Middle School Cluster RCT to Evaluate E-Cigarette Prevention Program: CATCH My Breath

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Study Coordinator: TBD

Population: 30 schools across the Texas

Number of Sites: Single Site: UT School of Public Health - Austin Regional Campus

Study Duration: September 1, 2018-August 30, 2023

Subject Duration: September 1, 2019 - August 30, 2022

General Information

The primary purpose of this study is to empirically assess the three year effects of the CATCH My Breath (*CMB*) program on delaying the onset of e-cigarette use with a 6th-8th grade cohort, using a 30-school group randomized controlled trial (RCT), with 2,400 students. The *CMB* curriculum is divided into four sessions lasting approximately 20-30 minutes each. A variety of educational strategies are used and include cooperative learning groups, large group discussions, interviews, role-play, media, reports, and goal setting.

The *CMB* program is based on well-established educational best practices and empirical evidence, and has been piloted tested for feasibility; feedback on the pilot program was received from 42 teachers and 2,255 6^{th} - 8^{th} grade students. Pilot test results were largely favorable, and the program was revised based on findings from the pilot study. *CMB* is ready for a larger, RCT with teachers and students.

Our ultimate goal is to bring scientifically accurate information to inform and educate teachers, parents and health professionals in the school/afterschool setting about the health risk of e-cigarettes. Our aim is to equip students with answers about e-cigarettes and to make informed decisions about the use of e-cigarettes.

E-cigarette use is epidemic among middle school children, and schools have few rigorously prepared resources to educate students and families. Dr. Kelder is one of several scientific editors of the 2016 Surgeon General Report on E-cigarette Use among Youth and Young Adults and is well versed in the health effects of e-cigarettes. Our goal is to rigorously evaluate the *CMB* program in order to provide educational agencies evidence-based resources to coincide with the recently released Surgeon General Report.

Background Information

E-cigarette consumption among youth is of concern because of the harmful effects of nicotine on human growth and development in terms of addiction and brain development, and fetal development among pregnant teenagers. The rapid increase in use among teens is of concern and portends the possibility of nationwide health consequences. The epidemic calls for a coordinated and scientifically accurate response.

CMB will utilize the gold standard RCT approach to evaluate the effectiveness of the intervention. We will evaluate *CMB* using a cluster group randomized trial design comparing 15 usual care schools implementing Texas Education Agency required tobacco prevention objectives to 15 schools implementing the *CMB* program. We intend to measure children before and after implementation of the program to assess changes in knowledge, attitudes and intentions to use e-cigarettes. We will assess students with a brief survey tool, assess student likes and dislikes, judge the length of time to implement the curriculum, and assess teacher reactions to teaching the program. The effectiveness of *CMB*, and user experience, will be assessed mixed method qualitative and quantitative approaches, including: (a) the impact of *CMB* on student susceptibility to use e-cigarettes; (b) the impact of *CMB* on initiation of e-cigarette use (ever use); (c) the impact of *CMB* on intermediate program outcomes (such as harm perceptions, outcome expectations, self-efficacy); and (d) the feasibility, fidelity and dose of program implementation.

CMB is a *best-practice* based program that was modeled after an *evidence-based* program called the Class of 1989 Study and elements from the Coordinated Approach to Child Health (CATCH) Program. Both the Class of 1989 and CATCH were NIH-funded studies, and both have statistically reliable research results. The Class of 1989 formally studied two communities and a school-based tobacco prevention program, which showed strong effects in reducing student smoking from 6th to 12th grade. CATCH studied children in 3rd to 8th grades and showed strong effects in improving student dietary intake and physical activity, and in later versions of the program, effects on child obesity. *CMB* was modified from the Class of 1989 tobacco prevention program and designed to be added to the CATCH portfolio of school health programs. The same study teams that worked on Class of 1989, and CATCH, have created the *CMB* program.

CMB is also informed by new scientific literature on the rise in use of e-cigarettes in the United States, and the emerging science regarding the harmful consequences of e-cigarette use by preteens and teens.

Objectives

The objective of this study is to evaluate the effectiveness of an E-cigarette curriculum for middle school. The overall goal of *CMB* is to prevent E-cigarette use among adolescents. This study will be guided by the following aims:

> **Aim 1.** Quantify the direct program effect on susceptibility and first use of e-cigarettes on a cohort of children exposed to the *CMB* program in 6th, 7th, and 8th grades, compared to same-aged students in usual care schools.
>
> **Hypothesis 1**: After three school years of exposure to the *CMB* school-based prevention program, 8th-grade students in 15 intervention schools will report: (a) lowered susceptibility to use e-cigarettes; and (b) lowered first time (ever) use of e-cigarettes compared to students in 15

comparison schools.

Aim 2. Quantify the mediating effects of intermediate program outcomes (such as intentions to use, resistance skills, self-efficacy, and media literacy) to understand the mechanisms by which program effects occur.

Hypothesis 2: After three school years of exposure to the *CMB* school-based prevention program, 8th-grade students in the 15 intervention schools will improve scores on intermediate program outcomes compared to students in the 15 comparison schools.

