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VAPGAMO trial protocol: a cluster-randomised controlled evaluation of a digital game-based learning intervention to reduce adolescent vaping intention in Malaysian public secondary schools

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ABSTRACT

Introduction Youth vaping remains a global public health challenge. We will evaluate a pragmatic, theory-driven digital game-based learning intervention (VAPGAMO), delivered in public secondary schools to reduce adolescents' intention to vape at 3-month follow-up.

Methods and analysis Parallel cluster-randomised controlled trial with schools as clusters. Eight public secondary schools in an urban Southeast Asian district (Klang, Malaysia) will be randomised 1:1 to intervention or attention-matched online flash game. The intervention is a single 90 min, facilitator-led module grounded in the Theory of Planned Behaviour. Surveys at baseline, immediately postintervention and 3 months. The primary outcome is intention to vape at 3 months. Secondary outcomes are knowledge, attitudes, injunctive norms and refusal self-efficacy (perceived behavioural control). Prespecified implementation outcomes include acceptability, fidelity, reach, time-on-task and cost per student. Primary analysis will use generalised estimating equations with cluster-robust SEs, adjusted for baseline covariates; the intra-cluster correlation coefficient and design effect will be reported; intention-to-treat will be applied.

Ethics and dissemination Universiti Putra Malaysia JKEUPM-2024-887; approvals from the Ministry of Education, Malaysia. Findings will be disseminated in peer-reviewed outlets and shared with education and health authorities to inform school-health programming. De-identified data and code will be made available on publication, subject to approvals.

Trial registration number Thai Clinical Trial Registry (TCTR20241222001).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Pragmatic cluster-randomised design embedded in routine public schools, enhancing external validity for similar systems.
⇒ Theory-driven digital module with prespecified implementation outcomes to inform scale-up decisions.
⇒ The analysis plan uses appropriate cluster methods with intra-cluster correlation coefficient reporting.
⇒ Single 90-minute dose and 3-month follow-up may limit durability of effects.
⇒ Conducted in one district; generalisability to other settings will be empirically assessed via implementation metrics.

BACKGROUND

Adolescent vaping has emerged as a global public health threat, complicating efforts to curb nicotine addiction and tobacco-related harm among youth.[1] Electronic cigarettes (ECs) or electronic nicotine delivery systems (ENDS), including cig-a-likes, pod-mods and customisable vapourisers, are increasingly popular due to their sleek design, flavour appeal, ease of access and discreet usage among youth worldwide.[2] These devices deliver nicotine through aerosolised e-liquids, mimicking traditional smoking behaviours while exposing users to ultrafine particles, carcinogens and other harmful chemicals.[3–6] Early exposure heightens the risk of lifelong nicotine addiction and has been linked to neurodevelopmental disruption, particularly during adolescence.[7–9]

The prevalence of adolescent vaping is accelerating globally. A global meta-analysis estimates that one in six adolescents has tried vaping, with 4.8% being current users.[10] A ninefold increase in daily vape use among 14–15-year-olds in New Zealand was reported between 2015 and 2023, with 10% of adolescents in this age group currently vaping.[11] In the UK, experimentation with vaping,

defined as having tried vaping at least once, increased by 50% from 7.7% in 2022 to 11.6% in 2023.[12] These trends underscore the urgency of addressing vaping intention among adolescents, a key predictor of initiation. Intention, or one's cognitive motivation to engage in a behaviour, is a core construct in behaviour change theory and is strongly associated with future vaping uptake.[13–15] For instance, a cohort study found that adolescents who intended to vape were 2.5 times more likely to initiate vaping within 6 months.[16]

Despite international concern, many existing school-based prevention initiatives remain focused on conventional tobacco products.[17 18] In Malaysia, adolescent vaping prevalence has surged from 1.1% in 2011 to 14.9% in 2022, with over 40% of users initiating use before the age of 14, particularly in high-burden states such as Selangor.[19 20] Current school-based programme, such as the 'Kesihatan Oral Tanpa Asap Rokok Programme', and IMFree largely emphasise traditional smoking and may not resonate with today's digital-native adolescents.[17 18 21] There is a growing consensus on the need for innovative, culturally relevant and theory-driven interventions. Game-based learning (GBL), which integrates interactive digital experiences with behavioural science, holds promise in shaping health behaviours among adolescents. Over 90% of youth globally play video games, spending an average of 6.3 hours per week.[22 23] In Malaysia, over half of the nation's 20.1 million gamers are school students and young adults, reflecting a unique opportunity to embed public health interventions in digital platforms. GBL has demonstrated effectiveness in influencing behaviours related to sexual health, obesity and mental health.[24–26] A recent systematic review also supports GBL's utility in improving vaping-related knowledge, attitudes and harm perceptions.[27]

