive case will be required to quarantine for 2 weeks.

It is expected that 1000 adolescents and their parent/legal guardian will be interested and eligible. Parental permission and child assent forms will be presented online, and in detail by a study staff or the PI.

Both program implementers and ASP staff members will receive adult consents to participate in focus group discussions and interviews.

- **Baseline assessment at Day 1:** In a classroom setting, participating adolescents will be invited to complete the baseline 20-minute psychosocial survey (time 1) and the baseline 20-minute social network survey (time 1).

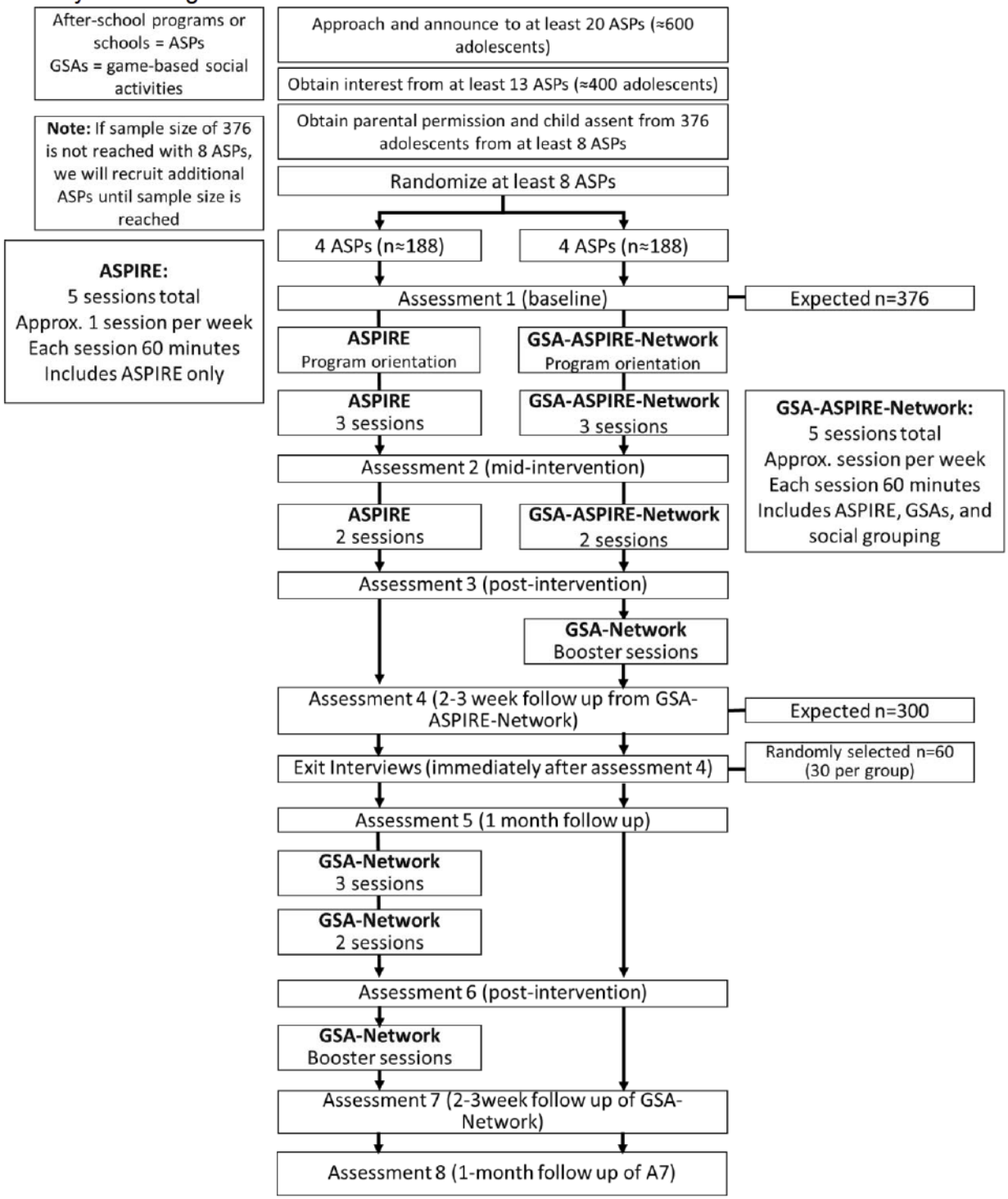
- **Randomization at Day 1:** Immediately after baseline assessment at Day 1, the participating clubs will be randomly assigned to either ASPIRE or GSA-ASPIRE-Network. Details on each intervention are described in the following sections. After-school programs (ASPs) will be randomized in a single-blinded format to 1 of 2 conditions: the ASPIRE program or the GSA-ASPIRE-Network program. We will use a covariate-constrained approach[33] in randomizing ASPs to minimize between-group differences in club characteristics (e.g., adolescent volume in a cluster, proportion of adolescents with intent to use tobacco or users, age, gender).

