# Design of Classroom Intervention for Teaching Preschoolers to Identify and Avoid Inhaling Secondhand Tobacco Smoke

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**Abstract**

Secondhand smoke (SHS) is caused by burning tobacco products that emit up to 7000 chemicals and over 70 carcinogenic compounds. Thirdhand smoke (THS) is solid residue remaining on furniture and carpets, including suspended particles derived from a burned tobacco product. Exposure to these compounds occurs through inhalation, oral ingestion, or dermal uptake. Examples of the tobacco smoke pollutants can include nicotine, benzene, naphthalene, formaldehyde, and nitrosamines related to tobacco. Exposure to SHS and THS are preventable. Infants and young children suffer disproportionately from tobacco-related pediatric disease since they spend much of their time indoors in households and cars. Despite growing awareness of the need to protect children from exposures, a recent survey reported more than 50% of children aged 3 to 11 were exposed to SHS. Although school-based health interventions have targeted healthful nutrition and physical activity among preschoolers and kindergarten, data are scarce for school-based activities addressing prevention of exposures to SHS and THS among those aged 4 to 6. We describe the design and future testing of such an intervention. This will be a pilot randomized controlled trial designed to evaluate the feasibility of conducting an intervention for teaching children to protect themselves from exposure to SHS and THS. We will use a mixed methods approach. Qualitative methods will be used to determine perceptions of classroom teachers and student participants aged 4 to 6 about refining the intervention before the feasibility trial. During the trial, three preschools will be recruited for a total of 12 classrooms and randomized to either control or intervention curriculums. The control classrooms will receive a mathematics curriculum. The intervention classrooms will receive a curriculum about awareness and health consequences of exposures to SHS and THS. The primary outcome is the feasibility of conducting the intervention, including recruitment and retention of participants from pre-k and kindergarten classrooms. Two exploratory outcomes will be effectiveness among child participants and acceptance and response of the parents to the intervention. We will evaluate program effectiveness with the Preschool Health and Safety Knowledge Assessment, a reliable and valid measure for gauging the effectiveness for teaching health and safety knowledge. The story depicted in the intervention program chronicles how the main characters identify and successfully avoid SHS and THS. Activities are designed to allow children to play and discover “clean and dirty air.” If the study is successful, we anticipate pursuing external funding sources for conducting a large group-randomized controlled trial. Future intervention iterations will incorporate the use of technology.

## Introduction

Best known for high quality research in cancer care and treatment, MD Anderson Cancer Center has a large division of cancer prevention and population-based scientists. MD Anderson's mission has evolved to accelerate breakthroughs in cancer prevention with programs focused on intervening during the developmental years. Recognizing that cigarette smoking is the number one cause of preventable morbidity and mortality, (U.S. Department of Health and Human Services 2014), MD Anderson is investing in research to learn the best approaches for decreasing cancer risk caused by tobacco. This endeavor is titled, "Lung Cancer Prevention Moon Shot." (MD Anderson Cancer Center 2016). Besides targeted cancer treatment research and advanced strategies for tobacco cessation, MD Anderson is leading development in infrastructure for school-based educational interventions. One of the most widely used intervention programs is A Smoking Prevention Interactive Experience (ASPIRE) (Prokhorov 2008; Prokhorov et al. 2008). It is an evidence-based curriculum designed for preventing uptake of tobacco among individuals aged 11 to 18 and posted on the National Cancer Institute's Research-Tested Intervention Programs (RTIPs 2016). This stream of research has focused on preventing tobacco and motivating cessation among adolescents, young adults, and families. Investigating families, smoking, and indoor air tobacco smoke, this team conducted an intervention among Mexican American households with at least one smoker. A series of written health materials were distributed to the families. The content described protecting children from tobacco smoke. The intervention resulted in a significant decrease of nicotine levels in the homes of participants as measured from nicotine monitors installed in the homes. This intervention was reformatted for dissemination as the Tobacco-Free Family app (also featured on RTIPs) (Prokhorov et al. 2013). Conveying accurate information about smoking is critical for influencing the health of children in preparation for a productive future.