Digital interventions such as gamified learning align well with the preferences of Gen Z and Gen Alpha learners, who favour fast-paced, interactive and segmented content.[28] Gen Z refers to individuals born approximately between 1995 and 2012, while Gen Alpha refers to those born from 2010 onward.[29] These approaches not only correct misconceptions and strengthen refusal skills, but also build intention to resist vaping.[30] By providing a multisensory, active and experiential learning environment, gamification fosters the development of decision-making and problem-solving skills throughout the gameplay.[31]

Moreover, embedding such interventions within school environments provides an ideal platform for scalable primary prevention.[32] The primary and secondary outcomes in this study are patient-reported outcomes (PRO), as they reflect adolescents' self-reported intentions, beliefs and perceptions related to vaping. These outcomes are appropriate because intention and its cognitive determinants are internal psychological constructs that cannot be directly observed and are central to the Theory of Planned Behaviour (TPB) framework guiding the intervention. Grounded in the TPB and aligned with the WHO Framework Convention on Tobacco Control (FCTC), this study aims to develop and evaluate a culturally tailored, theory-based GBL intervention to reduce vaping intention among adolescents in Malaysia. This intervention targets the key cognitive antecedents of intention, which are subjective norms, attitudes and perceived behavioural control to strengthen adolescents' capacity to resist vaping initiation.

METHODS AND ANALYSIS

Overall study design

This is a parallel cluster-randomised controlled trial, with schools being the unit of randomisation (clusters). The trial will be used to assess the effectiveness of a GBL intervention programme on vaping intention, knowledge, attitude, subjective norm and perceived behaviour control of national secondary school students in Klang district, Malaysia. The Klang district was selected as the trial location as it is one of the largest districts in Selangor, a state with one of the highest reported prevalence of vape use. There are 22 eligible schools in the Klang district. Eight of the schools were selected as clusters (schools), and randomly assigned to the intervention and control groups. The intervention group will receive a GBL intervention on vaping. Those in the control group will receive an attention-matched online flash game of comparable duration and digital format to the intervention. The control activity does not contain any tobacco- or vaping-related information and is designed to control for time, attention and exposure to a digital gaming environment. Both intervention and control groups will complete the same self-administered questionnaires at baseline, immediately postintervention and at 3-month follow-up. On completion of the final follow-up assessment, control schools will be offered access to the GBL intervention materials.

Eligibility criteria

The inclusion criteria for schools will take into account the following requirements: (a) being a national secondary school; (b) they are located in the Klang district; (c) and they want to participate in the study. The exclusion criteria will disqualify national schools that are religious-based schools, non-coeducational schools, boarding schools and upper form (form four and above) or form six only schools and schools without a computer lab facility from the study. The inclusion criteria for students take into consideration the following requirements: (a) participants must be Malaysian citizens; (b) participants are aged between 13 and 15 years old; (c) they are literate in Malay or English language to take part in the study. The only exclusion criteria for students are those who are attending special education classes. Those who reported current or ever used vaping at baseline will not be excluded from participation. Baseline vaping status will be measured and retained in the analysis to reflect the real-world school population and to avoid selection bias.

Table 1 Outline of game-based learning intervention on vaping intention

Module	Topics	TPB constructs	Strategy of delivery
Vape unmasked: uncovering the hidden risks	► Basic components of vape devicesContent of e-liquid and vapour ► Type of vape devices	► Knowledge	► Truth orbs mission ► Cutscene video ► Word-cloud shooting mission ► Spot the vape
Breaking the chain: escaping nicotine's grip	► Myths versus facts of vaping ► Nicotine and vape effect on health	► Attitude	► Exploratory Myth orb and discovery mission ► Defeat Mythical vapester ► Cutscene video
Changing tides: rethinking vaping trends	► Deceptive marketing strategies of vaping ► Law and regulations on vape ► Shaping normative belief	► Subjective norm	► Pro-vaping material kit mission ► Cutscene video ► Interactive branching dialogue
Saying no: building resilience and empowering choices	► Building self-confidence and imparting self-efficacy skills to resist vaping	► Perceived behaviour control	► Refusal skill training missions through case-based scenarios
Future quest: choosing a vape-free path	► Towards a vape-free lifestyle	► Behaviour intention	► Goal setting mission ► Cutscene video ► Defeat Gigantamax vapester

TPB, Theory of Planned Behaviour.

