Study Protocol

NCT Number: N/A

Dec 14, 2020

Study Protocol

Proposed Research Topic

Using a Protection Motivation Theory framework to reduce vaping in a student population.

Background and Significance

According to Statistics Canada, more than one-third of Canadian students have tried vaping products at some point in their lives with the highest rates of trying vaping being among young adults (18-24 years). These data points reinforce the trend that vaping is becoming increasingly popular among Canadians, specifically among Canadian students. Although the levels of toxicants are lower in aerosol from vaping products compared to tobacco smoke, long-term exposure to e-cigarette vaping may lead to nicotine dependence and an increase in respiratory and cardiovascular health effects. In addition, though vaping has shown to assist with smoking cessation in adult smokers, the robust association between smoking and vaping could undermine reductions in smoking among young adults and increase their risk of subsequent smoking, and vice versa. The health outcomes of longstanding vaping behaviour are evident; however, the most effective means of limiting vaping behaviour, remains unclear. As the vaping market continues to evolve rapidly in North America, owed to the JUUL e-cigarettes and similar vaping products, research identifying effective health behaviour change strategies are becoming increasingly paramount.

Specific Aims

The aim of the proposed study is to investigate if/how the use of an 8-minute informational video, following the threat appraisal applications of the Protection Motivation Theory (PMT) framework, may help reduce and manage vaping intention and behaviour in Canadian university students.

Hypothesis

H1. Those exposed to threat appraisal information grounded in the PMT components of severity and vulnerability will show lower intention to vape and subsequent habitual vaping, compared to their attention information (general nutrition and lifestyle group) control counterpart.

H2. Both severity and vulnerability of vaping usage will be associated with reduction in intentions to vape and overall vaping use among the PMT intervention group.

Methods

Submission for ethical approval will be presented to Western University's Health Sciences Research Ethics Board. All participants included in this study will read the Letter of Information and submit an Informed Consent form prior to participation in the study.

Participants

Participants will (N=150) be full-time Canadian university students. Inclusion criteria include (1) aged 18 and over, 2) ability to read and understand English, 3) have internet access, 4) self-report as current users of vaping products (vaping >3 in the past 30 days) 5) stated willingness to comply with all study procedures and availability for the duration of the study 6) enrolled full-time within a registered Canadian university during the 2020-2021 schoolyear 7) willingness to stop or at least decrease their frequency of vaping. Exclusion criteria includes (1) activity restrictions that limit one's ability to engage in questionnaire testing and 2) currently practicing in behavior therapy treatment specific to vaping or attending a rehab center. Among participants recruited for the current study, we are interested in examining the potential behaviour changes in Canadian university students, both male and female, that identify as regular or casual vapers. The classifying of a Smoker scale (Berg et al., 2011) is used to assess criteria for

classifying regular and casual vapers, consisting of ten items rated on a 7-point Likert scales with anchors of 1 “strongly disagree” to 7 “strongly agree”. Total scores are summed by items (i.e., I vape every week), with the aggregate values indicating the type of vaper they identify as. Participants will be recruited through public university student Facebook groups from across Canada. To facilitate the process, the SI will post a recruitment poster to the public page wall, instructing students to email the SI directly for further information, if interested. In addition, the SI will send out recruitment emails through the Mass Email Recruitment system at Western.

Procedure

Participants will be randomized into one of two treatment conditions: PMT present or PMT absent (attention control). Two separate online videos will be developed and delivered: One video incorporates the two major components of PMT threat appraisal; perceived vulnerability (PV) and perceived severity (PS), featuring specific vaping health consequence information, while the other features general nutrition and lifestyle information. At baseline, both groups will complete purpose-questionnaires which assess their beliefs towards vaping, their intentions to vape less, and their mood. At Time 1 (T1), following watching the intervention videos, self-reported measures of behaviour intention and vaping behaviour will be assessed and then repeated at 1 month (T2) and again two weeks after (T3).