Secondary Aim. Given the longitudinal study design and large number of student participants, we also intend to examine important secondary hypotheses to understand the nature of the e-cigarette epidemic, including nicotine addiction, transition to combustible tobacco use, and e-cigarette assisted marijuana use.

We will also assess students knowledge, attitudes and possible experience with tobacco and e-cigarettes before and after they receive *CMB* through a pre-post survey. A subset of students, parents, and teachers will be invited to participate in focus groups to gather input for continuous quality improvements to the program and online delivery system.

Study Design

We will evaluate *CMB* using a cluster group RCT design comparing 15 usual care schools implementing Texas Education Agency required tobacco prevention objectives to 15 schools implementing the *CMB* program (a total of 30 schools). Thirty schools will be recruited from a pool of 188 public middle schools within 100 miles of The University of Texas School of Public Health in Austin, matched by key demographic variables (percent male and female, percent free and reduced lunch, percent race and ethnicity, percent English as second language) and randomized into intervention and comparison conditions. To ensure comparability, we will recruit 15 matched pairs of schools and randomize them into either treatment or control usual care conditions.

There are no known risks associated with this study. The potential benefits include equipping adolescents with the appropriate knowledge and refusal skills for e-cigarettes.

Study Population & Procedures

The project will identify 30 Texas schools (at least one teacher and/or class per school) to evaluate the effectiveness of four developmentally appropriate e-cigarette lessons (approximately 20-30 minutes long) for middle school aged youth (6^{th} 8^{th} grade). Consistent with the RCT design, we will randomize 15 usual care schools and 15 schools with *CMB* school-based prevention program with cluster size 80 in each school (total sample size = 2,400). We will exclude schools that have participated in our previous 2 pilot tests, or are currently implementing *CMB*.

The study team will draw a convenience sample from interested schools, who will then be matched and assigned to study conditions. School matching will be based on data available through the Texas Education Agency (TEA) online database and will include: the size of school, percent free and reduced price lunch, percent limited English proficiency, percent midyear student transfers, percent staff in school with less than five years experience, percent staff leaving midyear, percent passing state mandated reading and math tests, and attendance rate.

A recruitment presentation, directed at the principal and a curriculum committee or another decision-making committee, will be delivered to interested schools. School recruitment and randomization will be done in Year 1 (July 18 June 19). Implementation of the curriculum will occur in Years 2-4 (Fall 19 Spring 22). Data analyses, presentations and manuscript developing will be ongoing in Years 2-5. We will obtain a Memorandum of Understanding (MOU) from each participating school which delineates responsibilities of the school and research team. Active parental consent will be obtained at back-to-school parent nights by inclusion of consent forms in the school packet of forms that parents sign at the beginning of the school year. For parents not in attendance, students will receive a recruitment packet to take home in the schools weekly take-home folder. Small incentives to schools ($500 stipend for a site coordinator) and students ($15-$20 for t-shirts, water bottles, etc) greatly facilitate return of consent forms, recruitment and retention.

CMB will provide study materials to teachers and schools through a state-of-the art online delivery portal. Teachers will access *CMB* program materials and resources through the CATCH digital access portal (www.digitalcatch.org), built with Ruby on Rails, a highly scalable, efficient and popular web application framework. A site based management team will oversee program implementation. Teachers will be trained via webinar. Project staff will visit all participating schools to assemble and train the CATCH site-based management team, and answer questions about the study. Teachers in *CMB* intervention schools will be provided with *CMB*-specific training for implementing the lessons with fidelity through a one-hour live webinar with Dr. Kelder, which will be offered at multiple times to accommodate teaching schedules.

All student assessments (1 pre-test and 5 follow-up tests) will be conducted online to improve reliability and validity of the survey. Online assessments offer a variety of strengths including utilizing skip patterns, which decrease survey burden; presenting pictures of the products, which increases validity; and providing increased confidentiality in answers that paper surveys cannot provide. In addition to basic demographic information, data will be collected on e-cigarette use behaviors, susceptibility to e-cigarettes, addiction to and dependence on nicotine and e-cigarettes; risk perceptions, reasons to use or not to use, perceived prevalence, normative beliefs, outcome expectations, self-efficacy to resist use (intermediate outcomes); and additional covariates and exploratory factors that include peer and parental use of tobacco products, other tobacco use behaviors, and marijuana and alcohol use behaviors.

CMB will also provide assessment to teachers and site coordinators at both intervention and at usual care schools to measure implementation of the CMB program and usual care program. All teacher and site coordinator assessment will be conducted online to improve reliability and validity of the survey. The online questionnaire will collect data on basic demographic; what program was taught (usual care schools) and validate the CMB program in the intervention schools; how the program was taught (as directed), how well the program was taught (training involved) and exploratory factors on the implementation of the programs taught in both intervention and usual care schools. This assessment will be done every school year of implementation.

