Maximizing the reach of universal child sexual abuse prevention: Protocol for an equivalence trial

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ABSTRACT

Background: Child sexual abuse (CSA) affects 1 in 5 girls and 1 in 12 boys before age 18. Universal school-based prevention programs are an effective and cost-efficient method of teaching students an array of personal safety skills. However, the programmatic reach of universal school-based programs is limited by the inherent reliance on the school infrastructure and a dearth of available alternative delivery modalities.

Methods: The design for this study will use a rigorous cluster randomized design ($N = 180$ classrooms) to determine the equivalence of two delivery modalities of *Safe Touches*: as usual vs. modified. The as usual workshop will be delivered by two facilitators with live puppet skits ($n = 90$). Whereas, the modified workshop will be delivered by one facilitator using prerecorded skit videos ($n = 90$). We will determine the equivalence by measuring concept learning acquisition preworkshop to immediate postworkshop (Aim 1) and retention at 3-months postworkshop (Aim 2) among students in classrooms that receive the as usual or modified workshops. To conclude equivalence, it is imperative to also examine factors that may impact future dissemination and implementation, specifically program adoption among school personnel and implementation fidelity between the two modalities (Aim 3).

Conclusion: Study findings will inform the ongoing development of effective CSA prevention programs and policy decisions regarding the sustainable integration of such programs within schools.

Clinical trial registration: NCT06195852.

1. Introduction

1.1. Background and rationale

Child sexual abuse (CSA) – any sexual act with a child under the age of 18 involving direct physical contact and/or noncontact sexual acts, including nonconsensual texting and online image sharing [1,2], is a public health priority. Global estimates suggest 1 in 5 females and 1 in 12 males will experience CSA prior to age 18 [3,4]. In 2022, over 60,000 children in the U.S. were determined to be victims of CSA by statewide child protection service systems [5]; the highest prevalence observed among children aged 7–13 years old [6]. CSA is associated with life-long biopsychosocial consequences [7] including psychological [8–17], biological [18–21], and interpersonal [22,23] outcomes, altogether conferring a lifetime economic burden estimated to exceed $9.3 billion

[24]. CSA is not limited to a particular gender, socioeconomic class, or racial group – all children can be at risk for victimization. Given the scope, gravity, and cost of CSA, universal, primary prevention efforts are crucial and have the potential to create long-lasting public health benefits.

Since the 1980s, the most pervasive CSA primary prevention strategy has been universal school-based programming. School systems provide the ideal infrastructure for cost-effective universal programming [25]: (1) schools serve children across every racial, ethnic, and socioeconomic status; (2) programs employ the same social cognitive learning theories and principles as used typically in the classroom [26,27], thus creating a consistent learning approach to maximize student attention and success; and (3) school staff (e.g., teachers, counselors, nurses), who are trained to identify signs of abuse, have frequent and continued contact with students, positioning them to recognize and report instances of abuse.

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Indeed, school staff are the most frequent reporters of suspected child maltreatment, including CSA, to child protective services [6]. Broadly, school-based CSA prevention programs teach children personal safety skills, knowledge to identify boundary violations and unwanted forms of touch or contact, how to refuse approaches or invitations effectively, and increase agency and access to needed resources [25,28]. Universal prevention programs delivered during the school day are accessible to children with minimal disruption to parents, thereby reducing implementation barriers such as cost and access. Several universal school-based programs have demonstrated effectiveness in increasing children's knowledge of self-protection skills [26,29,30], and some have been linked with facilitating disclosures (i.e., a report to statewide hotlines) [31,32], including *Safe Touches*. [33].

1.1.1. Safe touches

Developed by The New York Society for the Prevention of Cruelty to Children (NYSPCC), *Safe Touches* [30] is an evidence-based CSA prevention curriculum designed for children in K-3 classrooms (Fig. 1). Based on developmental learning theories, the ~50-min interactive workshop uses two facilitators, racially diverse puppets to role-play scenarios (i.e., skits) and interactive discussions to help students learn and practice CSA-related safety concepts [34,35]. Puppets have been shown to be an effective method for engaging young children when discussing emotionally complex material because they stimulate curiosity and imagination, provide neutral and safe role models, and engage learners [36]. Along with the in-class workshop material, activity booklets are distributed after the workshop to facilitate children and parents reviewing the safety concepts together at home. The *Safe Touches* workshop includes a standard protocol for following-up with students who make statements suggestive of possible abuse, which includes a minimal facts interview, including appropriate school personnel, and placing calls to the state reporting hotline as needed.

