Study Protocol and Statistical Analysis Plan

Title of Study: Pittsburgh and Rural Area High School Tobacco Prevention

ClinicalTrial.gov Identifier: NCT05081843

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Study Protocol

Objectives:

Despite advances in tobacco control, tobacco use among adults continues to be a major clinical and public health challenge in the United States. This is exacerbated by the recent increase in adolescent overall tobacco use, likely prompted by the increased popularity of alternative tobacco products (ATPs) such as e-cigarettes. These products are marketed aggressively to adolescents online, and adolescents who engage with this marketing are more likely to initiate tobacco use. Considering adolescent tobacco initiation is associated with persistent nicotine addiction into adulthood, prevention efforts should be targeted at this population. Adolescent tobacco prevention programs that utilize a media literacy approach teach adolescents how to critically evaluate tobacco-related media messages. Designed for 9th grade students, the web-based media literacy program *AD IT UP* demonstrated initial feasibility and acceptability in 2011. In 2019, *AD IT UP* was updated to include ATPs and online tobacco marketing. However, the updated program has not yet been tested. The purpose of this study is to assess the feasibility and acceptability of the updated *AD IT UP* program among 9th grade students. We will conduct a cluster randomized trial comparing *AD IT UP* to usual substance use education in both high schools. Feasibility endpoints will assess completion of *AD IT UP* and associated assessments, while acceptability endpoints will assess student perceptions of *AD IT UP*. Secondary objectives are assess changes in intentions to use tobacco, attitudes, normative beliefs and tobacco media. Data collected from this study will inform a subsequent large-scale randomized controlled trial of *AD IT UP* to assess efficacy in decreasing tobacco initiation in high school students.

Design:

We will conduct a cluster randomized controlled trial (RCT) in two high schools in Pittsburgh, PA.

Methods:

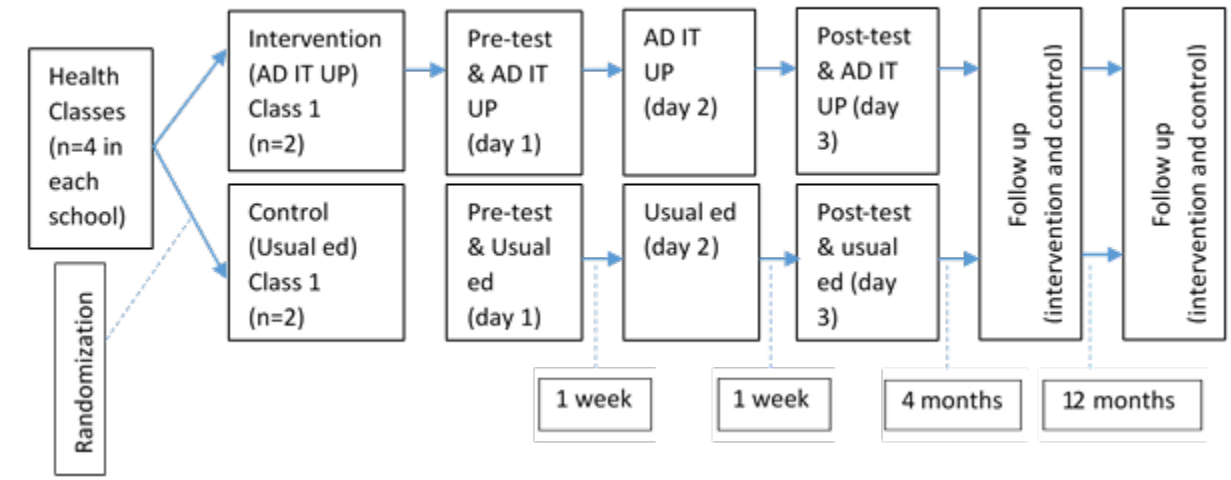
Sample and Recruitment. The two high schools will be selected according to the following criteria. Schools will have an adequate number of 9th-grade students (at least 130 at each school) to power this study. Each school must have at least 4 health classes to participate in the trial. One school will be located in a rural area and the other will be located in a suburban area. Parents will be sent a letter from the school informing them of the study aims and the procedure for opting out of consent. Student assent will be obtained before the all assessments. All assessments (intervention and control) and completion of AD IT UP (intervention) will be completed during regular class time in the school computer lab or on student devices (i.e., ChromeBook, iPad).

