

Expanding the Click City Tobacco Prevention Program
to Include E-cigarettes and Other Novel Tobacco Products

Study Protocol and Statistical Analysis Plan

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Design of the Effectiveness Trial

We recruited 44 schools across Oregon (N=18) and Arizona (N=26), stratified them by state and size of the school (small, medium, large), yoked them according to their desired start dates, and randomized them to intervention (received the *Click City®: Tobacco* program) or control (implemented their standard curriculum). Schools were randomized after they agreed to participate in the trial and signed a Memorandum of Understanding⁴. For students in the intervention schools, participation in the trial consisted of a baseline assessment one-week prior to starting the program, completing two lessons a week over a four-week period, and a follow-up assessment one-week following completion of the program. To control for the effect of history, students in control schools completed the baseline and follow-up assessments during the same week as students in their yoked intervention school.

We began the effectiveness trial in January of 2020, and by March 13, a total of 26 schools had completed their participation in the trial (16 schools in Arizona and 10 schools in Oregon). At that time, schools in both Arizona and Oregon were ordered to close due to the COVID-19 Pandemic. After schools re-opened, we were able to recruit an additional 17 schools and used the same procedure as that used prior to the pandemic to randomize them. Among the 44 anticipated schools, 43 completed the trial, and 22 schools were assigned to the intervention arm and 21 schools to control.

Procedures

A school liaison was selected within each school to facilitate the trial. A research assistant (RA) contacted the liaison and provided an overview of how the program worked and offered troubleshooting assistance should any issues arise with the program. The RA entered the school, district and the participating 5th grade teacher's name(s) and email(s) within the

administrative portal. The liaison sent a link and instructions to teachers the week before they were to begin the program. This process is like what we expect in a “real-world” setting when the program is marketed.

Each teacher set-up their respective account by entering their basic information and naming their class. The program automatically generated a unique class code to share with their students. When the student first logged into the program, they entered their class code, their name, birthdate, student ID, and a unique username. This information populated the class roster in the teacher’s portal. Teachers had the ability to view and edit each student’s name, username, birth date and student ID. They also had the ability to track each student’s progress through the program. If necessary, they could change the standard administration of the program of one lesson a day and two lessons a week over four weeks, allowing individual students or their entire class to do two or more lessons a day.

Assessments. Upon prompting by the research assistant, teachers facilitated the baseline assessment, one week prior to program implementation, and the follow-up assessment, one-week following the last activity in the program. Assessments were completed using Qualtrics in the school setting. The measures assessing the outcomes and etiological mechanisms associated with e-cigarette use were like measures assessing outcomes and mechanisms associated with cigarette use used in the previous efficacy trial of the original version of *Click City®: Tobacco* (Andrews, et al., 2011).

Analysis Strategy

The sample consisted of those who completed the baseline and/or the follow-up assessment in 5th grade. This approach maximized the 5th grade sample and missing data was estimated using full information maximum likelihood methods. This intent to treat approach assumed that all those who completed at least one assessment participated in Click City: Tobacco and received the entire intervention or their usual curriculum.

Data were analyzed using a general linear mixed model with students nested within schools and schools nested within condition using the GLM procedure within SPSS, version 24. Since schools were randomized to condition, both the student and the school were random effects. Using this method, we examined the effect of the intervention on changes in major outcomes and all etiological mechanisms that were targeted in the program.