Intervention

The intervention group will be introduced to a GBL intervention programme on vaping intention. This intervention is grounded in the TPB and developed by using the GBL approach, whereby educational elements are embedded into the interactive gameplay and players would subconsciously learn while playing. TPB-based smoking and vaping prevention interventions have been associated with improvements in intention-related outcomes through modification of attitudes, subjective norms and perceived behavioural control.[33–35] The GBL intervention programme uses four constructs of the TPB: attitude, subjective norm, perceived behaviour control and behaviour intention. This intervention was prepared and designed to bridge the gap in vaping knowledge and to improve vaping avoidance among these students. Table 1 gives an outline of the GBL intervention on vaping intention, along with the application of TPB concepts in the GBL intervention.

The intervention sessions will be conducted in designated school computer laboratories under supervised conditions. Students will be seated at individual computers with adequate spacing to minimise interaction and contamination between participants. Headphones will be provided to ensure audio privacy during the game-based intervention. A trained researcher and teacher will be present throughout each session to provide technical assistance and to monitor session completion. Completion of the intervention components will be tracked through the in-game progress indicator and session attendance records to ensure intervention fidelity. Students will be instructed to complete the entire session independently without discussion with peers during the intervention period.

The GBL intervention consists of five modules and is pending copyright protection by the Intellectual Property Corporation of Malaysia (MyIPO). Module 1 (*Vape unmasked: uncovering the hidden risks*) provides a general overview of vape devices and their harmful contents in order for participants to have a clear understanding of the topic. Module 2 (*Breaking the chain: escaping nicotine's grip*) gives information on the health implications of vaping, potential nicotine addiction and correct misconceptions about vaping. Module 3 (*Changing tides: rethinking vaping trends*) further explores strategies to denormalise vaping behaviour, reduce social acceptability and raise awareness to discourage vaping experimentation. Module 4 (*Saying no: building resilience and empowering choices*) will strengthen participants' belief in resisting vaping and enhance their self-efficacy to refuse usage. Module 5 (*Future quest: choosing a vape-free path*) offers guidance to set personal goals for maintaining a vape-free lifestyle.

Following the development of the GBL intervention, face and content validity were checked and assessed by five professional expert panellists from the Community Health Department at the Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, Selangor State Health Department and Klang District Health Office. The experts endorsed the educational material as effective in meeting the study's objectives. They emphasised the importance of clarity and simplicity, recommending the use of fewer words and replacing them with more illustrations to

enhance engagement and using characters that resemble the participants to help them relate better and improve understanding. They also suggested that the video game be made available in the Malay language and incorporate common teenage slang, as most young, vulnerable vapers are Malays. Additionally, they recommended incorporating scenes that depict peer influence in avoiding vape use, highlighting family roles and promoting skills that encourage good and healthy behaviours.

The GBL intervention involves a 90-minute session for 1 day. The study researcher will conduct the session for the intervention group at each respective school. It is expected that four sessions will be carried out each week. Although the implementation date of the intervention may differ from one school to another, its duration will be the same for all. Participants in the control group will engage in an attention-matched online flash game during the study period, which does not contain any tobacco- or vaping-related information. However, they will be given the same GBL intervention materials on vaping intention prevention at the end of the study, and they will also answer the same sets of questionnaires at baseline, immediately after the intervention, and then, 3 months after the intervention. The following is a breakdown of the gameplay to be played:

a. The player assumes the role of a young teenage boy who serves as the virtual avatar, navigating the game world and progressing through challenges. The player will engage in combat with the vape-like monster (vapester) and collect valuable items to enhance their abilities and knowledge. In a 15-minute level 1, the player will engage in combat with the first and second generation vapester while collecting 'Truth orbs' to gather information on the vape device and its basic components. The player will encounter three mystery boxes to unlock a cut-scene video on how vape devices work and their harmful contents. Other mystery boxes will unlock mini-games called 'Word-cloud shooting mission', which teach players about the harmful chemicals in vapes and identifying various designs of vapes in the 'Hidden in a plain-sight' mini game.
b. Players will progress to level 2, to combat with more difficult third and fourth generation vapesters, while discovering the 'Myth orbs' to uncover myths and facts of vaping. Similarly, the player will encounter another two mystery boxes. This will unlock a cut-scene video on the effects of nicotine and vaping on health. At the end of level 2, players will unlock another mini-game to test their knowledge and information gathered to defeat the fourth-generation *Mythical vapester*.
c. In a 30 min level 3 game, players' goals are to denormalise vaping and reduce its social appeal by finding and destroying the marketing kit to promote vapes. This will reveal the hidden truth behind the marketing kits and their role. The player will further uncover the truth through the mystery box cut scene video on tricky marketing strategies to deceive youngsters. Next, the mini game aims to empower players to denormalise vaping through existing regulations by playing a tag-match game to transform various vape-related situations into a vape-free environment. The last mini-game in this level is an interactive branching dialogue. Players will engage in two settings (at home and school setting) to rethink what others expect of them to change the tide.
d. In a final level, the player will continue the exploration and collect the goal and strategy cards to set a personal goal and aim to remain vape-free. Concurrently, players will enhance their self-efficacy and refusal skills, while refusing peers in risky social situations through a series of scenarios, making the best choices. Finally, the player will unlock one cut-scene video to empower vape-free youth and the final epic combat with '*Gigantamax vapester*' by using all the information and items gathered to defeat this final enemy.