Timetable

September 2020-August 2021

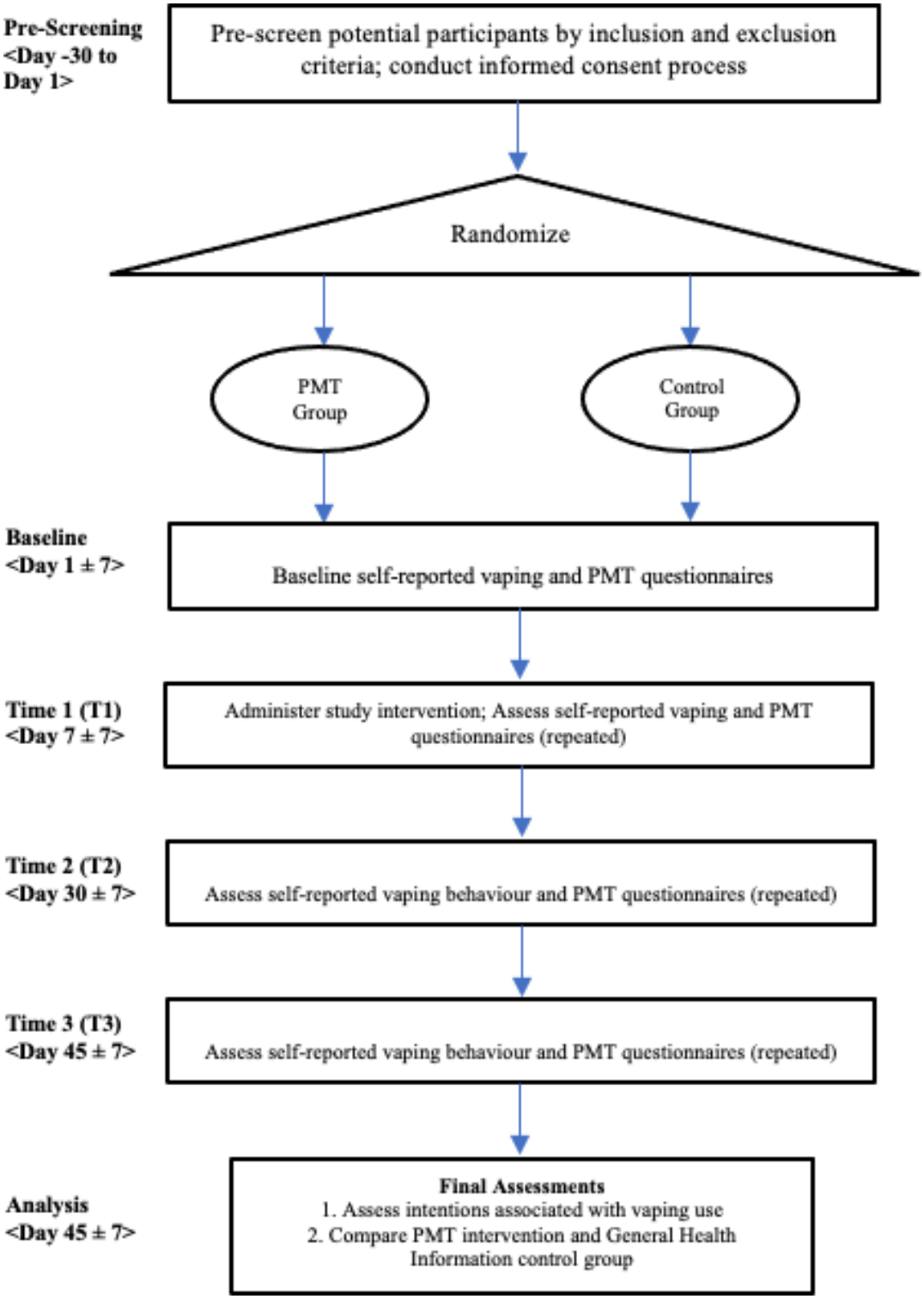
Potential Limitations

To date, the social restrictions as a result of the COVID-19 pandemic will inhibit our ability to contact participants in-person, instead we will contact and conduct the study through email communications. In adherence with these social restrictions, participants will self-report their behaviour-intention and action-behaviour for limited vaping through the questionnaires following intervention. As a result, we cannot corroborate their self-reporting vaping use. As vaping is a relatively new behaviour, there is no literature to support the notion that those who stop or reduce the amount that they vape will actually receive health benefits or minimize health costs.

Significance/Impact of the Proposed Study?

Since the spike in vaping-related illness in 2019, the Lung Association of Canada has been calling for stricter regulation of vaping products and aid in educating the public on the implications of vaping and strategies to help mitigate its use. Despite the attributable risk from vaping for oral, pharyngeal, and esophageal cancers, statistics Canada bears out that young adults were the most likely to think that vaping is less harmful than smoking at 27.9%, compared to 11.6% of users 25 and older; 10% having tried vaping without knowing whether or not it contained nicotine (Weikle, 2020). The function of this study is to identify if using a threat appraisal intervention with a PMT model can elicit significant change to ultimately reduce and manage vaping behaviour in Canadian university students. Through increasing the awareness of the risks associated with vaping within our PMT-present intervention group and illustrating the effectiveness of threat appraisal and PMT, we aim to illustrate the effectiveness of threat appraisal and PMT methods to influence health psychologists and public-health campaigns to instill these powerful health behaviour strategies in future efforts to reduce the percentage of Canadian students and young adults who vape.