Randomization. Each school will have 4 health classes. Prior to the intervention (**Figure 2**), in each school, two classes will be randomized to the intervention condition and two classes to usual education using a random number generator

Pre-test Assessment and Assignment of Identifiers. In each school, all students (intervention and control) will be assigned a unique identifier and password, which will facilitate access to *AD IT UP* (intervention students), track progress through modules (intervention students), and link to the assessments (all students).

Intervention Condition. The intervention will be the updated *AD IT UP* web-based tobacco media literacy program. *AD IT UP* is self-paced and typically takes approximately 120 minutes to complete (including pre- and post-test assessments). In previous studies of the original *AD IT UP*, students completed *AD IT UP* over a series of 3 class periods delivered 1 week apart. **Figure 2** presents this scenario.

Figure 2. Overview of Study Procedures and Data Collection.



Control Condition. Many schools develop their own substance use prevention programming, so schools' usual programming will be used to mimic what is expected in a future trial. Students in the control condition will complete assessments on similar schedules as intervention students (**Figure 2**).

Post-test and Follow-up Assessments. Following the completion of the final *AD IT UP* module, all students will complete the post-test. Follow-up assessments will be completed at 4 and 12 months after the post-test (**Figure 2**).

Measures:

Feasibility Metrics. ***(Primary Outcome)***. Data for the assessment of feasibility will be descriptive with point estimates and 95% confidence intervals. **One highly important quantitative outcome to inform a subsequent cluster randomized trial is overall retention of students.** Therefore, our main outcome of feasibility will be determined by at least 60% of students completing the pre-test, post-test, and both follow-up assessments, consistent with previous research. Other feasibility outcomes and related cut-offs are presented in **Table 1**.

Acceptability Metrics. Intervention participants will be asked to complete a series of acceptability items on the post-test assessment via close-ended 5-point Likert-type items (**Table 1**). These items are as follows: (1) I enjoyed *AD IT UP*, (2) I understood *AD IT UP*, (3) *AD IT UP* was easy to use, (4) I tried my hardest when I was doing *AD IT UP*, (5) I think *AD IT UP* would be helpful to other kids my age, (6) I would recommend *AD IT UP* to a friend, and (7) I agree with *AD IT UP*'s message.

Secondary Outcomes. Although efficacy cannot be assessed through this pilot trial, we include as part of all assessments quantitative items that will be used in a future RCT (**Table 1**), which include

susceptibility to future use of tobacco products, attitudes toward tobacco products, normative beliefs about tobacco products, and tobacco-related media literacy. These will be assessed at all 4 assessments.

- Susceptibility. Susceptibility will be assessed by asking participants whether they would use each tobacco product if it was offered to them by their best friend. Responses were *Definitely Yes, Probably Yes, Probably No,* and *Definitely No*. Separate items assessed susceptibility for cigarettes, cigars/cigarillos, e-cigarettes, and hookah. Consistent with previous literature, a participant was considered susceptible to use of an NTP if they answered anything other than "*Definitely No*" for that product.
- Attitudes. Attitudes will be assessed via 8 items asking participants to assess their agreement with statements about NTPs using a 10-point Likert-type scale (Strongly Agree to Strongly Disagree). Items include: (1) E-cigarettes are not as bad for your health as other products, (2) Using tobacco products at parties is fun, (3) Tobacco products help you deal with problems or stress, (4) Smoking helps people stay thin, (5) People who use e-cigarettes are more fun to be around than people who don't use e-cigarettes, (6) If someone starts using tobacco products every day, it is very hard for them to stop, (7) Smoking makes a person look more attractive, (8) It would be very easy for me to get e-cigarettes if I wanted them. NOTE: An additional item (Using e-cigarettes at parties is fun) was added, making this a 9 item scale. A summary scale will be created for attitudes by calculating average scores across all items.
- Normative Beliefs. Normative beliefs will be assessed via 6 items asking participants to assess their perceptions about their friends' acceptance of NTPs using a 10-point Likert-type scale (Very Acceptable to Very Unacceptable). Items include: (1) It is OK for people your age to smoke cigarettes, (2) It is OK for people your age to use e-cigarettes, (3) It is OK for people your age to use hookahs, (4) It is OK for people your age to smoke cigars or cigarillos, (4) A wealthy person is more likely to use tobacco products than a poor person, and (6) A successful person is more likely to use tobacco products than an unsuccessful person. A summary scale will be created for normative beliefs by calculating average scores across all items.
- Tobacco-related Media Literacy. Tobacco-related media literacy will be assessed via adapted items from the Smoking Media Literacy Scale with 8 items using a 10-point Likert-type scale (Strongly Agree to Strongly Disagree). Items include: (1) To make money, tobacco companies will do anything they could get away with, (2) Certain tobacco products are specially designed to appeal to young children, (3) Tobacco advertisers try to link tobacco products to things that people want like love, beauty, and adventure, (4) There are often hidden messages in ads for tobacco products, (5) Movies scenes with people using tobacco products in them are constructed very carefully, (6) Tobacco product ads show scenes with a healthy feel to make people forget about the health risks, (7) Most movies and TV shows that show people using tobacco products make it look more attractive than it really is, (8) When you see a tobacco product ad, it is very important to think about what was left out of the ad about potential health problems. A summary scale will be created for tobacco-related media literacy by calculating average scores across all items.