Participant privacy

To ensure sincere responses, honesty will be emphasised to the participants. Each participant will be assigned a unique study identification number at baseline. A secure linkage file mapping study identification numbers to student names will be maintained by the research team solely for the purpose of longitudinal follow-up. This linkage file will be stored separately from the research dataset and accessed only by authorised personnel. No personal identifiers will be entered into the analysis dataset, and all analyses will be conducted using coded data only. The linkage file will be destroyed after completion of data collection.

Outcomes measures

Primary outcomes

The primary outcome variable in the present study is vaping intention. It will be measured using a modified questionnaire consisting of items adapted from Evans, Bingenheimer[36] and Noar, Rohde.[37] This self-administered questionnaire consists of four items as follows: (a) do you think you will use a vape (even one puff) within the next few months?/(b) in the next year?/(c) in the next 5 years?; (d) thinking about the future, if one of your best friends offered you a vape (even one puff) in the coming year, would you smoke it? These variables will be the average of four items, which will be answered on a 5-point response scale ranging from 'not at all likely' (1) to 'extremely likely' (5). The reliability of the scale was good (Cronbach's α=0.84).

Secondary outcomes

The secondary outcome variables in this study are described in the following sections.

Attitude towards vaping

Attitude towards vaping will be measured using the Electronic Cigarette Attitude Survey instrument. Developed by Diez *et al*,[38] this instrument incorporates 12 items pertaining to attitude for adolescents' vape use. Participants will be asked to rate their level of agreement with

these 12 statements comparing vape use to conventional cigarettes. Each item will be coded on a Likert scale ranging from 1 to 5 with 1='strongly agree' and 5='strongly disagree'. The average mean score will be calculated and a higher score indicates a positive attitude. The internal consistency for the overall measure was good (Cronbach's α=0.84).

Subjective norm of vaping

Subjective norm of vaping will be assessed by questionnaire consisting of items adapted from Wang *et al*.[39] The questionnaire consists of three items as follows: (a) most people who are important to me think I should use vapes instead of conventional cigarettes; (b) most people who are important to me would want me to use vape; (c) people whose opinions I value would prefer that I use vape. Each item will be rated through a 5-point Likert scale ranging from strongly disagree (1) to strongly agree (5). All items have good internal consistency (Cronbach's α=0.82).

Perceived behaviour control

Perceived behaviour control from vaping behaviour will be assessed by items adapted from Wang *et al*.[39] The questionnaire also consists of three items as follows: (a) whether or not I use vape is entirely up to me; (b) I am confident that if I want, I can buy and use vape; (c) I have resources, time and opportunities to buy and use vape. Each item will be rated through a 5-point Likert scale ranging from strongly disagree (1) to strongly agree (5). All items have acceptable internal consistency (Cronbach's α=0.72).

For interpretability, subjective norm and perceived behavioural control items will be reverse-coded so that higher scores indicate greater social disapproval of vaping and higher refusal self-efficacy.

Knowledge of vaping

Knowledge of vaping will be measured using a modified questionnaire consisting of items adapted from Rohde *et al*,[40] Hafiz *et al*[41] and Le *et al*.[42] Participants are required to determine whether each statement is 'true', 'false' or 'don't know'. A total of 20 items will be used to assess knowledge of vaping. Each correct answer received 'one point' and incorrect/'Don't know' response received 'zero points'. The scale score ranged from 0 to 20. The level of knowledge was measured by the sum of the scores obtained, with a higher score indicating greater knowledge.