- **Orientation at Day 1:** Also, after baseline assessment at Day 1, participants will receive a session of orientation, allowing them to learn how to take part in the program (ASPIRE or GSA-ASPIRE-Network), depending on their assigned condition. The orientation will be in the form of a presentation and some attempts at engaging in the program for the first time.

- **Intervention details:** The first session of the assigned intervention (ASPIRE or GSA-ASPIRE-Network) will occur three to five days after orientation (depending on the ASP's availabilities).
  - In the ASPIRE condition (other treatment), participants will engage in five 70-minute sessions of ASPIRE spread over a period of 5 weeks (1 session per week). During each session, participants will alternate between 10 minutes of ASPIRE use and 5-minute breaks.
  - In the GSA-ASPIRE-Network condition (intervention), on the other hand, participants from each club (expected to be between 24 and 50 participants) will be purposely seated in groups, with 3 to 6 adolescents per group. Participants' group allocation will be determined based on findings from social network analysis (details below). Each group will engage in five 70-minute sessions of ASPIRE spread over 5 weeks (1 session per week). During each session, participants will either receive ASPIRE, or the GSAs, or both. Along with the game board, GSA content will be presented to participants via the "Kahoot! 360 Pro" platform. Study data will not be captured nor stored on Kahoot. Participants will not complete any assessment question of identifiable questions via "Kahoot!". They will engage in the program as a team. After each session, with a timeline of a week, participants will have the opportunity to engage in off-session activities at their own pace. These activities will allow participants to practice what they learn during the sessions. To receive credit for completing the activities, participants will be asked to keep track of their progress in these activities and present evidence of completing the activities. To this end and depending on the activities, they may record themselves completing the activity via photo or video and submitting the recording to the research team via the secure system REDCap. Recording and submitting the photos or videos will not be required to participate in the research project, and alternative methods of presenting evidence of activity completion will be provided. If participants choose to submit videos or photos for their activities, they will be asked to capture these videos and photos without having a non-participant in the background. If a non-participant is visible in the background, the recording will be censored to remove the non-participant.
  - Adolescents who decline to be part of the study will engage in the usual ASP activities provided by the ASP staff. These activities are comparable to the "control" (non-network) condition, but without the surveying.

- **Additional assessment points:** In addition to baseline (time 1; Assessment 1), all participants will complete psychosocial surveys and social network surveys after 3 sessions (i.e., mid-intervention; time 2; Assessment 2), following the last session (i.e., post-intervention; time 3; Assessment 3), and 2 to 3 weeks post-intervention (i.e., follow-up; time 4, or assessment 4). After time 4, we will conduct one-on-one interviews with 60 adolescents randomly selected from ASPIRE (n=30) and GSA-ASPIRE-Network (n=30). We will also conduct exit interviews with 2 ASP staff members per ASP and all program implementers. Exit interviews and the intervention sessions will be audio-recorded, in order to capture user's experience. Survey assessments 5 through 8 will also be completed as delineated in the above study design for Study 2. Figure 1 presents the study flow diagram.

Figure 1. Study Flow Diagram



Note: Approximate days: Assessment 1 and orientation at day 1 (time 1, baseline), session 1 at 3-5 days after assessment 1, session 2 and assessment 2 (time 2; mid-intervention) at day 12, session 3 at day 19, session 4 and assessment 3 (time 3, post-intervention) at day 26, and assessment 4 (time 4 or assessment 4, follow up) at day 56, assessment 5 at 1 month after assessment 4, Assessment 6 immediately after GSA-Network, assessment 7 at 2-3 weeks later, and assessment 8 at 1 month after A7.

- **Instruments for Study 2.** Several variables will be measured through psychosocial (Measures in Appendix 3), and social network surveys (Appendix 4), using previously validated measures delineated below. In a private classroom setting, a study staff or the PI will conduct and collect the surveys and audio recordings.