Data and Safety Monitoring

No adverse events are expected. Unanticipated problems, to include protocol deviations, will be reported to the PI and IRB. Staff will receive training, certification, and retraining in consent procedures and data collection procedures to assure accurate information and confidentiality. The survey tool is very short and we anticipate will be completed by students in less than 8 minutes.

Data Collection and Management: Research Electronic Data Capture (REDCap) was designed through NIH funding, specifically to provide research institutions with the ability to collect, house and process data in a secure platform. REDCap has Zone 100 security which is accepted by The University of Texas Health Science Center (UTHSC) to adhere to Health Insurance Portability and Accountability Act (HIPAA) and Federal Information Security Management Act (FISMA) compliance standards and is accessible from anywhere with Internet capability and useable offline on Android and iOS mobile devices. Along with offering a high level of security, REDCap also provides many advanced features such as branching logic, calculated fields, and file uploading as well as fully formatting data export directly into all of the major statistical packages. The data manager will utilize computer software to detect errors in the data files such as skip pattern error, duplicate or incorrect identification numbers, and inconsistent responses. To assure security of study data, weekly backup copies of the master file will be made and stored in a physically remote secure area.

Statistics

From each of the 30 schools, we will recruit 80 6th-grade students, for a total n=1,200 per study condition and 2,400 total students. Follow-up measurements will be conducted post-intervention in spring in 6th, and spring and fall in 7th and 8th grades, for a total of 6 measurements per student.

Statistical analysis will follow state of art cluster randomized trial methodology. The statistical analysis will be conducted in four phases: (1) Descriptive Analysis, (2) Analysis of Aim 1, (3) Analysis of Aim 2, and (4) Secondary Exploratory Analyses.

(1) Descriptive Analysis will be conducted with baseline data to produce a profile of demographics and baseline characteristics. Analysis will consist of descriptive statistics such as frequencies, means, cross-tabulations and graphical representation of data. Results will provide information on imbalances between treatment groups that should be accounted for in the confirmatory analysis.

(2) Analysis of Hypothesis 1 is to test the proposed hypothesis that after three years exposure to the *CMB* school-based prevention program, 8th grade students in the intervention schools will report lower a) susceptibility to use e-cigarettes and b) ever e-cigarette use prevalence compared to students in the comparison schools. Multi-level regression models will be used to test for intervention effects while controlling for baseline differences through the use of covariates. Three-level hierarchical models will be used to assess the impact of the intervention where level 1 is the repeated measurement of individual students, level 2 is the student, and level 3 is the school. Multi-level models provide a powerful and flexible framework for the analysis of repeated measures data in the presence of possible cluster effects, allowing for the inclusion of subjects with incomplete data, thus maximizing power and minimizing the Type I error rate.

(3) Analysis of Hypothesis 2 is to test the hypothesis that after three years exposure to the *CMB* school-based prevention program, 8th grade students in the intervention schools will improve scores on intermediate program outcomes compared to students in the comparison schools. Treating these variables as outcomes, we will employ the same statistical strategies as described in analysis of Aim 1. In addition, we will also analyze these intermediate variables as mediators of program effect to determine which act as a mechanism for explaining the effect of the intervention on the two primary outcomes (susceptibility and ever use).These analyses will allow further examination of these possibilities, and will build on the multi-level models developed for the analyses described in Aim 1.

(4) Secondary Exploratory Analyses. Given the longitudinal study design, we intend to examine

important secondary hypotheses to understand the nature of the e-cigarette epidemic with the respect to nicotine dependence and progression to combustible tobacco, marijuana, and alcohol use. Multi-level regression models will be used to assess the longitudinal relationships between independent and dependent variables, while controlling for intervention effects, and baseline differences through the use of covariates.

Ethics, data handling and record keeping

For the school personnel questionnaires, consent will be inferred with the completion of each questionnaire. A coversheet will be attached to each survey describing the purpose, risks, and benefits of the self-report surveys. A personal identification number will be assigned to each survey participant to maintain anonymity. After the final confirmation at the end of the study, the names associated with the identification numbers will be destroyed. For the student measures, each student will receive a recruitment packet to take home to parents or guardians. Active parental consent will be obtained at parent back to school night by inclusion of consent forms in the school packet of forms that parents sign in the beginning of the year. Students will be assigned a personal identification to maintain anonymity. The names associated with the identification numbers will be destroyed after the final confirmation at the end of the study. No personal identification information (e.g., name, address, etc.) will be reported in any manuscript.

Confidentiality of all subjects will be fully protected. All study records will be kept in locked file cabinets and secured computer files. Only aggregate data will be reported and released, and at no time will individual names appear in any report/article related to the study.

Quality control and assurance

All data will be collected and stored in secure rooms with secure computers following the UTHealth data storage and retrieval protocols, and the Michael & Susan Dell Center. Access to data will be managed by Dr. Kelder.

Publication Plan

We intend to publish at least one publication reporting the effectiveness of the *CMB* program. Participating schools will be given no-cost copies of the program for their future use and a copy of the pilot test report. Results will be reported in aggregate.