A pilot study was conducted to assess the internal consistency of the study instruments. Cronbach's α values indicated acceptable to good reliability for intention (α=0.84), attitude (α=0.84), subjective norm (α=0.82) and perceived behavioural control (α=0.72). The knowledge questionnaire demonstrated acceptable internal consistency (KR-20=0.70), supporting the suitability of the instruments for use in the main study. All primary and secondary outcomes, including vaping intention, knowledge, attitude, subjective norm and perceived behavioural control, will be measured at baseline prior to intervention delivery (T0), immediately postintervention (T1) and at 3 months postintervention (T2). The repeated measurements are intended to assess both immediate and short-term sustained effects of the intervention. Intention to vape at 3 months postintervention is designated as the primary endpoint of the study, while immediate postintervention and other secondary outcomes will be used to evaluate short-term changes following the intervention.

Other outcomes

Participants' personal information

This part of the questionnaire consists of five questions conducive to assessing the sociodemographic factors of the participants (ie, age, gender, ethnicity, academic form and school location).

Lawshe's method was used to examine the content validity index (CVI) of the questionnaire, which aimed to assess the clarity, relevance and cultural appropriateness of each construct using the item-level content validity index (I-CVI). This self-administered questionnaire was reviewed by five professional expert panellists, comprising three public health physicians from the Community Health Department at the Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, one family medicine specialist from the Ministry of Health and one secondary school teacher from the Ministry of Education. According to Lynn,[43] an acceptable I-CVI should not be lower than 0.78. In addition, the scale-level content validity index (S-CVI) was calculated to determine the proportion of items deemed content valid across the entire scale. Waltz *et al*[44] recommended an S-CVI value of 0.90 or higher. The I-CVI scores for all constructs ranged from 0.93 to 1.00, while the S-CVI scores ranged from 0.92 to 1.00. The face validity of the questionnaire was initially done by the 10 target participants, who were not included in the study. Then some changes on the relevant items were made depending on the suggestions provided by these professional experts and every student's feedback.

Implementation outcomes

We will assess five implementation outcomes: acceptability (post-session 5-item student rating, 5-point Likert, higher=more acceptable), fidelity (facilitator checklist of core components delivered; % of items delivered), reach (proportion of eligible students who attend the session), engagement (time-on-task and levels completed from in-game logs) and cost per student (micro-costing of personnel time, materials and overhead). These will be summarised descriptively with 95% CIs and compared between arms as exploratory analyses.

Translation of the questionnaire and study module

The questionnaire and study module were translated according to the process of professional translation, while the back translation was used as an approach for the adaptation of instruments. The questionnaire was presented

in dual language format (Malay and English language) within the same instrument to facilitate comprehension among students. These instruments were originally administered in English. The translation process into the target Malay language for use in this study will follow the steps outlined as follows:

i. Forward translation to Malay language by two native speakers of Malay language and fluent in English language; any discrepancy will be discussed and resolved.
ii. Back-translation to English language by another two independent translators who are proficient in both English and Malay language and had no prior knowledge of the questionnaire and module.
iii. The back-translation will be compared with the original questionnaire and module to ensure accuracy of the forward translation.
iv. Pretesting of the translated questionnaire and module among 30 secondary school students, who are not participants in the study. The clarity, understandability and quality of the module and questionnaire were discussed with them individually. Then, phrases that were unsuitable and difficult to understand were identified, and accordingly, adjustments and modifications thereto were made following their evaluation.
v. Subsequently, the final version was approved for the study.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Sample size

The required sample size was first estimated for an individually randomised comparison of mean vaping intention scores at 3-month follow-up (two-sided α=0.05; power=80%). The expected effect size was informed by *Rethink vape*, a risk-communication intervention targeting youth e-cigarette use, which reported a mean difference of 0.35 in intention scores between intervention and control groups with a pooled SD of approximately 0.96, corresponding to a small-to-moderate standardised effect (Cohen's d≈0.36).[45]

The sample size was then inflated to account for the cluster-randomised design using the design effect, DE=1+(m–1)×ICC, where m is the average cluster size. An intra-cluster correlation coefficient (ICC) of 0.01 was assumed, consistent with values reported in school-based digital smoking prevention trials targeting early adolescents.[46] Assuming an average cluster size of approximately 41–46 students, the resulting design effect was approximately 1.4.

Allowing for an anticipated attrition rate of 10%, the final required sample size was 366 students across eight clusters (four schools per arm). Although the number of clusters is limited, this is typical of pragmatic school-based trials. The primary analysis will use generalised estimating equations with cluster-robust SEs and incorporating repeated measurements to improve precision of effect estimates rather than to increase statistical power. The observed ICC and design effect will be reported in the trial results.