- **Psychosocial survey:** At all 4 time points, the psychosocial survey will measure tobacco use status[27] and intention to use tobacco.[28] At time 1, this survey will include psychosocial determinants of smoking and factors that may affect an online experience, social influence, social activity engagement, and game play.[29-31] At time 3 only, the psychosocial survey will include measures to check for any expected differences and similarities between groups (i.e., manipulation check): Attitude toward the intervention,[34] perceived medium interactivity,[35] perceived social interactivity,[35] and perceived entertainment value.[36] To capture adolescents' tendency to positively influence others, the survey will measure interpersonal communication,[37,38] ability to persuade others,[39] and diffuse health information to others.[39]

    - **Social network survey:** At all 4 time points, the social network survey will present a list of names of all participants in the classroom. They will be asked to pick and write the names of their six best friends at their club. Best friends are defined to adolescents as "people your age with whom you feel at ease and can talk about personal matters".[40] To measure friendship strength, the survey will ask the respondent to rank nominated friends from strongest to weakest friendship (coded 1 through 6).[41] To measure positive influence, the survey will ask the respondent: (1) how likely he/she may ask each nominated friend for general advice, (2) how likely he/she may accept a tobacco product when offered by each nominated friend (reverse coded), and (3) how likely he/she may avoid a tobacco product when advised by each nominated friend. The strength of a tie between the respondent and each nominated friend will be: Friendship strength × Positive influence. Tie strength will allow the structuring of the social network for each club. Based on the social network at time 1, adolescents will be grouped for their intervention sessions. The survey will also consider participants' nominated advisors and leaders in their ASP. Positive social influence is defined as connection with and support from others who do not intent to use tobacco.

- **Exit Interview questions** (Appendix 5)**:** With adolescents, these questions will address (1) adolescents' most and least favorite elements in the program, (2) their teamwork experience, (3) ways to improve activities, and (4) opportunities for peer-to-peer interaction. With staff members of the ASPs, these questions will address (1) feasibility of the intervention at their location and (2) how they would want to improve the intervention. With intervention implementers, these questions will address (1) feasibility of the intervention, (2) difficulty of implementation, and (3) how they would want to improve implementation.

- **Adolescent Grouping.** To group adolescents during the GSA-ASPIRE-Network condition (details in Appendix 6), the variable indicating intention to use tobacco will be dichotomized (0=no intention; 1=some intention). At time 1, adolescents who intent to use or are using tobacco will be matched with 2 to 4 adolescents who are closest in distance and do not intent to use tobacco. This ratio is chosen based on previous research showing that 20%-40% of adolescents report some intention to use (average, 33%).[42] If assignment of adolescents to group faces difficulties, we may rely on a continuous measure of intention to use tobacco. Adolescents who indicate intent/use will remain the minority in each group. This design should play a role in preventing at-risk adolescents from influencing their group peers.

  The PI along with a statistical analyst and statistician will privately meet in-house at the department in order to make decisions about the intended groupings based on the network data. The study staff will not be present at these meetings. They will be blinded to the basis of the grouping. As a result, they will implement the groupings at the ASPs without knowing the basis of the grouping, thereby insuring that the intended groupings are achieved without disclosing its basis to the participants.

- **Sample Size Considerations for Study 2.** Summary statistics were obtained from the original trial.[13,43] For H1, given 2 clusters per arm with an average of 25 adolescents who intent to use tobacco in each cluster (n=100) and intra-class correlation (ICC) of 0.3, 80% power is achieved using a two-sided test, with significance $p<0.05$ to detect a difference in positive social influence in the ASPIRE arm of 1.0 and the GSA-APIRE-Network of 2.43 assuming a common standard deviation of 0.8. A difference will be detected

in intention to use tobacco in the ASPIRE arm of 1.3 and GSA-APIRE-Network of 0.17 assuming a common standard deviation of 0.5.

Susceptibility to use tobacco is a clinical and epidemiological screening questionnaire of 3 items that has been shown to be the most potent predictor of actual tobacco initiation among adolescents.[42] The continuous version of this scale is termed "intention to use tobacco". Sample size and power have been calculated based on the hypothesized difference between groups that render participants in the GSA-ASPIRE-Network group non-susceptible to use tobacco, based on the "intention to use tobacco" scale and previous research.