The original evaluation of *Safe Touches* used a cluster randomized trial design to evaluate the impact of *Safe Touches* in New York City public schools serving low-SES, minority students [30]. Of 890 eligible children recruited across schools, 528 (59%) returned signed parental permission forms to participate in the research, and, of whom, 492 (93%) assented. Student's acquisition of key concepts was measured pre-workshop (~1 week prior to workshop), immediately post-workshop, and at a 4-week follow-up. Compared to peers who did not participate in the workshop, those who received the *Safe Touches* workshop demonstrated significant knowledge gains; gains were greatest among students in 2nd grade (i.e., 7–8 years old, or Grade 2).

1.2. The state of school-based CSA prevention

Though several universal school-based prevention programs have been deemed evidence-based, including *Safe Touches*, CSA prevalence rates have been stagnant for >20 years [37], which may be a function of inadequate program reach. Program dissemination is affected by three implementation weaknesses that limit program reach. First, there is a lack of rigorous and continued research on universal school-based CSA prevention programs. A meta-analysis of 24 studies demonstrated that school-based strategies effectively increase CSA-related knowledge, and these gains can be maintained [38]. However, the authors note methodological limitations of the studies, including replication and expansion. A notable exception is the work by Tutty who has researched *Who Do You Tell?* in Canada for more than 20 years [39,40].

Second, even single-session, in-person programs require a significant investment of provider time and travel costs. Like many other school-based programs, *Safe Touches* requires two facilitators per workshop which compounds costs and may preclude implementation in schools geographically distant from the providers' site. In the first cost analysis [41] of *Safe Touches*, the per student cost ($154,243 US) was most significantly driven by personnel (i.e., facilitator) time [42]. Indeed, facilitator wage and fringe (i.e., additional employment benefits) accounted for 64% of costs. School-based programs comprised of multiple sessions have exponentially higher implementation costs. Given the lack of federal funding to support school-based CSA prevention programming, efficient and economical implementation options are essential in taking a program to scale.

Third, as programs are delivered in the classroom, they are dependent upon the school setting for implementation. Schools have consistent contact with children over extended periods of time, which makes them a successful point of intervention for preventive education. This was most recently highlighted by the unprecedented school closures to mitigate the spread of COVID-19 wherein the infrastructure for prevention programming – and therefore the potential for school staff to identify potential abuse and disclosures – was eliminated [43,44]. In response to the unprecedented circumstance, and unsure of what the future would hold for school-based programming, the NYSPCC training team adapted *Safe Touches* for virtual delivery [45]. The adaptation prioritized fidelity of the model and did not make substantive changes to the evidence-based curriculum. The delivery format was modified such that the program would be delivered by one facilitator and the script was modified accordingly to reflect the format changes. The facilitator joined the classroom via interactive video conferencing platforms (e.g., Zoom or Google Classroom) to lead interactive discussions in real time. Students participating in the workshop could join individually from
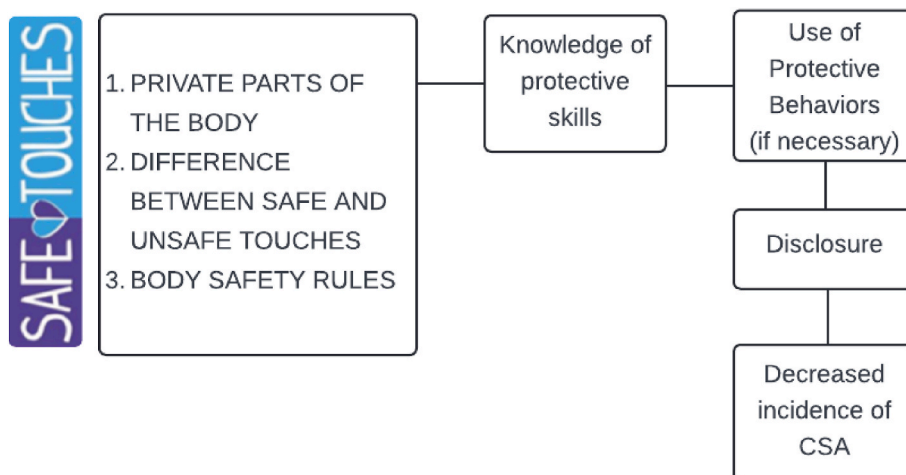

Fig. 1. Conceptual model.

home (e.g., at home due to school closure or isolating) or all students could participate together physically in the classroom. An acceptability and feasibility pilot of the virtually delivered curriculum found that mean concept knowledge scores and response patterns from students who received the virtual workshop were comparable to the student scores from the in-person workshop [45]. Qualitative input from the facilitator and school staff was also positive, indicating high student engagement.