Although new tobacco products are increasing in popularity (Lee et al. 2014), cigarette smoking remains the most frequently used tobacco product (Lee et al. 2014; Jamal et al. 2015). The majority of tobacco use continues to involve smokers burning cigarettes, cigars, pipes, and water pipe tobacco. The gases emitted by the burned products are comprised of 7000 chemicals and over 70 carcinogenic compounds (Homa et al. 2015). This toxic mixture is termed "secondhand smoke" (SHS) and often referred to as secondhand smoke exposure (SHSe). Adults exposed to SHS can develop atherosclerosis and lung cancer. Mothers who cannot quit smoking during the prenatal period increase risks for long-lasting impact of smoking on their infants (see Table 1) (Vardavas et al. 2010; Winickoff, Van Cleave, and Oreskovic 2010). Parents, caregivers, and other adult smokers may smoke indoors within the home. It is estimated that babies and young children spend 85% of their time indoors and suffer more than adults from SHSe (McCormack et al. 2008). Another term linked to SHSe is "thirdhand smoke," (THS). It is solid residue remaining on furniture and carpets, including suspended particles derived from a burned tobacco product. Exposure to these compounds occurs through inhalation, oral ingestion, or dermal uptake. Examples of the tobacco smoke pollutants can include nicotine, benzene, naphthalene, formaldehyde, and nitrosamines related to tobacco (Matt et al. 2011; Langford et al. 2014). Schools play a role in educating children about behaviors to promote health. Traditionally health education classes, including alcohol, tobacco, and drug avoidance programs begin in middle school grades. A recent systematic review of schools providing health promotion programs found an increase in multiple risk behavior change strategies (Langford et al. 2014). Examples included healthy diet and exercise, which are being introduced as early as preschool and kindergarten. Studies of school-based education to young children about avoiding SHSe were scarce. One exception was a program in China. Researchers offered a study to caregivers and students attending kindergartens (Wang et al. 2015). Caregivers were targeted primarily, alerting them to protect their children's health and quit smoking. Interestingly, the kindergarteners were encouraged to convincingly persuade others to not smoke and reduce indoor smoking. The frequency of advice offered to caregivers by kindergarteners was not reported. Results indicated a substantial decrease of 40.6% in indoor SHSe at 6-month follow-up. This study from China among young children is an exception. Results of a literature search described studies to protect nonsmokers and children from SHSe and THS. The majority of these

investigations were conducted by clinicians serving pediatric populations (e.g., parents questioned about smoking and advice to quit) (Rosen et al. 2012; Rosen et al. 2014). A large body of evidence has found smoking bans effective in protecting health on the population level (Frazer et al. 2016). This intervention is titled, "Children Against Nicotine and Tobacco" (CHANT).

Table 1. Health effects of exposure to tobacco smoke

| Developmental period | Impact |
|---|---|
| Prenatal | |
| | Developmental delays |
| | Impaired lung function |
| | Small for gestational age |
| | Miscarriage |
| | Neurological problems |
| | Obesity |
| | Stillbirth |
| Postnatal | |
| Short-term | Asthma and exacerbations |
| | Otitis media |
| | Pneumonia |
| | Decreased immune function |
| | Sudden infant death syndrome |
| Long-term | Premature progression of atherosclerosis |
| | Impaired lung function |
| | Metabolic syndrome |
| | Dental caries |
| | Increased rates of malignancy |

This pilot randomized controlled trial will aim to evaluate the feasibility of conducting an intervention about teaching children to protect themselves from SHSe and THS. We will use a mixed methods approach. Qualitative methods will be used to determine perceptions of classroom teachers about the curriculum. Preschool children will also be invited to view a demonstration of the curriculum, and asked for feedback in focus groups. Inviting input during preparation is essential before conducting a randomized controlled trial. This project will be divided into two phases, the preparation stage and feasibility trial.

**Aims and objectives**

The aims of Phase 1 are to:

1. Recruit leadership of preschools to ask permission about allowing their teachers to pretest a draft of the printed educational curriculum
2. Engage classroom teachers to assess their perceptions of the curriculum, obtain their input about the curriculum during pretesting. The goal of this endeavor will be to anticipate and eliminate possible problems with the process of delivering program contents.
3. Contact parents and legally authorized guardians of preschoolers, obtain consent for their children to pretest materials before a randomized trial is conducted.