Flow diagram of study procedures



Analysis Plan

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Statistical Analysis Plan

Data collected by the participants will be presented among 5 categories: Vulnerability, Severity, Intention, and Behaviour. All continuous data will be presented in means with standard deviation, median, and range. For primary and secondary endpoints, nominal scales will be used to assess single endpoint/summary measures. The statistical procedure will use a repeated measures ANOVA to measure outcomes at different times during the study timeline (e.g., Time1, Time2...). This repeated measure model will be used to average the repeated measures data for each study arm to perform the relative correlation. Similar to a Pearson correlation coefficient (r), the repeated measure correlation (rmcorr) model represents the strength of the linear association between the PMT intervention and the control arm. Also akin to the Pearson correlation, the null hypothesis for rmcorr is $\rho rm = 0$, and the research hypothesis is $\rho rm \neq 0$. Unlike the Pearson correlation, which assesses the inter-individual association, rmcorr evaluates the overall or common intra-individual association between two measures. Following the strength of the repeated measures ANOVA analysis in multilevel modeling, we contend that this model of statistical analysis is appropriate for the utility of our iterative research study.

Letter of Informed Consent

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Dec 14, 2020

Western HealthSciences

Letter of Information and Consent

Study Title: Information Interventions to Reduce Vaping in a Student Population

Principal Investigator:
Dr. Harry Prapavessis, PhD
Department of Kinesiology
Western University
hprapave@uwo.ca

Co-Investigator:
Babac Salmani, MA
Department of Kinesiology
Western University
bsalmani@uwo.ca

INVITATION

You are invited to participate in a study because you have self-described yourself as someone who vapes. The purpose of this study is to determine which types of sources of information are more effective in helping university students reduce their vaping habits. You are being invited to participate in this research study because, as a student, you are part of a population in Canada where the use of vaping products is relatively higher compared to the rest of the Canadian population.

BACKGROUND INFORMATION

According to Statistics Canada, more than one-third of Canadian students have tried vaping products at some point in their lives with the highest rates of trying vaping being among young adults (18-24 years). These data points reinforce the trend that vaping is becoming dangerously popular among Canadians, specifically among Canadian students. The purpose of this study is to find out what effects an individual's behaviour-intention and action-behaviour and how we can potentially reduce and manage the uptake of vaping behaviour in Canadian students.

WHAT'S INVOLVED

Up to 150 students will participate in this study and it is expected that you will be in the study for six weeks. You will not have to pay for any of the procedures/interventions with this study. If you decide to participate then you will be "randomized into one of the groups described below." Randomization means that you are put into a group by chance (like flipping a coin). Of the two groups providing information, each will consist of different content. Participants in either group are required to complete all four sets of surveys. There is no way to predict which group you will be assigned to. You will have 1 in 2 chance of being placed in either/any group. Neither you, nor the study staff can choose what group you will be in; group one will contain information regarding the risks associated with vaping to your overall health. Group two will focus on tips associated with diet choices and lifestyle. At the start of the six-week timeframe you will have to (all will be sent by the student investigator (SI) to the email you provide):

- Complete a purpose-questionnaire and self-report questionnaires regarding vaping
- Watch an 8-minute online video
- Complete three self-report questionnaires over the remaining five-weeks of the study period

The purpose of the questionnaires is to understand how your intention and desire to vape changes over time. The questionnaires will assess your past and current vaping behaviour, your perceptions of vaping, your intentions to try and reduce vaping behaviour, as well as assess some potential changes in mood. The questionnaires will be filled out at four time points: upon entry into the study (Day 1), one week later (Day 7), two weeks later (Day 30), and at the end of the study (Day 45). All questionnaires will be sent to the email you provide to the SI, following the schedule above. Each set of questionnaires will take about 15 minutes to complete.

The following exclusion criteria will effectively terminate your inclusion in this study and prevent your data from contribution to study analysis:

1. Activity restrictions that limit one's ability to engage in questionnaire testing
2. Currently practicing in behaviour therapy treatment specific to vaping or attending a rehab centre
3. At the time of signing/submitting this consent form you are under the legal age of 18
4. Failure to complete and submit completed questionnaires within the 7-day study timeframe, starting the day that set of surveys is emailed to you by the student investigator

Participants will be notified immediately by the SI, via emails provided by individual participants, of their exclusion from the study and the immediate termination of their study data.