Sampling method

A total of eight schools with 366 participants that have met the inclusion and exclusion criteria will take part in the study. Following cluster sampling, four of the schools will be involved in the intervention group, while the other four are the control group. Then, the proportionate allocation number of students to participate in the study will be calculated based on the density of the students in each school (probability proportional to size). Participants' selection will be conducted by using a simple random sampling technique.

Participant recruitment

Forty national secondary schools were assessed for eligibility. There were 18 schools not eligible to take part in the study as they did not meet the selection criteria for school by being a religious-based school, non-coeducational school, boarding school, consisting of upper form or Form six only school and school without computer lab facility.

With respect to the 22 eligible schools, eight schools were randomly selected and were adequate to contribute to the necessary sample size for this study. Written permission will be obtained from the respective education authorities at the ministry, state and district levels. With the help of school administrators, the school coordinator, counsellor and information and technology teacher would be invited to attend small meeting groups in each school. During such meetings, the researcher will explain the objectives and advantages of the study, along with the inclusion and exclusion criteria. After selecting the required participants' number in each school, written informed consent was obtained from parents or legal guardians of all participating students, as all participants were below 18 years of age. Information about the study objectives, procedures and voluntary nature of participation was provided to parents or guardians, and consent links were distributed by the research team via WhatsApp. Students whose participation was approved by their parents or guardians were subsequently invited to participate. Accordingly, participants who agree to participate will be asked to fill in the questionnaire. Assent was obtained from all participating students prior to questionnaire completion. A liaison officer verbally explained the study procedures and participant assent process at the school. Participants will be informed of the importance of providing honest and complete responses to the questionnaires, as their self-reported answers are essential for evaluating the effectiveness of the intervention. On providing assent on the first page of the online questionnaire, participants were directed to complete the baseline questionnaire (T0) using Google Forms. Completed responses were automatically uploaded to a

secure, access-restricted Google Drive created specifically for this study.

Access to the electronic database will be restricted to authorise research team members via password-protected institutional accounts. Data will be de-identified using unique study identification numbers, and the linkage file will be stored separately in a password-protected file accessible only to the principal investigator. All data will be stored on secure institutional servers in accordance with university and ethical requirements. Data will be retained for the required period before secure disposal. Given the minimal risk nature of this school-based behavioural intervention, a formal Data Monitoring Committee is not deemed necessary. Study oversight and data quality assurance will be managed by the principal investigator and research team, with regular monitoring of data completeness and accuracy.

Later on, educational interventions (GBL) on vaping intention will be delivered to the intervention group. Following that, the participants will be requested to fill in the same set of questionnaires (with the exception of the personal information form) in the post-immediate and follow-up assessment. To minimise loss to follow-up and selective non-attendance, outcome assessments will be conducted during scheduled school hours in coordination with school administrators and teachers. All eligible participants present on the assessment day will be invited to complete the questionnaire regardless of intervention exposure or vaping status. Participation will be emphasised as voluntary and confidential to reduce differential non-response related to vaping behaviours.

Study timeline

This manuscript reports a study protocol. At the time of submission, participant recruitment had commenced and baseline data collection was ongoing in January 2026. The GBL intervention will be delivered during scheduled school sessions. Immediate postintervention assessment will be conducted on the same day, and the primary outcome assessment is planned at 3 months postintervention. Data collection is expected to be completed by March 2026 and study completion by October 2026.

Study principles

The reporting of this protocol followed the Standard Protocol Items: Recommendations for Interventional Trials Protocol Extension (online supplemental table S1).[47] The study reporting will be in accordance with the Consolidated Standards of Reporting Trials (CONSORT) extension for cluster randomised trials. Figure 1 illustrates the CONSORT extension for cluster randomised trials flowchart.[48]

Randomisation

The unit of randomisation in this current study is a school. To allocate the eight selected clusters (schools) to the study groups, each school will be assigned a number one to eight. A simple randomisation technique will be done using online random group allocation to create the randomisation sequence, with 1:1 allocation. Thus, four clusters were randomly allocated to the intervention group (SR3, JK5, CV2 and RP7) and four clusters to the control group (TJ8, SA6, MK4 and TG1).