The aims of Phase 2 will be to:

1. Assess the feasibility of recruiting leadership from three schools that teach preschoolers and obtain approval to permit four of their preschool classrooms to participate in testing the curriculum. Within four classrooms, two would be assigned to the intervention (intervention about avoiding SHSe and THS) and two would be the controls (classroom lessons about geometric shapes in art).
2. Assess recruitment and retention rates among participants.
3. Obtain parental assessments as to whether preschoolers discussed the program at home
4. Assess delivery of the program components in the intervention groups
5. Compare differences for the pre- and post-tests between the intervention and control classrooms
6. Estimate parameters needed for the design of a definitive future randomized controlled study

**Methods/Design**
Phase 1 will be a pretest of the intervention materials designed to address avoiding SHSe and THS. This aspect will involve an average of 10 preschoolers per class. They will be aged 4 to 6 years. Up to 12 certified preschool teachers will be invited to review the curriculum for their perspectives about appropriateness for covering required educational outcomes. Phase 2 will be a randomized trial of classrooms receiving the SHSe and THS intervention versus control classrooms will receive a curriculum in geometric shapes in art that aligns with state standards. Three schools in the Houston area will be selected. The schools will be eligible if they have two pre-kindergarten and two kindergarten classes. The researchers will select schools with students whose parents are from similar socioeconomic households. Data will be collected from teachers using surveys. Data will be collected from students by researchers individually using an instrument with pictures. Surveys will be used to collect data from parents.

**Setting**
Researchers plan to recruit schools located within the greater Houston area (Harris County, Texas). The racial ethnic composition of the area is about 42.8% Latino, 19.5% black, 31.4% white, 7% Asian (United States Census Bureau 2014). Twenty-seven percent of children in Harris County lived in poverty in 2014. Publically funded pre-kindergarten (pre-k) and kindergarten programs are available. Data revealed 86% were economically disadvantaged (US directory 2016). Data on socioeconomic status of the community served by schools is available on the internet.

Regarding tobacco use in Texas, about 14.5% of adults over age 18 reported smoking cigarettes in 2014. Rates of tobacco use are 16.3% among whites and blacks, with Hispanics at 13.5%. In terms of assessment of home smoking rules among Texans, the majority (68.4%) of adult smokers with children living in the home self-reported smoking indoors was not allowed in their residences. (King et al. 2016).

**Eligibility**
Student participants, for both Phases 1 and 2 will be enrolled in pre-kindergarten or kindergarten. They must be aged 4-6, speak and understand English. The parent or guardian must provide written informed consent. Teacher participants will be certified and assigned to the classroom where the intervention is being conducted.

**Recruitment**
Recruitment at Phase 1 involves three levels. We will obtain cooperation of 1-3 schools, 1-3 classroom teachers, and an average of 10 consented classroom students within a class. In Phase 1, leadership from preschools will be contacted by the MD Anderson research team about interest in study participation. If interested in participating, a letter and information sheet will be emailed. A week later, the research team will follow-up by telephone to learn about the decision by the preschool leadership to participate. After leadership from three schools with comparable sociodemographic characteristics among students agrees to participate, we will brief preschool teachers about the study purpose, procedures and ask whether their

classroom and students will participate. If approval is secured, the research team will email the curriculum to each individual teacher. Teachers will be called a week later to discuss their perceptions of the curriculum using semi structured interviews. Study participation will be construed as informed consent for teachers. Three focus groups will be scheduled during regular preschool classes. Researchers will be able to assess preferences of child participants of illustrations of storybook characters. We will also assess the familiarity of participants with terms such as "tobacco" and "smoking." The focus groups will be audio-recorded to capture qualitative and quantitative data.
Children younger than age 7 were determined as being incapable of assenting to engaging in research (i.e., MD Anderson Institutional Review Board). Parental consent for child participation will be conducted by MD Anderson research staff. Written informed consent will be required from parents or legal guardians, for both intervention and controls. Before research begins, study protocol approval will be secured by the protection of human subjects committees for participating facilities, with data confidentiality assured for data.

