STUDY PROTOCOL

Availability of shared vs separate places for tobacco and e-cigarette use: study 1

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Abstract

Background
The aim of this study is to estimate the impact of exposure to two different types of e-cigarette cues on tobacco smoking and vaping urges.

Methods
Four groups of UK adults, varying in smoking (i.e., current or former) and vaping (i.e., uses or does not use) status, will be randomly assigned to view one of four short videos and complete a questionnaire online. The videos will show the same conversation between two actors but vary in the following: (a) someone vapes using a cigalike e-cigarette; (b) someone vapes using a tank-system e-cigarette; (c) someone smokes a tobacco cigarette, (d) someone performs an action involving hand and face that does not involve vaping or smoking. Primary outcome: self-reported craving for tobacco cigarettes.

Study context
The results of this study will provide an estimate of the impact of viewing people using different types of e-cigarettes on tobacco smoking urges, relative to tobacco smoking or neutral cues. The results will inform current debates about the regulation of e-cigarette use in public spaces as well as informing the design of subsequent laboratory and field studies to assess the impact of shared or separate places for tobacco and e-cigarette use.

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Background

The impact of the use of e-cigarettes is debated within the public health community. Proponents argue for the beneficial role they can play in facilitating tobacco smoking cessation, while others express concerns for their potential to normalise smoking and question their safety (Adkison et al., 2013; Green, Bayer, & Fairchild, 2016). In Australia, the sale of e-cigarette liquid that contains nicotine is illegal and they are not promoted as a cessation device (NSW Government, 2018). In contrast, Public Health England (PHE) reported that e-cigarettes are 95% less harmful than smoking tobacco (McNeill et al., 2015), and they are recommended by the National Health Service (NHS) Smokefree advice (NHS, 2018). E-cigarettes are not included in UK legislation that bans smoking in public places; however, some local policies have been extended to e-cigarettes (Pippard & Shipley, 2017). Opposition to their use has also led some North American states to ban e-cigarette use in public spaces, where tobacco smoking is not allowed, including offices and parks (NYC, 2018). The appropriateness of such action has been challenged (Bauld, McNeill, Hajek, Britton, & Dockrell, 2017) and regulating the use of e-cigarettes in public spaces remains one of the more contested areas of tobacco control policy in the UK (Chapman, Daube, & Maziak, 2017; Patterson, Hilton, & Weishaar, 2016). One concern is the impact of vaping on current and former smokers, including the potential for both negative cross-cueing of tobacco smoking on vapers (i.e., seeing smoking cues reduces vaping urges) and positive cross-cueing of vaping on tobacco smokers (i.e., seeing vaping cues increases smoking urges).

Previous research has focussed on the impact of vaping cues on cross-cueing of tobacco smoking. These previous studies have used ‘cigalikes’ (i.e., e-cigarettes which are visually similar to tobacco cigarettes) and found that cigalike cueing increases tobacco smoking urges. For example, in a previous laboratory experiment, daily smokers were randomised to either passive exposure to tobacco cigarettes or cigalike e-cigarettes (King, Smith, McNamara, Matthews, & Fridberg, 2014). During a five-minute conversation with the participant, a confederate either used a tobacco cigarette or an e-cigarette. While being exposed to the tobacco cigarette increased desire to smoke a regular cigarette only, being exposed to the e-cigarette increased desire to use an e-cigarette and smoke a tobacco cigarette. Similarly, other research has found that, as compared with no cueing, e-cigarette cueing through e-cigarette advertisements increases urge to smoke a tobacco cigarette among daily smokers, with some evidence that e-cigarette cueing also reduces former smokers’ intentions to remain abstinent from tobacco (Maloney & Cappella, 2016).

However, first generation cigalike e-cigarettes are increasingly less popular than tank and modular systems, which are not designed to look like tobacco cigarettes and are now used by the majority of vapers in the UK (West, Beard, & Brown, 2017). The extent to which these newer types of e-cigarette may also cue smoking urges requires further investigation. King, Smith, McNamara, and Cao (2017) found that second generation vape pens, which are the size and shape of a large pen or laser pointer, had a similar cueing effect on tobacco smoking urges, compared to cigalike devices used in their previous studies with young adult daily and non-daily smokers.

The present study intends to extend these findings to directly compare the impact of viewing e-cigarette cues, from either first generation cigalikes or advanced third generation tank systems, which are larger and bulkier than vape pens, to tobacco smoking or neutral cues among current daily smokers or former smokers. Previous research has focussed on the effect of e-cigarette cues on smokers and former smokers; this study will also examine the impact of e-cigarette cues on e-cigarette users with different smoking statuses. The results of this study will inform the ongoing debate around the regulation of e-cigarette use in public spaces, as well as informing
subsequent lab and field studies in this area to understand the impact of having either shared or separate places for tobacco and e-cigarette use.

