TITLE: Evaluating the Impact of Community-Driven Grassroots Vaping Interventions on Changing the Attitudes, Perceptions, and Knowledge of Adolescents in Grade 7 and 8 Classrooms

PROTOCOL IDENTIFYING NUMBER: REB23-1437

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GENERAL INFORMATION

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STUDY SUMMARY

Title	Evaluating the Impact of Community-Driven Grassroots Vaping Interventions on Changing the Attitudes, Perceptions, and Knowledge of Adolescents in Grade 7 and 8 Classrooms
Short Title	Vaping Intervention Study
Protocol Identifying Number	REB23-1437
Phase	N/A
Methods	Randomized Control Trial
Study Duration	45 - 50 minutes
Study Center(s)	Muriel Clayton Middle School
Objectives	The primary objective of this research is to assess if a video produced locally, incorporating extensive stakeholder participation and feedback, is more effective than a conventional, information-focused video created in a different location.
Number of Participants	Approximately 100
Diagnosis and Main Inclusion Criteria	Adolescents in grade 7 or 8 at Muriel Clayton Middle School
Study Product, Dose, Route, Regimen	Airdrie Board of Youth Affairs Vaping Intervention Video
Duration of administration	5 minutes
Reference therapy	***https://www.youtube.com/watch?v=IN7iCZJ3H6w*** ***What Are the Health Risks of Vaping? - National Institute on Drug Abuse (NIDA/NIH)***
Analyses	The statistical analysis in the study will focus on using t-tests, Mann-Whitney U tests, and linear regression models in Stata 18 to assess the effectiveness of an intervention on e-cigarette perceptions, adjusting for potential imbalances and exploring specific survey items for significant changes.

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LIST OF ABBREVIATIONS

ABYA	Airdrie Board of Youth Affairs
NIH	National Institute of Health
CHREB	Conjoint Health Research Ethics Board

1 Background

1.1 Investigational Agent

There is no investigational agent. Instead, we are evaluating the locally produced Airdrie Board of Youth Affairs Vaping Video

1.2 Preclinical Data

This is not applicable.

1.3 Risk/Benefits

There are no potential risks anticipated with the intervention or the assessments. The intervention is non-invasive and the assessments do not ask for sensitive information at all and the only personally identifying information collected is age, gender, and grade. The data will be managed such that the responses are confidential.

The topic of substance abuse may be sensitive to some of the participants. If participants are distressed by the subject matter in the intervention or evaluation their classroom teacher and school counselors will be informed and they can be withdrawn from the study without any negative consequences.

By participating in this trial participants may develop social and emotional competencies, critical thinking and problem-solving abilities, and changed attitudes towards vaping which may help prevent youth vaping abuse. Therefore, this intervention provides an opportunity for participants to better safeguard themselves from vaping abuse and the negative associated consequences. Furthermore, there are also wider potential benefits to study participation. If the intervention works, then it can be widely adopted and thousands could reap the same proven benefits.

1.4 Administration and Dose Rationale

The ABYA video will be administered once to ensure generalizability to real-world implementation of the intervention that will also involve a single viewing.

1.5 Trial Conduct

This study will be conducted in compliance with the protocol approved by the University of Calgary Conjoint Health Research Ethics Board (CHREB), and according to ICH Good Clinical Practice. No deviation from the protocol will be implemented without the prior

review and approval of the CHREB except where it may be necessary to eliminate an immediate hazard to a research participant. In such a case, the deviation will be reported to the CHREB as soon as possible.

1.6 Participant Population

Grade 7 and 8 students from Muriel Clayton Middle School in Airdrie, Alberta, Canada. Students must be able to understand the language of the video and the evaluation questionnaires, any students unable to understand the language due to either language barriers or developmental delays will be identified by the teachers and excluded from the analysis—although they will be provided the option to be present for the room viewings and even fill out the questionnaires to avoid singling them out.

1.7 Literature Review

Vaping refers to the act of inhaling and exhaling aerosol produced by electronic cigarettes (e-cigarettes) or similar devices[3]. These devices heat a liquid containing nicotine, flavorings, and other chemicals, creating an aerosol that is inhaled by the user[3,4]. Clinical manifestations of vaping-related lung injury have been observed, and vaping is associated with a range of serious health hazards including nicotine addiction, lung damage, respiratory issues, and cardiovascular problems[3,4,5]. Furthermore, the presence of harmful chemicals and additives such as acetone, formaldehyde, and heavy metals in e-liquids is of concern, and may also contribute to acute and chronic health issues[3].