Sample size calculation is done for H1 and satisfies H2. These power estimates are conservative. We will have more power using mixed-effect models. Sample size was calculated based on 2 clusters per arm, however, we will have more power with the proposed 8 clusters (4 clusters per arm). Considering that about 33% of adolescents generally intent to use tobacco,[42] the required sample size is 300 participants. Considering 40% retention and 50 potential non-eligible, we will recruit 800 participants. In addition to this sample size, we will work to reach a representative Florida sample of adolescents. For the interviews, thematic saturation with adolescents is expected by 60 interviews (20% of the final 300 participants).[44]

- **Quantitative data analysis for Study 2.** To test H1, a linear mixed-effect model (LMM) will be conducted to compare the conditions with respect to intention to use tobacco (continuous outcome variable), in a 2 (condition) × 4 (time) design. Using a second LMM, the 2 conditions will be compared over time with respect to positive social influence. In both models, intervention effects on outcome trajectories over time will be measured with the condition × time interaction term. To test H2, a third LMM will be conducted with positive social influence as a mediator. Each individual will be modeled as a random effect nested within the club, club membership will be modeled as a random effect nested within treatment condition, and treatment will be modeled as a fixed effect. If manipulation checks indicate problems, particularly differences or similarities between arms that are not supposed to occur, we will control for such differences or similarities within our models.

- **Qualitative data analysis for Study 2.** Qualitative data analysis will be conducted to answer the research question RQ2. The audio-recordings of the interviews and intervention sessions will be transcribed verbatim by the study staff or by a professional transcription service. Then, the data will be analyzed using techniques described by Stewart and Shamdasani.[32] The transcripts will be read independently by two study team members and major emerging themes will be identified. Following the identification of themes, inter-coder reliability will be conducted. The sessions will allow for the exploration of relevant adolescents' experience with the intervention, gaming features that are salient to adolescents, and how the design of the activities should be reshaped for better outcomes. Themes will be defined as psychological, social, or emotional experiences of adolescents, and issues or ideas that are repeated and common to several participants in a group.

- **Justification for number of participants for Study 1 and study 2**

	Study 1	Study 2	Studies Combined
Participants needed to complete study:	63	300	363
Additional participants enrolled but may discontinue:	30	450	480
Additional participants needed to undergo screening:	7	50	57
Total number of participants:	100	800	900

8. Data Safety and Monitoring for Study 1 and Study 2:

- **Responsibility:** The PI will be responsible for data monitoring. The PI will hold responsibility to make sure that the Data and Safety Monitoring Plan outlined below will adhere to the protocol outlined by the institutional review board (IRB) of the University of Florida and the National Institute of Health. The Data Safety and Monitoring Plan is written to ensure the safety of the participants and verifying data validity and integrity. In this project, data will be collected via survey instruments and video and audio recording (during focus group sessions, interviews, program sessions, and off-session activities).

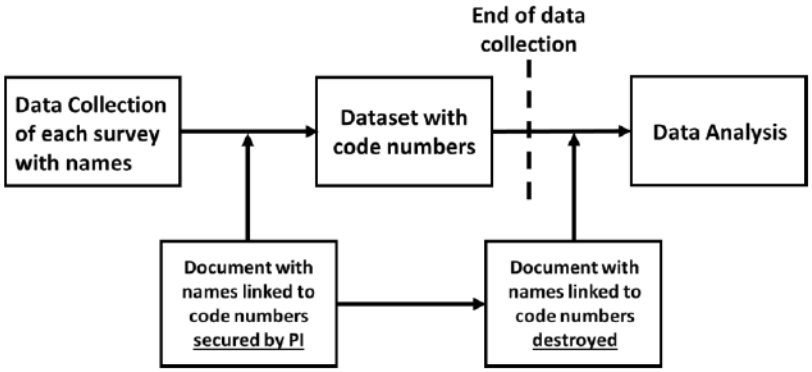
- **Storage of consent documents:** Study staff or the PI will securely store consent documents (both assent forms and parental permissions) in an encrypted and password protected hard drive, and physically locked in the department HOBI.

- **Data collection, management, and storage:** Questionnaire data will be obtained and will assess tobacco use status, intention to use tobacco, beliefs regarding tobacco use, psychological and social determinants of tobacco use behavior, psychological outcomes of intervention-use, social connections, and sociodemographic information. All data will be collected specifically for research purposes and will be coded to maintain confidentiality.