Pandemic circumstances, though unusual, highlight the need for innovation and flexibility in modes of delivery for effective school-based preventive education programs even outside of pandemic times. In 2024, students are back in classrooms and the demand for virtual workshops is markedly decreased. However, the modified *Safe Touches* delivery with one facilitator and pre-recorded puppet skits still offers a relevant solution to documented implementation barriers (e.g., limited budgets, staff turnover). For example, one partner site with a long history of implementing *Safe Touches* and with staff trained in the virtual option during the pandemic, experienced a sudden staffing change leaving only one trained facilitator and organizational budget constraints (e.g., unable to invest in the staffing and training of the required second facilitator). With only one trained facilitator, the site was at risk of being unable to continue (or sustain) its workshop implementation schedule, and leaving their recipient schools without the *Safe Touches* preventive education program – which many schools had adopted and integrated into their curriculum. To follow through on their commitment to schools with whom the site had long-established relationships, the remaining one facilitator, on her own accord, continued implementation by delivering the *Safe Touches* workshop in classrooms using the pre-recorded videos.

Leveraging this natural experiment, we conducted a small pilot study with our partner site to examine the feasibility of modified *Safe Touches* implementation with one facilitator and pre-recorded skits [46]. In total, the site implemented *Safe Touches* in 88 classrooms in 25 schools across two rural counties, reaching a total of $N = 1,480$ s-grade students ($n = 490$ *Safe Touches* as usual and $n = 990$ modified *Safe Touches*). The result of comparing post-workshop survey responses from students using an independent-samples *t*-test indicated nominally comparable mean item scores across delivery modalities (i.e., as usual and modified). Student-level data were also paired with teacher evaluations and an interview with the facilitator. A total of 76 teachers completed the post-workshop evaluation ($n = 23$ *Safe Touches* as usual; $n = 53$ modified *Safe Touches*). Across both modalities, most teachers reported that the workshop content was presented clearly (90%). The majority of teachers (80%) were in full agreement that they would recommend the workshop to their colleagues, with a nominally higher endorsement among those who viewed the one-facilitator-led workshop compared to teachers who viewed the workshop as usual, 85% vs. 70%, respectively. Feedback from the school personnel and facilitator was highly positive, which, when paired with the promising student data, signals the viability of empirically examining this alternative delivery modality to expand the reach of universal school-based CSA prevention programs.

1.3. Current study

The present study is the first step in a line of research to improve access to preventive education. In this study we will compare the effectiveness of the two delivery modalities of *Safe Touches* (i.e., as usual vs. modified) on students' CSA-related knowledge of self-protection concepts. Capitalizing on the evidence-base of *Safe Touches*, we will conduct an equivalence trial to determine if the modified *Safe Touches* workshop (experimental treatment) has a similar effect as the workshop delivered as usual (standard treatment). We will determine the equivalence of concept learning acquisition (Aim 1) and retention (Aim 2) among students in classrooms ($N = 180$) that receive the as usual ($n = 90$) or modified ($n = 90$) *Safe Touches* workshop. To conclude equivalence, it is important to examine factors that may impact future

dissemination and implementation, specifically program adoption among school personnel, fidelity, and cost (Aim 3). The assessment of fidelity is an especially important contribution of this study to the literature on school-based programs, as less than 30% of trials of school-based programs reported monitoring implementation fidelity [47]. Study findings will inform the ongoing development of effective CSA prevention programs and policy decisions regarding the sustainable integration of such programs within school systems. It is also our hope that this line of research functions as a catalyst for the greater CSA prevention field to empirically examine the effectiveness of alternative delivery modalities.

2. Methods

We will conduct a pragmatic cluster randomized trial to determine the equivalent effectiveness of two delivery modalities of *Safe Touches* (as usual vs. modified) on CSA-related knowledge of self-protection skills or concepts (i.e., recognition of unsafe touches, people, situations). Beyond assessing equivalent knowledge gains, it is imperative to understand the impact of implementation on equivalence to ensure equity between delivery modalities. Capitalizing on the evidence-base of *Safe Touches* (standard treatment), we will conduct an equivalence trial – not to be confused with an inferiority trial – to determine if modified *Safe Touches* (experimental treatment) has a similar effect as the standard treatment within a prespecified interval (known as the equivalence margin; -Δ to Δ) [48,49] informed by our pilot study [46].