POTENTIAL BENEFITS AND RISKS

An understanding of what information has the greatest influence on behaviour in students will help to design more effective interventions to help reduce negative health behaviour in the future. In addition, you may learn more about the risks associated with vaping or potential nutrition and lifestyle tips, depending on which group you are in, that may have a positive influence on your health behaviour choices and overall health. A risk associated with participation in this study is the potential for preliminary stress and anxiety as a result of reflecting on behaviour through surveys. Apart from the application of intervention, as personal identifiers are being collected for this study, there is the risk of breach of privacy which may be a cause of added risk in participation. To combat this risk, we have implemented the safe storage of all identifiable data on a password-protected, encrypted Personal Vault via OneDrive to ensure participant privacy. As a participant, you may also experience no benefit from participation in this study. If you notice a greater sense of mental distress or anxiety as a result of participation in the study procedures, please contact Dr. Lisa Lee, a clinical psychologist as part of the study team, by email at *info@drlisalee.com*, or by phone at (519) 878-4912. In addition, the Counselling Services of London, specialized in anxiety therapy and self-esteem counselling, have offered their services as part of our study team at *counselling@natashaminor.com* or by phone at (226) 270-1242, to any participants who feel distress. Both study team resources offer online services for study participants. Lastly, please consider contacting the Centre for Addiction and Mental Health in Canada, at (519) 858-5144 if you feel the need for additional aid.

SUMMARY OF TESTS AND PROCEDURES

The schedule below is a representation of procedures that will be accomplished at each study stage.

	Pre-screening (Day -30 to Day 1)	Baseline Day 1 (pre-intervention)	Time 1 (T1) Day 7 ± 7 (post-intervention)	Time 2 (T2) Day 30 ± 7	Time 3 (T3) Day 45 ± 7
Informed Consent	X				
Participant Stratification	X				
Demographics		X			
Vaping History		X			
Outcome Evaluation					
Vaping Purpose Assessment (Brief Activities Inventory)		X	X		
Randomization		X	X		
PMT Questionnaire		X	X	X	X
Action Planning Questionnaire		X	X	X	X
Coping Planning Questionnaire		X	X	X	X
Motivational Self-Efficacy		X	X	X	X
Pre-Actional Self-Efficacy		X	X	X	X
Coping Self-Efficacy		X	X	X	X
Recovery Self-Efficacy		X	X	X	X
Profile of Mood States		X	X	X	X
State Trait Anxiety Inventory		X	X	X	X

CONFIDENTIALITY

All information you provide is considered confidential; all identifiable information collected during this study will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study. Data collected during this study will be stored on an encrypted, password-protected, locked external drive in a secure and confidential location for 7 years, as per Western's data retention policy. Once the data retention period is over, the data will be analysed by the student investigator for significance and will be stored on a password-protected, encrypted Personal Vault via OneDrive. Access to this data will be restricted to the principal investigator and student investigator. Western University Health Sciences Research Ethics Board may require access to the study records to monitor the conduct of the research. The type of personal information that will be collected is age, gender, and ethnicity. Contact information of the participants will also be collected for this study. A description of this study will be available by contacting the student investigator at *bsalmani@uwo.ca*. You can contact the student investigator via email, at any time, regarding any questions and/or concerns related to this study.

VOLUNTARY PARTICIPATION

Participation in this study is voluntary. If you wish, you may decline to answer any questions or participate in any component of the study without effect on academic standing. Further, without effect on academic standing, you may also decide to withdraw from this study at any time. If you do wish to no longer be included in the study or you are removed as a participant and wish to withdraw your past questionaries from the study, you should tell the Principal Investigator, Dr. Harry Prapavessis, who will ensure no future data will be collected, the data related to your participation in the study will be removed, and you will no longer receive questionnaires from the study staff. You as a participant may be taken off the study if you are unable to tolerate the study intervention, if you are unable to complete all required study procedures, or if the research ethics board withdraws permission for this study to continue. If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form. If you are removed from this study, the study staff will discuss the reasons with you.

It is important to recognize that email is not secure. Email data can be stolen as it travels over the network and could be stored on mail servers, internet mail relays, as well as end devices. If, at any point, you feel unsafe or choose to no longer communicate on this platform, please email the student investigator and they will withdraw you from further study procedures and protocols. You will receive a copy of this letter of information and signed Informed Consent.

PUBLICATION OF RESULTS

Results of this study may be published in professional journals and presented at conferences. Feedback about this study will be available approximately 6 months after the completion of the study. If you wish to receive the results of the study, please provide either your email or mailing address: _____

CONTACT INFORMATION

If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Human Research Ethics (519) 661-3036, 1-844-720-9816, email: *ethics@uwo.ca*. The REB is a group of people who oversee the ethical conduct of research studies. The HSREB is not part of the study team. Everything that you discuss will be kept confidential. Thank you for your assistance in this project. Please keep a copy of this form for your records.

CONSENT FORM

Study Title: Information Interventions to Reduce Vaping in a Student Population

This study has been explained to me and any questions I had have been answered.
I know that I may leave the study at any time. I agree to take part in this study.

_____	_____	_____
Print Name of Participant	Signature	Date *(DD-MM-YYYY)*
_____	_____	_____
Name of Person Obtaining Consent	Signature	Date *(DD-MM-YYYY)*