  All databases will be stored in a centralized location on one of the departmental servers, which is backed up daily to a hard drive, with access limited to specific users at the discretion of the PI. The PI will assure that audits of selected subsets of data are performed once a month and that appropriate safeguards of participant privacy are maintained. Privacy safeguards will include appropriate password protection and physical security for all computer systems and the external hard drive.

  For Study 2, data collection will be conducted on computers, through an encrypted and secured online system provided by the institution, the University of Florida. In case there is loss of internet connection, the surveys will be completed on paper. First, following consent, eligible adolescents will complete baseline psychosocial and social network surveys (time 1). Two days after baseline, the clubs will be randomly assigned to either ASPIRE or GSA-ASPIRE-Network. All participants will complete psychosocial surveys and social network surveys after 3 sessions (i.e., mid-intervention; time 2), following the last session (i.e., post-intervention; time 3), 2 to 3 weeks to post-intervention (i.e., follow-up; time 4 or assessment 4). Assessments 5 through 8 will also be completed as delineated in the above study design. The social network survey will include participants' names. Participants will be assured that this information will remain confidential. During the off-session activities, participants may share via a secure system (REDCap), videos and photos of engagement in these activities. Participants will be asked to capture videos and photos without having a non-participant in the background. If a non-participant is visible in the background, the photo will be censored to remove the non-participant. The videos and photos will be coded and deleted immediately upon completion of coding. A link to these videos and photos will remain stored within REDCap and can only be viewed by the research team in a private room.

  For Study 2, immediately after the collection of each survey or interview, participant names will be matched with code numbers, and the datasets will become de-identified by deleting names. Replacing names with code numbers for the psychosocial and network surveys will occur during the data collection phase of the study (i.e., immediately after the collection of each survey). The link between names and code numbers will be kept in a separate document only available to the PI. However, the links between codes and names will be discarded immediately after all survey documents have been linked to each other, and no longer than 1 year after the study has ended. Code numbers will be used alone for data analysis. Other than for the assignment to subgroups in the network group, we will not directly be making effort to identify responses, and we will use the links only for matching surveys across times. The figure below delineates this process.



For protection and management, all surveys will be stored securely in an encrypted and password-protected hard drive, and physically locked at the Department HOBI at the University of Florida. Such documents will also be saved in a secured server network in the department HOBI. The research staff and Research Coordinator may have access to the data on an encrypted computer, at the institution only. The data will not leave the institution.

Adolescents' conversations will be audio recorded during focus group discussions (Study 1), interviews (Study 2), and intervention sessions (Study 2). The PI, Research coordinator or other data collector from the research team will ask adolescents to refrain from mentioning anyone's name or any other identifying information during the recordings. The voice recording file is saved under a session number. The voice recorder is then closed and locked in a briefcase right after a session of data collection. The briefcase is taken back to the office and locked at the department HOBI. The voice recording file is reviewed to ensure no mention of identifying information from participants or moderators. Audio recording files will not be in the University of Florida server network to protect the confidentiality of participants. However, they will be kept in an encrypted external hard drive that will stay locked at the Department HOBI at the University of Florida. In case a participant mentions identifying information, an audio software program will be used to erase the segment that mentions identifying information.

For Study 1, as we collect surveys and group discussions, participant names will be turned to code numbers in our datasets. Datasets will hence become de-identified. Using code numbers, answers to the focus group discussion will be linked to answers in the questionnaire. The link between names and code numbers will be kept in a separate document only available to the PI. The links between codes and names will be discarded immediately after survey documents have been linked to each other, and no longer than 1 year after the study has ended.

For Study 1 and Study 2, Contact information and demographic information will be collected from participants after parents have signed the eConsent or paper consent. Contact information and demographic information will be collected via REDCap survey or via paper form. The contact information of a participant's legal guardian will also be collected. The purpose of obtaining the legal guardian's contact information is to compensate them.

Survey data collection will be conducted online, and survey data will be directly stored online. In case survey data collection must be conducted on paper due to lack of internet, safeguard procedures will be put in place to keep the data safely stored: While names may be initially used during survey taking, they are immediately replaced with code numbers during survey data collection and participants are urged not to provide identifying information. Surveys are collected, closed, and put in folders. Folders are put in a locked briefcase. The briefcase is taken back to the office and locked at the department HOBI. Survey data is manually revised by the PI to report the presence of any identifying information. The survey data is then entered electronically, saved, and kept in the secured server network and an encrypted external hard drive locked at the HOBI at the University of Florida.