Recruitment at Phase 2 involves four levels. We will obtain the cooperation of leadership at three schools. Eligibility requires there must be four classrooms teaching students aged 4 to 6 (two pre-kindergartens and two kindergartens). This requirement will entail recruitment of four to twelve classroom teachers, an average of 10 classroom students in a class, and consent by parents of participants. It will be explained to the leadership and the teachers that randomization to either intervention or control classrooms will occur. Both the curriculums for the intervention and control will be presented to the participating classes during regular school hours. Data from participants whose parents whose returned signed informed consents will be included in statistical analysis.

**Interventions**

Because mathematics is a focal educational domain specified by the Texas Educational Agency, the research team selected geometric shapes as the control intervention. Many cultures use geometry in art, providing a valuable tool for teaching mathematics in an interesting way. The primary objective of the control intervention will be to present basic shapes and encourage participants to identify simple patterns in art. Participants will listen to the content of books about shapes read aloud by the classroom teachers (Hoban 1996; Rissman 2009). The frequency of the educational sessions will be matched across school campuses to ensure the reliability and validity of the study. Classrooms randomized to the control curriculum will receive five, 20-minute sessions. In addition, participants in control classrooms will be evaluated with respect to correctly identifying basic shapes by the classroom teachers. The scheduling of interventions will depend on the discretion of the preschool leadership. Participants will be administered the same pre- and post-assessments as for intervention classrooms within one week before the interventions and within one week afterwards (Mobley and Evashevski 2000).

After pretesting the curriculum about avoiding SHSe and THS and pre- and post-test assessments, we expect the materials to be well-received. The research team prepared an instructional manual describing the conduct of the five, 20-minute sessions. Professional artwork will illustrate the program components. Curriculum content follows educational standards (See Table 2). The characters will be depicted as essentially neutral for race and ethnicity. The supporting materials include an original storybook titled, "Brady and Charlie's Brand New Day." It is accompanied by individual corresponding workbooks, stickers, flash cards, Brady and Charlie dolls, bandanas, and certificates for graduation. The narrative chronicles a mother, child, and their dog going to play in the park. The story uses rhyming words, with the text having a sing-song quality. It will be read aloud to the participants. The scene about exposure to SHS and THS will take place when the trio visits an uncle. This will be illustrated as an older man surrounded by a cloud of smoke. There will be no display of tobacco products so as not to provoke curiosity. The book characters react with concern to exposure to the SHS and THS. The story concludes by returning home and taking a bath. Classroom exercises will instruct about identifying clean and dirty

air. Participants will be instructed to cover their noses and mouths with their hands if exposed to SHS. Research team members possess advanced academic degrees, training and experience with conducting early child psychological assessments and educating young children in schools. Prior to the intervention and after the intervention, researchers will administer the pre- and post-test assessment (Mobley and Evashevski 2000). For the purposes of this feasibility study, the research team will conduct intervention lessons, and pre- and post-test assessments with a classroom teacher present. The classroom teacher will not facilitate or assist in moderating educational sessions but will be available to reassure the well-being and safety of the children.

Table 2. Education standards with examples for integrating SHSe and THS content

| Domains for pre-kindergarten and kindergarten | How incorporated into intervention curriculum |
|---|---|
| Social and emotional | Follows simple rules around handling written materials |
| Reading and communication | Uses books (pre-reading), practices listening, attains new vocabulary words |
| Mathematics | Identifies simple geometric shapes, stop and go signs, counts numbers from 1 to 10 |
| Science | Learns about having a pet, identifies clean versus dirty air |
| Health | Learns about coughing, sneezing, irritation to eyes, nose and throat. Identifies basic ways to protect self from smoke and sun's harmful rays, and consume healthful foods |