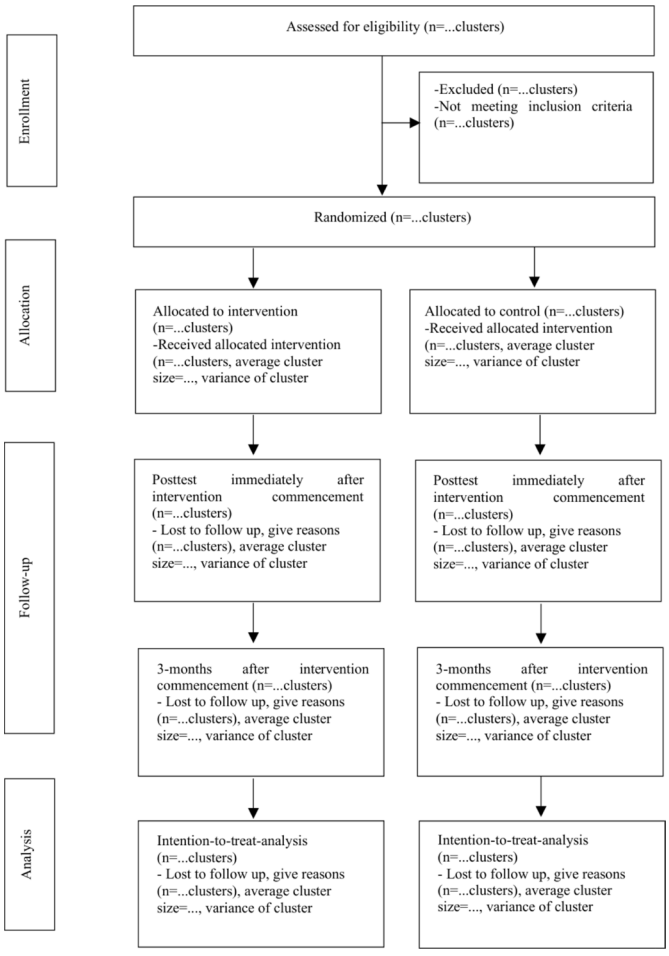

Figure 1 Consolidated Standards of Reporting Trials flow diagram of the study. Flow diagram of the cluster randomised controlled trial showing enrolment, allocation, follow-up and analysis phases of participating schools. Adapted from Campbell *et al*.[48]

Allocation concealment mechanism

To ensure proper allocation concealment, an independent assistant will be assigned to produce the allocation sequence list. Each cluster will be given a unique code in a sealed opaque envelope. Following that, the assistant will open the envelopes and assign the clusters to the intervention or control group based on the list of codes generated by the software.

Blinding

Single blinding will be applied in this study. The group that should receive the health intervention should be made known to researchers due to their involvement in study implementation. The participants will be blinded from the study to keep participants unaware of their group status to minimise performance bias.

Data collection

All study outcomes, including vaping intention, knowledge, attitude, subjective norm and perceived behavioural control, will be assessed at baseline prior to intervention delivery (T0) using self-administered online questionnaires delivered via the Google Forms platform. The same set of outcomes will be reassessed immediately postintervention (T1) and at 3 months postintervention (T2) to evaluate changes over time and the sustained effect of the intervention. A designated research team member will monitor PRO completion rates and data quality throughout the study.

Statistical analyses

Data will be analysed using SPSS (IBM SPSS, V.29.0). All analyses will be conducted under an intention-to-treat framework. The primary outcome (intention to vape at 3 months) will be modelled using generalised estimating equations with an exchangeable working correlation and cluster-robust SEs to account for clustering at the school level. Models will be adjusted for baseline outcome values and prespecified covariates, including age, sex, school and baseline vaping status (current or ever use). Baseline vaping status will be included as a covariate in both primary and secondary outcome analyses. Continuous secondary outcomes will use the same approach. We will report adjusted mean differences with 95% CIs, the ICC and the design effect. To assess and account for potential attrition bias, baseline characteristics, including vaping intention and self-reported vaping status, will be compared between participants who complete follow-up assessments and those lost to follow-up. Primary analyses will follow the intention-to-treat principle. Participants who discontinue or deviate from the assigned intervention will not be excluded from outcome assessments. All participants will be invited to complete follow-up questionnaires regardless of intervention adherence, in accordance with the intention-to-treat principle. Reasons for non-completion, where available, will be documented.

PRO completion rates of ≥80% at each assessment time point will be considered acceptable to preserve interpretability of findings. Assessments will be conducted within predefined time windows: baseline prior to intervention, immediate postintervention within the same session day and 3-month follow-up within ±2 weeks of the scheduled date. Deviations beyond these windows will be documented and considered in sensitivity analyses. Missing outcome data will be handled using multiple imputation under a missing-at-random assumption, with complete-case analyses conducted as sensitivity checks. Given the limited number of clusters, cluster-level sensitivity analyses will be conducted by comparing cluster-level summary measures between intervention and control arms, with adjustment for baseline cluster-level covariates where appropriate. In addition, longitudinal mixed-effects models will be explored as sensitivity analyses to assess the robustness of findings. These models will incorporate random effects to account for clustering at the school level and repeated measurements within individuals, and will include fixed effects for time, intervention group and their interaction. Full maximum likelihood estimation will be used to incorporate all available data under a missing-at-random assumption.