For protection and management, all paper-form survey, consent documents, and audio files will be stored securely in an encrypted and password protected hard drive, and physically locked in the department HOBI. Such documents and files will also be saved in a secured server network for the department HOBI.

- **Data entry methods:** For Study 2, while identifying information will be collected (i.e., names), the PI will ensure that the dataset is de-identified immediately after data collection. No identifying information will be collected other than names and mailing addresses. However, code numbers will be used to replace names. The links between codes and names will be discarded immediately after survey documents have been linked to each other, and no longer than 1 year after the study has ended. Other than for the assignment to subgroups in the network group, we will not directly be making effort to identify responses, and we will use the links only for matching surveys across times. The mailing addresses will be used to mail compensation to participants.

  For the interviews, the program sessions, and the focus group discussions, the voice and/or video recording file will be transcribed in a locked room by study staff or by a transcription company. The transcript is saved under the session number and kept in the secured server network of the department HOBI. All transcript data will be monitored, and saved under the code number of the participant. Transcripts will then be thematically analyzed. Such a procedure will be conducted by the research staff and the PI in a private office at the department HOBI. During analysis, only the research team will have access to the data (surveys, transcripts, and audio files).

  Data collection, management, and storage during COVID-19:
  Considering COVID-19, the transcription of video and audio recordings will be saved in the secured server network of department HOBI or through the password-protected Dropbox cloud. The transcription of voice recordings will be conducted by the research staff and the PI in a secure remote area or by a transcription company.

- **Quality assurance plan (checks for errors):** For all data collections from the proposed project, quality assurance procedures will include a data collection protocol delineating a report on how the data has been collected by each participant, and any potential deviation from the protocol. There will be a two-stage editing procedure for error-checking in data collection, consisting of the initial completion of the Data Collection Form (Appendix 7) by one staff, and a review of the form by another staff who will record any significant deviations from the protocol. Then, survey data is manually revised by the PI to report the presence of any identifying information. Quality assurance procedures will also include regular meetings (approximately monthly) between the study statistician, the PI, and the study staff to review problems and solutions, and discuss concerns in data quality. During data collection, reports will be issued weekly. Preliminary review will be initiated shortly after data collection begins to allow monitoring of data quality.

- **Procedures for preventing and addressing breaches of confidentiality:** Once the survey data is collected, they will be de-identified by replacing names with codes. We will be identifying subjects only by numbers in all data files. Identification numbers will only be connected to individual participant names in a separate file that will be accessible only by the PI. This file will be stored in an encrypted and password protected hard drive, physically locked at the Department of Health Outcomes and Biomedical Informatics at the University of Florida. All study data files will be server-maintained with limited access by using passwords and logins restricted to study staff. All information will be reported in aggregate form, and individual participants will not be identified in any public reports or documents.

  All survey, consent documents, and video/audio files will be stored securely in an encrypted and password protected hard drive, physically locked in the department HOBI.

  There are two main situations during which confidentiality may be breached because of mandatory reporting requirements: participants' report of child abuse/neglect and suicide risk. The PI or research staff will address child abuse/neglect by reporting it through the Florida Abuse Hotline (1-800-96-ABUSE). This Hotline will provide all reports to the Florida Department of Children and Families. The PI or research staff

will address suicidal ideation by asking the participant to immediately call the National Suicide Prevention Lifeline (800-273-8255), where immediate action can be taken. The PI will also report such an incident to the Florida Department of Children and Families. Child abuse/neglect, suicide risk, and any other adverse event will be reported to the national institute on drug abuse (NIDA; funding agency) and the University of Florida. The parental permission and assent form will mention that such reports may occur.

During the interviews and focus group discussions, we will ask participants to refrain from mentioning anyone's name or any other identifying information. Also in all program sessions, adolescents' conversations will be audio recorded. However, in case a participant mentions identifying information, research staff will erase the segment that mentions identifying information.

Procedures for preventing and addressing breaches of confidentiality during COVID-19 quarantine: Considering current COVID-19 quarantine, voice recordings will be taken via Zoom. The transcription of audio recordings will be saved in the secured server network of department HOBI. The transcription of voice recordings will be conducted by the research staff and the PI in a secure remote area or by a transcription company.

Based on IRB's full committee decision following reportable events, Appendix 18 presented the list of the type of data to keep and the type of data to permanently delete from the study.