**Study objective and hypotheses**

The study objective is to estimate the impact of viewing e-cigarette cues (both cigalike and tank systems) on smoking and vaping urges among four groups:

i. current smokers who do not vape;
ii. current smokers who vape (i.e., dual-users);
iii. former smokers who do not vape;
iv. former smokers who vape.

H1: Tobacco smoking urges are higher amongst current and former smokers following exposure to vaping cues (i.e., cigalike and tank-system), relative to control cues.

H2: Tobacco smoking urges are lower amongst current and former smokers following exposure to vaping cues (i.e., cigalike and tank-system), relative to tobacco smoking cues.

H3: Tobacco smoking urges are higher amongst current and former smokers following exposure to cigalike cues, relative to tank-system cues.

Analyses of all other main effects and interactions will be exploratory.

**Methods**

**Study design**

This will be an online study using a 16 group between-subjects design: 2 (smoking status: current smoker, former smoker) × 2 (vaping status: current vaper, non-vaper) × 4 (stimuli type: cigalike, tank-system, tobacco cigarette, control).

Participants will be randomised to view one of four videos of a conversation between two individuals varying in the behaviour of one of the two individuals who is shown: 1) vaping using a cigalike e-cigarette; 2) vaping using a tank-system e-cigarette, 3) smoking a tobacco cigarette, or 4) moving their hand to their mouth without smoking or vaping.

The primary outcome measure will be self-reported craving for tobacco cigarettes, assessed before and after viewing the cues.

Secondary outcome measures will include self-reported craving for e-cigarettes, intention to quit tobacco smoking (current smokers only), and self-efficacy to remain abstinent from smoking (former smokers only).

**Study site**

The study will be conducted online, designed and hosted on the Qualtrics online survey platform (http://www.qualtrics.com/).

**Participants and recruitment**

Participants will be recruited through the Prolific Academic crowdsourcing platform (https://www.prolific.ac/), which will advertise the study to existing members, who will be reimbursed after survey completion through their accounts. Study participants (n = 936) will be recruited to achieve similar numbers in each of four groups varying in vaping and tobacco smoking status (see Study objectives and hypotheses, above).

Those who want to take part will read an information statement before giving their
consent to participate. Participation is expected to take approximately 10 minutes to complete and participants will be reimbursed £1 on completion.

Participants who begin the experiment but do not complete it will not be reimbursed. In addition, those who do not meet the inclusion criteria (assessed immediately after consent is given and before randomisation), and those who fail the attention check question (assessed after study completion), will not be reimbursed. These participants will be replaced. Participants will be informed of this in the information displayed at the start of the study. The number of participants replaced in this way will be recorded and reported in a CONSORT flow diagram.

**Inclusion criteria**

- Aged 18 or over;
- Either:
  - a current smoker (smokes at least 5 cigarettes a day and has smoked this amount for at least one year);
  - a former smoker (previously smoked at least 5 cigarettes a day and smoked this amount for at least one year);
- And either:
  - a vaper (vapes at least once a day);
  - a non-vaper (vaped fewer than 20 times in their lifetime);
- Lives in the UK.

**Exclusion criteria**

- Currently trying to quit smoking

**Sample size determination**

A previous study examining the impact of e-cigarette advertisement cueing on urge to smoke a cigarette (Maloney & Cappella, 2016) found that those daily smokers in the cue condition had an urge score of 3.63 (SD = 0.90), while those in the no cue condition had an urge score of 3.14 (SD = 0.82), an effect size of \( d = 0.57 \).

A second study observed that exposure to a cigalike e-cigarette increase desire to smoke a tobacco cigarette from approximately 72 to 80 (SD ~22), an effect size of \( dz = 0.36 \), and increased desire to smoke an e-cigarette from approximately 43 to 50 (SD ~22), an effect size of \( dz = 0.32 \) (King et al., 2014).

Using a conservative effect size estimate of \( d = 0.3 \), comparing between two stimuli groups (H1 and H2), we will require 234 participants in each stimuli group (234 in the control stimuli, 234 in the tobacco stimuli and 234 jointly across the vaping stimuli groups) to achieve 90% power at an alpha level of 0.05 to test our main hypotheses. For H3, again a sample size of 234 in each vaping group would be needed for 90% power and alpha of 0.05, using the same effect size. Therefore, we propose using even group sizes of 234 participants across all four stimulus groups.

**Withdrawal of participants**

Participants will be informed that they are able to withdraw from the experiment by leaving the experiment webpage. None of their data will be saved if they do this. However, participants who withdraw will not be reimbursed. Data collected will be anonymous; therefore, participants will not be able to withdraw their data at a later point. Participants will be made aware of this in the information statement. Full details of ethics approval are provided below.
Randomisation

The study will be delivered on the Qualtrics platform, which will be used to pseudo-randomise participants into one of the four conditions (cigalike, tank system, tobacco cigarette or control) such that an equal number of participants from the four vaping / smoking groups are in each condition.