Vaping can contribute to a range of socio-economic issues. For example, the cost of vaping devices and e-liquids can place a financial burden on individuals and families. Additionally, the marketing and promotion of vaping products can disproportionately target vulnerable populations, such as youth and low-income communities[7,8,9,10]. Socioeconomic disadvantage has been associated with vaping among never-smoking youth and ex-smoking adults, which suggests a potential to widen health inequalities[9,10].

In Canada, approximately 13% of youth aged 15 – 19 and 12% of those aged 20 – 24 have vaped in the past 30 days, compared with only 3% of Canadians over 25[6]. Vaping has thus presented itself as a significant public health concern, especially among youth and adolescents in Canada[6]. The toxicity of electronic cigarettes in adolescents and young adults is of particular concern as the use of e-cigarettes or "vaping" has seen a significant uptick among these demographics[6]. Children and adolescents are particularly vulnerable to the negative effects of vaping due to several factors. E-cigarette companies employ targeted marketing strategies that make vaping products attractive and appealing to young individuals[11,12,13,14]. The ongoing brain development during adolescence increases susceptibility to nicotine addiction, potentially leading to long-lasting cognitive consequences and a higher risk of substance use disorders[7]. Additionally, peer pressure

and the desire to fit in or try new trends contribute to the likelihood of children and adolescents engaging in vaping[8]. Furthermore, the easy accessibility of e-cigarettes, both online and in retail settings, allows young individuals to obtain them despite age restrictions[4].

Misinformation surrounding vaping is a pervasive issue, contributing to its uptake among youth. Misinformation may downplay the risks associated with vaping and be partly responsible for the recent youth vaping epidemic[15,16,17]. Increasing perceived risk, making these risk perceptions more accurate, and lowering misinformation regarding vaping can reduce youth vaping-associated harm[17,18]. Therefore, effective public health interventions must be developed for youth to increase perceived risk and lower misinformation. The lack of evidence-based vaping cessation interventions is a concern, and leveraging social media for smoking cessation interventions has been proposed as a viable strategy, given its widespread use among young individuals[18]. Interventions observed have primarily been public education and school-based efforts, along with community-based interventions, healthcare provider interventions, aerosol-free policies, age restrictions, and advertising and promotion restrictions[19]. This multifaceted challenge requires a concerted effort from public health authorities, educators, parents, and the community at large to mitigate the adverse effects of vaping, particularly among the vulnerable youth demographic.

2 Trial Objectives

- To evaluate the grade 7 and 8 students' attitudes about vaping using the Knowledge and Attitudes regarding e-cigarette ingredients, safety, and addictive properties survey and Harm Perception and Reduction Items survey at baseline (before intervention) and immediately after the intervention.
- To determine student opinions regarding the intervention using the *Video Survey* (appendix) after the viewing.

Other objectives

- To inform on if future substance abuse interventions should involve more or less youth engagement.

3 Trial Design

3.1 Primary Study Endpoints/Secondary Endpoints

The primary endpoints are individual and aggregate item scores on the *Knowledge and attitudes regarding e-cigarette ingredients, safety, and addictive properties survey* (KAS) and *E-cigarette Harm Perception and Reduction Items* (EHI) post-intervention [20,21]. The secondary endpoints are the aggregate and item scores on the *Video Survey*.

3.2 Study Design/Type

This is a pre/post-randomized control study design. Research assistants will collect data at Muriel Clayton Middle School and conduct the statistical analysis. There will be a comparison group that receives a vaping video intervention developed by the National Health Institute, and an experimental group receiving the intervention. Questionnaires will be used to collect data.

Classroom teachers will be given a script that they will use to introduce the study to the students of both groups using the study introduction script. Students will be informed that their responses will be completely anonymized to minimize the risk of social desirability bias. School teachers will help to identify any students who do not meet the inclusion criteria and they will be excluded from the analysis. Each student participating in the study will be given an envelope containing a unique study ID, Personal Information Questionnaire, Video Survey, information sheet describing the study, and a copy of each of the KAS and EHI. KAS and EHI in the envelopes will be labeled "1", signifying pre-intervention. Following the intervention participants will receive another copy of the KAS and EHI labeled "2", signifying post-intervention, which they will place in the envelope after completion. None of the forms will have any identifying information (outside of age, grade, and gender) and the school teachers will not review the data collected. Individuals present in the rooms will include one or more school staff, research assistants going in between rooms if there are more than two rooms, and the student participants. The students will complete the Personal Information Questionnaire, KAS and EHI, prior to watching the intervention video. Following the intervention they will be provided with another copy of the KAS and EHI along with the Video Survey. Once students have completed the questionnaires they will be asked to place everything back in the envelope and hand the envelope to the research assistant.

After completion of the assigned video and associated evaluations, students will be shown the other video. This will be done to ensure that no student is excluded from any of the benefits of either of the treatments.