9. Possible Discomforts and Risks:

- **Possible discomforts and risks:** No health-related potential risks are expected as a result of the project. The only potential risk concerns confidentiality, because contact information (names and mailing addresses) will be collected from the participants during Study 1 and Study 2. Also, during the focus group sessions (Study 1), interviews (Study 2) and program sessions (Study 2), adolescents may mention someone else's name or their own.

- Also in this study, a participant may mention a concern with the content of the ASPIRE website, the activities, or the content of the survey items.

- **Procedures to protect against or minimize potential discomforts and risks:** While names will be collected, the PI will ensure that the dataset is de-identified immediately after data collection. No identifying information will be collected other than names. However, code numbers will be used to replace names. Also, survey material will be kept anonymous. Participants' names will be kept in locked cabinets and in a password-protected shared drive at the Department of Health Outcomes and Biomedical Informatics at the University of Florida. The links between codes and names will be discarded immediately after survey documents have been linked to each other, and no longer than 1 year after the study has ended. Other than for the assignment to subgroups in the network group, we will not directly be making effort to identify responses, and we will use the links only for matching surveys across times.

  In this study, participants will be asked about certain behaviors that they may not want to share with their parents or legal guardians (tobacco use). Their answers will be kept confidential and their parents or legal guardians will not receive their answers.

  In case a participant reports a concern regarding the content of the intervention, such participant is offered the opportunity to discontinue with the study. In such a case, any information obtained from this participant will be destroyed. However, a concern with the intervention is deemed unlikely, considering that it is designed specifically to adolescents, with adolescents.

- **Report of adverse events:** The PI and study staff will keep record of any adverse event that may occur, including a brief explanation of the event, when it occurred, the date of the event, description of what occurred, actions taken by research staff, planned follow up (if any), the intervention group/study arm of the

affected participant, whether the event appears to be related to the intervention, and whether the participant will continue in the study.

- The PI may withdraw a participant from the study if their safety may be compromised, when the study is being closed by the PI, the University of Florida, or NIH, or if the participant is non-compliant with required study procedures.

10. Possible Benefits:

- By taking part in this study, participants may learn more about general health information, ways to stay healthy, and how to maintain a healthy lifestyle. Future adolescents may benefit from what is learned. There is no additional direct benefit from participating in this study.

- Results from this research study will benefit future populations by allowing us to ensure that we disseminate to future adolescents a well-tested and validated program for tobacco prevention and cessation.

- As researchers, we may benefit professionally if the results of the study are presented at meetings or in scientific journals.

11. Compensation:

- **Participant compensation during Study 1:** Each study participant will receive $10 in cash or gift card for completing Study 1.

- **Parent compensation during Study 1:** As compensation for their time to bring the participant to the study, parent/legal guardian will receive $10 in cash or gift card.

- **Participant compensation during Study 2:** Each study participant will receive compensation at different stages of the trial, proportional to the amount of participation ($5 in cash or gift card for the baseline assessment, $10 in cash or gift card for the mid-intervention assessment and 2 sessions, $15 in cash or gift card for the post-intervention assessment and the remaining sessions, and $20 in cash or gift card for the follow-up assessment and interview). Participants will receive $5 in cash or gift card each time they complete Assessments 5 through 7, and $10 in cash or gift card for completing assessment 8.

- **Parent compensation during Study 2:** As compensation for their time to bring the participant to the study, parent/legal guardian will receive $20 in cash or gift card.

For Study 2, Appendix 19 presents a script of communication concerning compensation via e-mail, mail, or communication concerning compensation via phone.

- **Site compensation for Study 1 and Study 2:** Each participating ASP will receive a $30 per participating adolescent as compensation for using regular club hours to allow their adolescents to participate and for facilitating the study. To avoid ASPs coercing adolescents into participating for compensation, each ASP will be blind to the number of participants from their program.

- **Program implementers compensation during Study 2:** For participating in a focus group discussion, each of the 10 program implementers will receive a $20 compensation in cash or gift card after the focus group discussion.

- **After-school program staff compensation during Study 2:** For participating in an interview, each of the 10 ASP staff will receive a $10 in cash or gift card.

- **School teacher compensation during Study 2:** Two school teachers implementing the program in their classes will receive a $150 in cash or gift card for participating in the interview and implementing the program.

- The study team may request email address information from the Boys and Girls Clubs and PKY.

12. Conflict of Interest:

- The PI, co-I, or the University of Florida have no real conflicts of interest to this research project. The PI or the University of Florida currently have no intention in licensing or filing a patent application at a later date.

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