2.1. Experimental procedures

Experimental design and procedures (Fig. 2) are informed by the original trial design [30] – a clustered randomization design (each cluster represents a classroom). The *Safe Touches* as usual workshops ($n = 90$ classrooms by expectation) are delivered in classrooms by two facilitators, as designed, whereas the modified *Safe Touches* workshop ($n = 90$ classrooms by expectation) will be delivered by one facilitator in classrooms initiating live discussion but using pre-recorded skits. Randomization will occur at the classroom level using a Bernoulli randomization design. That is, we randomly assign (with equal probability ½) each classroom to either *Safe Touches* as usual or the modified *Safe Touches*. We will consider confounding variables using publicly available aggregate data on race/ethnicity, setting (rural/urban), and income (% of students eligible for free and reduced-cost meals) in analyses.

2.1.1. Setting and participants

The study will include school sites from a Mid-Atlantic state (Pennsylvania) with a sample target of $N = 180$ second grade classrooms. With the help of community-based partner sites, schools will be recruited prior to the start of the academic year to ensure a full academic year for study related tasks. These schools have previously contracted with our partner sites to receive the *Safe Touches* workshop. Over the course of the school year, trained facilitators will implement the two modalities of the *Safe Touches* curriculum. For both modalities, the guidance counselor and teacher will remain present for the workshop to help with participation and/or classroom management, as needed, and assist with any disclosures.

Across conditions, all second-grade students will be invited to participate in the *Safe Touches* workshop, regardless of their participation in the research. Participants in the research will be second-grade students in classrooms in schools, will be a native or fluent English speaker, and have a signed parental permission form. In the weeks leading up to the scheduled workshops, flyers and parent permission forms will be sent home explaining the research. (Note: the research is distinct from the *Safe Touches* workshop). Students who do not receive parental permission or who do not provide assent for the research will be given a separate quiet activity while the research is being conducted.
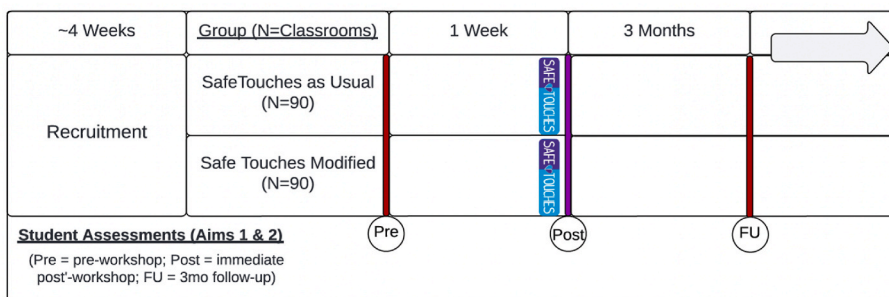
Fig. 2. Study timeline.

The students for whom parents have provided permission must provide assent at the time of the preworkshop survey. Student participants and schools will not receive any monetary incentive for their participation. All students will be sent home with a *Safe Touches* activity booklet to review with caregivers.

2.2. Measures

2.2.1. Student knowledge of CSA-related self-protection skills

At the preworkshop assessment, students will be asked to report their age and gender. The primary outcome of interest is a modified version of the Children's Knowledge of Abuse Questionnaire (CKAQ), which was designed to evaluate elementary school children's learning of the key concepts taught in most sexual abuse prevention programs [50]. The modified version includes only the six CKAQ items that showed the greatest pre-post gains in prior *Safe Touches* research [34] and has been used in most recent trials of *Safe Touches* [33,51]. Items are rated on a 3-point scale of true (2), in-between (1), or false (0), with higher summed scores indicating a higher level of knowledge [33]. Assessments will be conducted (1) pre-workshop (~1 week before the scheduled workshop), (2) immediately post-workshop, and (3) at 3-month follow-up to ascertain CSA-related knowledge gains and potential maintenance of those gains (Fig. 2). To ensure confidentiality, each student will be given a unique study identification number, which will be used for the reporting, storage, and analysis of data. Parents will provide household income and indicate race/ethnicity on the parental permission form.