3.3 Randomization

Each classroom of grades 7 and 8 at Muriel Clayton Middle School will be divided into group A and B evenly. Research assistants will alternatively place students in groups A

and B based on software (e.g Excel) to produce a randomized sequence of A's and B's. After all students have been assigned they will proceed to their groups' assigned room and receive an envelope. The envelopes will contain the students study ID and will start with the letter A or B corresponding to their assigned group. All students in group A will complete the questionnaires, watch the intervention video, and then complete the same questionnaires immediately after the intervention. All students in group B will complete the questionnaires, experience the control condition (NIH video) and then complete the same questionnaires. The teacher will introduce the study prior to group assignment.

Students not meeting the inclusion criteria will be assigned group C. A set of envelopes with a "C" code will be prepared beforehand and distributed to group C students. These Group C students will follow the same procedure as group A but will be excluded from analysis.

3.4 Decoding Procedures

Participants with study ID's starting with A will be in the intervention group and those with study ID's starting with B will be in the comparison group. Participants with C at the start of the study ID will be excluded from analysis.

3.5 Duration

The trial, including pre and post-assessments and intervention delivery, will last approximately 45 to 50 minutes (one school period) of a single school day.

3.6 Discontinuation

If there is an unexpected emergency related or not related to the intervention at the trial location the trial will be discontinued

3.7 Product Accountability

This is not applicable.

3.8 Data Identification

This is not applicable.

4 Selection and Withdrawal of Participants

4.1 Inclusion Criteria

- Attend Muriel Clayton Middle School
- Be in grade 7 or 8
- Be enrolled in the standard Alberta grade 7 or 8 curriculum
- Provides implied consent
- Parent or guardian provides written consent
- Able to understand the language of the video

4.2 Exclusion Criteria

- Younger than 11 years old
- Older than 16 years old
- Does not provide implied consent
- The parent or guardian does not provide written consent
- Unable to understand the language of the video or questionnaire due to language barriers of developmental delay

4.3 Participant Withdrawal

If participants show distress or do not want to continue during the study they will be withdrawn from the study and school counselors and or teachers will be informed. Consequently, they will be taken to another room by the teachers. Once the envelopes have been handed in, participants cannot withdraw from the study.

4.4 Medication

N/A

4.5 Monitoring for Participant Compliance

Research assistants present in the rooms during the intervention will support participants in complying with the study procedures.

5 Assessment of Efficacy

5.1 Efficacy Parameters

Attitudes and perception regarding vaping and participant perception of intervention.

5.2 Method and Timing

The two adapted versions of the validated surveys assess attitudes and perceptions in relation to e-cigarette or "vaping" use. The students will be informed by their teachers prior to survey distribution that e-cigarette terminology and vaping are interchangeable. For both of the surveys, participants rate how much they agree with each statement (on a numbered scale between "*strongly disagree*" and "*strongly agree*") related to vaping/e-cigarette use (*e.g. "e-cigarettes are safer than smoking"*). To determine if there was any difference in attitudes, knowledge, or harm perceptions related to vaping before and after the intervention.

Demographic information collected in the personal information questionnaire will include age, gender, and grade. This information will be used to describe the sample recruited and assessed for variations between different groups. No other identifying personal information will be collected (name, contact information, etc.) and all results will be anonymous.

The *Video Survey* is a questionnaire adapted from a previous study (Hollis et al., 2022) asking students regarding their opinion of the intervention's effect on their vaping knowledge, usefulness to others, and overall knowledge about vaping following the intervention [2]. This information will be collected to determine how the intervention was perceived by the participants. Students will also be asked if they have vaped to inform on the effect of prior vape use on the perception of the intervention and efficacy and changing attitudes. Short answer questions asking participants what they liked and what they disliked in the intervention will also be included to inform future directions.

6 Assessment of Safety

6.1 Safety Parameters

Mental distress during and or following the intervention and evaluation, although this is unlikely.

6.2 Method and Timing

Research assistants and school staff will monitor participants during the study period and assess any potential mental distress.

6.3 Adverse Event Reporting

Adverse events will be reported in accordance with CHREB and Health Canada policies as well as any applicable Rocky View County School Board procedures.

6.4 Adverse Event Definitions

If participants are seen to be engaging in abnormal behavior compared to their regular behavior expected in schools or if participants themselves indicate that they are facing mental distress and or any other form of an adverse event.

6.5 Adverse Event Follow-up

Participant's condition following an adverse event will be followed up with school staff and if there is reason to believe the adverse event was caused by the intervention information will be gathered either by talking with the afflicted participant (if appropriate given the circumstances) and or the school staff and parents.