Table 1. Summary of Measures and Related Cut-offs

Measure	**Assessments**					**Cut-offs** (if applicable)
	T0	T1	T2	T3	T4	
Feasibility						
• Completion of all assessments (**primary outcome**)		✓	✓	✓	✓	60% of students complete all assessments
• Number of parents providing consent	✓					95% of parents provide consent
Acceptability						
• Likelihood of recommending *AD IT UP* to peers			✓			85% reporting "agree" or "strongly agree"
• Understanding *AD IT UP*			✓			85% reporting "agree" or "strongly agree"
• Whether *AD IT UP* would be helpful to others			✓			85% reporting "agree" or "strongly agree"
• Level of enjoyment while participating in *AD IT UP*			✓			85% reporting "agree" or "strongly agree"
• Agree with the message of *AD IT UP*			✓			85% reporting "agree" or "strongly agree"
• Ease of use of *AD IT UP*			✓			85% reporting "agree" or "strongly agree"
• Tried hard while using AD IT UP			✓			85% reporting "agree" or "strongly agree"
Secondary Outcome Variables						**Measurement**
• Intention-to-use tobacco products (cigarettes, e-cigarettes, hookah, cigars)		✓	✓	✓	✓	4-item Likert-type scale ("Definitely no" to "Definitely yes")
• Attitudes and normative beliefs toward cigarettes, e-cigarettes, hookah, cigarillos		✓	✓	✓	✓	Attitudes: 8 items with Likert scale (Strongly Agree to Strongly Disagree) Norm Beliefs: 6 items with Likert scale ("Very Acceptable to Very Unacceptable)
• Tobacco-related media literacy		✓	✓	✓	✓	8 items with Likert-type scale; ("SA" to "SD")
Socio-demographic Factors						
• Age; Sex; Race/ethnicity		✓				Year; Male/Female/Other; Self-report

Statistical Analysis Plan:

Data will be analyzed using STATA.

Primary Outcome (feasibility): To answer the primary outcome of feasibility, we will calculate the number and percentage of students who completed each of the four assessments. We will answer the outcome of eligible students who participate we will calculate the number and percentage of students who were present in the classroom and (1) eligible (i.e., not opted out by parents) and (2) assent to participate (i.e., agree to participate by clicking "yes" on the assent form and completing the baseline assessment).

Acceptability: Acceptability will be assessed by calculating numbers and percentages for each of the seven overall program items. Acceptability is determined by answering "Agree" or "Strongly Agree."

Secondary Outcomes: Although efficacy cannot be determined by a pilot trial, we will also assess changes in susceptibility, attitudes, normative beliefs, and tobacco media literacy using descriptive statistics and compare changes in these scores from pre to post-test and from post-test to follow-up between the intervention and control groups using two-sample tests of proportion. NOTE: Due to insufficient retention

of students for the 1-year follow-up assessments, changes in NTP susceptibility we assessed these changes between baseline and post-test assessments.

Power & Sample Size Justifications. Based upon a feasibility estimate of 60%, a sample size of 130 students (65 in each condition) in each school will afford the ability to estimate feasibility with a 95% confidence interval width of 0.17.