2.2.2. Program adoption

School personnel (i.e., teacher or counselor) from each participating classroom ($N = 180$) will be invited to participate in the adoption survey. Using Likert-scale items (1 = Strongly Disagree – 5 = Strongly Agree) and open responses, the goal is to gauge the level of adoption (i.e., willingness to have *Safe Touches* delivered in their classroom) and their intention to recommend or advocate for sustainability of the program beyond the study. The project-developed survey will be administered during the workshop presentation and completed on paper. The survey measures satisfaction with program content and pedagogy (e.g., "I would recommend the *Safe Touches* workshop to my colleagues."), perceptions of the implementation format (e.g., "The children were engaged during the workshop."); and levels of individual comfort with the topic (e.g., "I will reinforce the CSA prevention and body concepts taught in today's workshop.").

2.2.3. Implementation fidelity

We will measure fidelity using multi-informant (i.e., Facilitator(s) and Observer) methods across stages of implementation (Fig. 3). Facilitators and Observers will be able to complete their respective fidelity assessments on paper or on their phone/tablet in real-time. The facilitator(s) will fill out a short checklist (i.e., implementation form) when they deliver the *Safe Touches* workshop (of either modality) to ensure consistency across the numerous sites. The implementation form asks them to document preparation (e.g., number of students with permission to participate, start time of the workshop), administration (e.g., disruptions in the workshop, concerning statements or disclosures made), and post-implementation (e.g., end time, survey distribution, etc.) tasks.

Stage	Purpose	Who
Preparation	Assess completion of pre-workshop steps (e.g., distribution of handouts, prepared with appropriate materials). Facilitators document the number of children present for the workshop and the start time for the workshop.	Facilitator
Administration	Assesses model fidelity (e.g., if the facilitator adhered to the script, engaged in the correct use of puppets/props, completed the "*Safe Touches* Disclosure Tracking Form" if a child had made a concerning statement or disclosure) and whether any disruptions occurred that may have affected the implementation of the workshop.	Facilitator & Independent Observer
Post	Documents end time for the workshop & if there were any other constraints to implementation (e.g., fire alarm going off).	Facilitator

Fig. 3. Facilitator fidelity plan.

Independent observation of administration will occur in 30% of workshops. The observation focuses on fidelity to the structural components of the workshop (e.g., "Did the facilitator(s) observe any behaviors or other indicators that any child was feeling anxious and/or uncomfortable with the workshop material?"), content of the workshop (i.e., checklist of scenes delivered), and facilitation (e.g., "Were the facilitators able to manage the room?"). The Observer, a member of the research staff, will be trained by the PI and will achieve 85% reliability in practice before in situ observations. A percentage (10%) of these observations will be double-coded (i.e., coded independently) by the PI or a Co-Investigator to ensure reliability throughout the study.

2.2.4. Cost

A cost analysis will be conducted to compare the implementation costs of the two modalities (per participant, classroom, school, or site). Following the ingredients method approach [41] used in the prior cost-analysis [35], we will track costs in five categories: program activities and materials (e.g., booklets, puppets, extra materials), personnel and travel (includes fringe), indirect costs (e.g., site overhead, equipment), facilities (e.g., extra space if needed), and societal costs (e. g., caregiver time to fill out permission forms and answer questions).

2.3. Statistical plan

2.3.1. Sample size and power

To calculate sample size, we leveraged available data comparing post-workshop means of *Safe Touches* as usual (Mean = 1.69; $SD = 0.30$) and modified (Mean = 1.71; $SD = 0.21$) workshops. We operationalized equivalence as a mean outcome score within an equivalence margin ($-\Delta$ to Δ) [48,49] of -0.18 to 0.18. We conducted a two-tailed equivalence test in Minitab and determined that with 68 classrooms in each group ($N = 136$), we will have 80 % power ($\alpha = 0.05$) if the difference between the two groups is 0.05. To allow for attrition and any unforeseen challenges (e.g., school staff turnover), we expect to recruit 90 classrooms in each group ($N = 180$). Assuming a classroom size of 20, we expect to deliver *Safe Touches* to a total of 3,600 students, with 2,340 (approx. 65% [52]) participating in research.