7 Statistical Plan

7.1 Statistical Methods

Data from questionnaires will be entered into an Excel spreadsheet by research assistants. A double entry will be performed to reduce the frequency of data entry errors. New variables will be created by taking the difference in the individual items and overall scores for KAS and EHI pre and post-intervention for each participant [20,21]. In order to ensure that higher scores reflect an increased likelihood of vape abuse, question 10 on the KAS will be reversed scored as a study showed that on this question vape non-users were more likely to score higher than users [20]. Descriptive statistics and graphics for participant demographic characteristics and questionnaire responses will be performed prior to primary analysis to detect errors in data, such as missing data and variables being outside of the plausible range. If errors are found they will be addressed. After this, the database will be locked.

Initially, to confirm the validity of creating a total score, we will confirm internal consistency using Crohnbach's alpha. We assume that internal consistency will be adequate and therefore describe an analysis of total scores on the scale in the remainder of this section.

The analysis will begin by describing sample characteristics. Following this, a primary analysis will be undertaken to evaluate the success of the intervention. Imbalances in randomization will be looked at using graphical methods and tables and will be adjusted using linear regressions if the distributional assumptions and the assumption of linearity

are met as assessed with a scatter plot. If the distributional assumptions are not met then quantile regression will be used. T-tests will be performed to assess if the intervention group had a significant change between pre and post-intervention compared to the comparison group on the KAS and EHI. If data is not normally distributed non-parametric tests will be used. The robustness of the primary analysis will be assessed by adjusting for other variables through linear regression models.

An exploratory analysis will be done and will involve using T-tests to determine if the individual item scores for the first 5 questions on the Video Survey are significantly different between the experimental and comparator groups. Mann-Whitney U test will also be used to determine if the two groups responded differently for questions 5 and 6 on the Video Survey.

An exploratory analysis will be undertaken to specifically explore if the intervention group had a significant change between pre and post intervention compared to the comparison group on the KAS questions 1, 3, and 7 and for the EHI questions 1, 2, 6, 7, 11, and 13. Further analysis looking at all individual items on the KAS, EHI, and video survey will be done to explore if the intervention group had a significant change between pre and post intervention and if the personal information collected impacts scores.

All analyses will be performed on *Stata 18*.

7.2 Sample Population(s) for Analysis

Our sample size is limited to the number of grade 7 and 8 students at Muriel Clayton school, approximately 100 students with 50 in the control group and 50 in the experimental group. Based on existing literature on standard deviation (SD) of the surveys we determined the effect size our study can detect with 80% power [20, 21]. We determined that our study can detect a difference of 1.52 points on the KAS scale and a 3.58 points on the EHI with 80% power. A study showed that for the KAS cigarette/e-cigarette users and non-users had a mean score of 21.04 and 18.86 respectively when reverse scoring question 10 [20]. Considering the difference between the two groups in this study is similar, we have the statistical power to detect it.

7.3 Significance

The alpha value to be used in the study is 0.05.

7.4 Termination Criteria

Not applicable.

7.5 Accountability Procedure

Equator reporting guidelines will be used to ensure transparency.

7.6 Deviation Reporting

This report will be archived on PRISM at University of Calgary.

8 Direct Access to Source Data/Documentation

There are no permits, contracts, or regulatory audits.

9 Quality Control and Quality Assurance

Quality control and quality assurance will be done in adherence to GCP

10 Research Ethics Considerations

This study will be conducted according to the Tri-Council Policy Statement 2022 and international standards of Good Clinical Practice for all studies. University of Calgary research policies and procedures will also be followed.

This protocol and any amendments will be submitted to the University of Calgary CHREB for review and approval prior to conduct. The decision of the CHREB concerning the conduct of the study will be provided electronically to the investigator. An application will also be submitted to the Rocky View Division Research Committee in order to obtain permission to conduct research at Murial Clayton Middle School.

All parents/guardians of the participants for this study will be provided a consent form describing this study and providing sufficient information for parents of participants to make informed decisions about their children's participation in this study. The consent form must be signed by the participant's parent/guardian or legally acceptable surrogate/third-party. This consent form will be submitted with the protocol for review and approval by the CHREB. The implied consent of a participant will be obtained before that participant is submitted to any study procedure.

11 Data Handling and Record Keeping

The Excel file and analysis files will be stored in an encrypted drive in a password-protected computer that will be stored in a secure location. The dataset stores will have no names in them.

12 Finance and Insurance

No personnel costs, and minor costs (e.g. printing) will be covered by the Cuthbertson & Fischer Chair in Pediatric Mental Health.

13 University of Calgary Legal Approval

Legal approvals are not required for this study

14 Supplements

Supporting Documents (Questionnaires and Surveys) are attached

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