DISCUSSION

This study presents a protocol for evaluating a theory-driven GBL intervention programme (GBLIP) aimed at reducing vaping intention among national secondary school students in Selangor, Malaysia. Given that a significant proportion of adolescent vapers report intention to vape before the age of 14, the findings underscore the urgency of addressing early susceptibility to nicotine use in line with broader tobacco control efforts. By integrating digital technology, behavioural theory and school-based delivery, this intervention offers a promising pathway to reshape health communication for digital-native adolescents.

Crucially, the GBLIP model (VAPGAMO) aligns with international tobacco control policy frameworks, particularly the WHO FCTC. Specifically, this intervention operationalises elements of Article 12, which calls for education, communication, training and public awareness, and supports Article 14 by contributing to demand-reduction strategies targeting tobacco and nicotine dependence. The use of interactive digital content, which is designed to improve knowledge, shift social norms and enhance behavioural control, embodies a modernised approach to achieving these global objectives.

The significant improvements expected in knowledge, attitudes, subjective norms and perceived behavioural control can inform national-level curriculum reform and adolescent-focused public health campaigns. Moreover, the intervention's culturally tailored yet modular design makes it scalable and adaptable across diverse international contexts, particularly in low- and middle-income countries facing rising adolescent vaping. Although this study was conducted in Malaysia, the GBLIP model is not country-specific; its underlying structure is anchored in behavioural science and gamified delivery, which can be adopted or localised by ministries of health, school health units or international NGOs in settings with similar youth risk profiles.

Beyond demonstrating statistical significance, the study aims to generate actionable evidence for education ministries, school administrators and youth-focused public health organisations. Policymakers may consider integrating such digital tools into existing tobacco control programmes to expand their reach and impact among adolescents. Health professionals and school stakeholders can use the content to spark discussions, reinforce refusal skills and counter the normalisation of vaping culture on social media and peer groups. Limitations include a single 90-minute dose, a 3-month follow-up and self-reported outcomes, with potential inter-school contamination. Given the limited number of clusters, this study

has characteristics of a pragmatic pilot cluster randomised trial. The primary objective is to estimate the intervention effect and assess feasibility, while informing the design of a future definitive trial with a larger number of clusters. We will mitigate these through cluster-appropriate analysis, fidelity checks and implementation metrics (reach, engagement, cost). Repeated questionnaire administration may also introduce a testing effect; however, as both intervention and control groups undergo identical measurement schedules, any such effect is expected to be non-differential and unlikely to bias between-group comparisons.

This study is also among the first in Southeast Asia, to the best of the researchers' knowledge, to evaluate a video game-based intervention grounded in the TPB targeting vaping intention among adolescents. While long-term evidence on gamified interventions in tobacco control remains limited, the early implementation of such innovative approaches is critical to preempt the vaping epidemic among future generations. By promoting not only knowledge acquisition but also critical thinking, digital resilience and decision-making skills, GBLIP fosters more than just behavioural intent as it nurtures personal agency and informed resistance in the face of aggressive nicotine marketing tactics.

In summary, this GBLIP study contributes to the global evidence base on digital strategies for tobacco demand reduction. If proven effective, it offers a cost-effective, scalable and engaging educational tool that addresses the complex interplay of beliefs, social influences and behavioural control in adolescent vaping. Such innovations are essential for accelerating global progress towards WHO FCTC goals, especially in reaching hard-to-engage youth populations.

Ethics and dissemination

This trial protocol has been approved by the Ethics Committee of Universiti Putra Malaysia (*JKEUPM*) (Ref No. JKEUPM-2024-887). Written informed consent will be obtained from parents or legal guardians as well as participants prior to enrolment. We will communicate with investigators, trial participants, trial registries and journals and submit related reports following the rules of the ethics committee for any important protocol modification during the trial process. All procedures in this study will be carried out in accordance with the ethics committee guidelines and regulations and the study protocol will be conducted in accordance with the Declaration of Helsinki and the Malaysian Good Clinical Practice Guideline. Results and findings of this trial will be disseminated in peer-reviewed journals and professional conferences. Participants will receive a summary of study findings at study completion. This study was registered with the Thai Clinical Trial Registry (TCTR), registered on 22 December 2024.

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