2.3.2. Analytic plan

We will test the equivalence between the two delivery modes of *Safe Touches*, i.e., the null hypothesis (H$_0$) is $|\text{Mean}_{standard} - \text{Mean}_{modified}| \geq \Delta$, where Mean$_{standard}$ and Mean$_{modified}$ denote the mean outcome score of the standard (as usual) *Safe Touches* and that of the modified *Safe Touches*, respectively, and the $\Delta > 0$ is some prespecified equivalence margin. We will report p-values under the null hypothesis H$_0$ with various Δ (including $\Delta = 0.10, 0.15,$ and 0.20) using a two-tailed equivalence test, i.e., using the two one-sided tests (TOST) procedure [53] with the two-sample Welch t-test. The H$_0$ is rejected (i.e., the two delivery modes of *Safe Touches* are deemed equivalent) under the considered Δ if and only if the corresponding p-value reported by our equivalence test falls below the significance level 0.05. We will also report the minimal value of the equivalence margin Δ under which the null hypothesis H$_0$ can be rejected under the significance level 0.05. Moreover, we will construct a two-sided 95% confidence interval (using the method of Welch's t-interval) for Mean$_{standard}$ − Mean$_{modified}$.

To understand if the equivalence pattern is maintained (i.e., the same level of knowledge and skills are retained), we will repeat the above analysis procedure but replace the post-workshop test scores with the 3-month follow-up test scores. When missing records exist (i.e., when there are students who completed the post-workshop test but not the 3-month follow-up test), we will conduct a complete case analysis [54] (i. e., the mean outcome score for each classroom will only be based on the students who completed the 3-month follow-up test). All statistical analyses will be conducted using R. To ensure rigor and reproducibility, we will follow reporting guidelines on the modified CONSORT statement [55].

The school personnel survey and fidelity data will be analyzed descriptively and will be important in concluding true equivalence. Variation in school personnel's adoption of the program as measured by satisfaction, perceptions of convenience, and levels of comfort could impact implementation. These factors will not deter from the analysis of equivalence but may be useful in future dissemination and implementation efforts across diverse settings. The cost per unit (participant/ classroom/school/site) will be calculated for both as usual and modified workshops. Results will be juxtaposed to effect estimates and, ultimately, will inform future scaling of the two delivery modalities in future dissemination and implementation efforts.

3. Conclusion

This research provides the opportunity to not only extend the research base for *Safe Touches*, but to foster the development and implementation of universal, school-based CSA prevention programs that reach a greater number of students. Through conversations with our partner sites, we have noticed an overwhelming emphasis on administrative and budget barriers in terms of conducting *Safe Touches* workshops. If these two modalities prove equivalent, the new delivery modality that only requires one facilitator may address some of these constraints (i.e., more workshops can be scheduled with fewer facilitators). Facilitators will also feel more comfortable staying home when they are sick or taking time off without fear of having to manage the administrative burden that comes with rescheduling workshops. A one-facilitator format may also allow for school counselors themselves to be trained in the implementation of the *Safe Touches* workshop, thereby increasing program sustainability in some contexts. Altogether, innovation in the implementation of universal, school-based prevention programming ensures that all students within the targeted age-range would have access to the content without the need for an outside organization.

All children should have access to effective preventive education to improve their CSA-related knowledge and reduce their potential for victimization. Universal school-based CSA prevention programs are far-reaching but are met with inherent implementation constraints that hinder equitable access to important preventive education. Additionally, improving reach is increasingly imperative as more States pass "Erin's Law." [56] Currently passed in 37 states, including the two Mid-Atlantic states participating in this study, Erin's Law requires all public schools to implement a prevention-focused CSA program that teaches students age-appropriate techniques to recognize CSA and to tell a trusted adult. (Note: the age range that needs to be provided with this education per Erin's Law varies by state). Should this study indicate that the modified delivery of *Safe Touches* is equivalent to the effectiveness of the as usual workshop, it will promote the realization of Erin's Law, particularly for schools and or states that struggle or fail to meet the requirements due to many competing demands on time and resources. As more states pass Erin's Law, the demand for these programs will exponentially increase. This will be the first cluster randomized trial to test the equivalence of two delivery modalities for a universal, school-based CSA prevention program. While other programs with varied empirical support may have adapted their curricula for virtual delivery, to our knowledge, no rigorous, empirical research has been done to demonstrate the equivalence of effectiveness across modalities. An effective universal CSA prevention program with multiple available delivery modalities increases the reach of prevention programming and holds the greatest promise for reducing rates of CSA. Though constraints were amplified in the pandemic, the unwavering gap in accessible CSA prevention education is not new and will persist. The current study aims to produce results that will provide solutions to the various problems contributing to the gap in access.

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CRediT authorship contribution statement

Kate Guastaferro: Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis. **Mia S. Melchior:** Writing – review & editing, Writing – original draft, Project administration. **Siyu Heng:** Writing – review & editing, Writing – original draft, Formal analysis. **Jessica Trudeau:** Writing – review & editing. **Jacqueline L. Holloway:** Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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