**Measures**

The primary outcome will be feasibility throughout the study involving administering an intervention among pre-k and kindergarten classrooms. There will be five criteria: ability to recruit participants, completion of the pre- and post-tests, adherence to the five educational sessions, acceptability of the curriculum among students, and among classroom teachers. The exploratory outcome will be the assessment of intervention effectiveness using a modified version of the Preschool Health and Safety Knowledge Assessment (PHASKA) (Mobley and Evashevski 2000). Previously tested among 308 participants with a mean age of 53 months, the PHASKA was found to be a reliable and valid measure. It is appropriate for children aged 4 to 6. The instrument is a nonverbal method for assessing knowledge of protective behaviors in the household, prevention of accidents, and health recognition. An example of a question on the PHASKA shows a drawing of a child finding a book of matches on the sidewalk. The test administrator would ask the child participant, "What should the child do to be safe?" "Should the child strike one to see if it lights or should they give the matches to an adult?" Responses are scored for correct or incorrect answers. The original instrument included 53 items. For the purposes of this project, we selected only 20 behavioral items most relevant to the contents of the intervention. Twenty minutes is anticipated to be the length of time required to conduct the pre- and post-assessments. Participants in both the control and intervention classrooms will be individually administered the test items by a researcher pre- and post-test. In addition, we will also assess the perceptions of the classroom teachers and students regarding the acceptability of the interventions. Lastly, as another exploratory objective, we will ask parents to complete a questionnaire after the intervention is complete. The component of acceptability to parents will assess whether children discussed the curriculum content at home, the responses of the parents, and self-report of any possible change to the behavior of the child at home.

**Analysis**

We will have one primary outcome, feasibility throughout the study involving administering an intervention among pre-k and kindergarten classrooms. The specific criteria for deeming the feasibility will be: at least 80% of parents will provide consent for their children to participate, at least 80% of participants will complete assessments, at least 60% of the five, 20-minute educational sessions will be conducted, and the acceptability rate for the intervention will be greater than 70% among both students and teachers. This would be indicated by the percentage of participants agreeing with the statement that they liked the CHANT curriculum. Exploratory objectives assess the pre- and post-tests (i.e., PHASKA scores for students) and acceptance of the intervention by parents. Assessment for each of the feasibility criterion will be determined by calculating summary statistics (i.e., paired-tests, Wilcoxon signed-rank, and two-sample t-tests with the corresponding 90% confidence intervals adjusted accordingly for various intraclass correlations). This will involve comparing classroom mean scores and differences between the mean scores for the intervention and control classrooms. Assessment of parental acceptability of the intervention will be collected to use for future study.

The justification for the sample size will involve recruiting 12 classrooms (average of 10 students) from three schools (each school will have 4 classrooms, 2 from pre-k and 2 from kindergarten). The classrooms will be randomized on a 1:1 ratio to control or intervention and stratified by grade within each school. With regard to the feasibility objective, assuming an 80% consent rate among parents, we will have 96 students. Half of the students will be from the control and half will be from the intervention.

**Data monitoring, participant safety plans, ethical considerations**

The research team and investigators will supervise and review the implementation and evaluation. This is a low risk study where participants will be informed they can withdraw from participation at any time. This will not impact school grades. Aggregate data summary data will appear in reports and publications. No individuals will be identified. Data will be destroyed within five years after data analysis. The study protocol and informed consent documents will be approved by the MD Anderson Institutional Review Board (IRB) and any other committees as required by participating schools. For compensation for their time, participants (teachers and parents) will receive $30 gift certificates. Student participants will receive back packs, Charley and Brady dolls, and other appropriate items.

**Status and timeline for the feasibility trial**

The protocol is scheduled to be reviewed and approved by July 2016. The preparation of the curriculum and study materials is in progress. Recruitment of schools for pretesting of draft materials for Phase 1 is scheduled for Fall 2016. This will be followed by recruitment of schools for Phase 2 anticipated to launch in early 2017. Data collection and analysis will be completed by mid-year 2017. Findings will be disseminated in reports, publications and during conferences.

## Conclusion

Conveying accurate information about smoking and avoiding SHS and THS exposures are critical for influencing the health of children in preparation for a productive future. Most intervention studies reporting protecting nonsmokers and children from SHS and THS exposures were conducted by clinicians serving pediatric populations (e.g., parents questioned about smoking and advice to quit). No school-based studies of educational curriculums targeting students aged 4 to 6 were located. This intervention is titled, “Children Against Nicotine and Tobacco” (CHANT) and will help to fill the gap. It will be a randomized trial of 12 classrooms in Houston, Texas. Six will receive the SHS and THS intervention versus 6 control classrooms which will receive a curriculum about geometric shapes in art. If the study is successful, we anticipate pursuing external funding sources for conducting a large group-randomized controlled trial. Future intervention iterations will incorporate the use of technology.

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