Materials and measures

Videos

Each of four bespoke videos will feature two adults (actors: aged 30-39, of different gender and ethnicity) having a conversation. They will differ in the behaviour of one of the actors:

- Video 1: uses a cigalike e-cigarette;
- Video 2: uses a tank-system e-cigarette;
- Video 3: smokes a tobacco cigarette;
- Video 4: performs a matched control action.

In each video, the actor will use the e-cigarette, smoke the tobacco cigarette or bring their hand to their mouth (in the control condition) the same number of times. The conversation and environment will be the same in each video and each will last one minute. The videos will be filmed by Cambridge Filmworks Ltd (http://www.cambridgefilmworks.com).

Measures

Tobacco and e-cigarette urges (primary outcome measures)

The brief Questionnaire of Smoking Urges (QSU-Brief) (Cox, Tiffany, & Christen, 2001; Tiffany & Drobles, 1991) will be used to assess urges to smoke tobacco cigarettes. The QSU-Brief will also be modified for e-cigarettes to assess urges to vape (St.Helen, Havel, Dempsey, Jacob, & Benowitz, 2016). Each question will be rated on a scale from 1 (‘strongly disagree’) to 7 (‘strongly agree’) with the total score ranging from 10-70.

Two visual analogue scales (VAS) will assess ‘desire for a regular cigarette’ and ‘desire for an electronic cigarette’ (King et al., 2017). We will also ask participants how long they have been smoking (current smokers) or how long they have been abstinent from smoking (former smokers).

Filler questions

Additional VAS will assess desire for a range of other substances and experiences (e.g., conversation, water, salty foods etc.) (King et al., 2017).

Intentions to quit smoking and self-efficacy of remaining abstinent (secondary outcome measure)

To assess intentions to quit smoking, smokers will be asked: ‘Are you planning to quit smoking within the next 6 months?’ (on a five-point scale: 1=‘very unlikely’, 2=‘unlikely’, 3=‘maybe, maybe not’, 4=‘likely’, 5=‘very likely’) (Hummel et al., 2017). To assess how likely they are to remain abstinent from smoking, former smokers will be asked: ‘How confident are you that you will remain a non-smoker?’ (on a five-point scale: 1=‘not at all sure’, 2=‘slightly sure’, 3=‘moderately sure’, 4=‘very sure’, 5=‘extremely sure’) (International Tobacco Control (ITC) Policy Evaluation Project, 2017).
Video questionnaire

Participants will be asked a series of questions about the videos, including the quality of the acting, the relationship between the two individuals and specific questions about the content of the conversations.

Screening and demographics

Participants will be asked to provide demographic information including age, sex, where they currently live (with the options: ‘England’, ‘Wales’, ‘Scotland’, ‘Northern Ireland’, ‘Other (please specify)’, or ‘I do not live in the UK’) and their smoking / vaping status as per the inclusion criteria.

Participants will report their highest qualification attained (with the options: ‘Higher Education or professional / vocational equivalents’, ‘A levels or vocational level 3 or equivalents’, GCSE / O Level grade A*-C or vocational level 2 or equivalents’, ‘Qualifications at level 1 and below’, ‘Other qualifications: level unknown’, or ‘No qualifications’) (ONS, 2015).

Attention checks

Given concerns regarding the attention participants may pay in unsupervised settings, two items will be hidden within the questionnaire to check attention. We have used this approach previously (Hollands & Marteau, 2016). Participants will be asked if ‘You have been to every country in the world’ and ‘You sleep for more than an hour per night’. These will both be assessed on seven-point scales from -3 strongly disagree to +3 strongly agree. Answers on any of the three points of the scale in the right direction, negative for the former question and affirmative for the latter question (as opposed to choosing zero or anything the wrong side of zero), will be deemed satisfactory.

Participants will be given the following information:

‘Important – data quality!!!

Data quality is of the utmost importance for this survey, please be aware that there are simple test questions in the survey that are there to check you are paying due care and attention to answering all the questions.

Please note that if you answer these simple questions incorrectly, you will fail the quality control for the survey and we will not be able to reimburse you.’

Manipulation check

Participants will be asked about the study purpose and to describe the action of the actor in the video who is smoking / vaping / performing a neutral action to ensure that vaping behaviours and devices are recognised as such.

Procedure

Participants will be recruited using the Prolific Academic online crowdsourcing platform, which provides participants with a link to the study on the Qualtrics platform. The videos will be optimised for viewing on small devices (e.g., mobile phones) as well as desktops and laptops. Participants will first be shown an information statement explaining the study and what they will be required to do. Participants will be told that purpose of the study is to provide feedback on videos being developed for another study being run by the researchers. Participants will be informed that they are able to withdraw from the study by closing their browser. Before commencing the study, participants will complete a tick-box consent page.

Participants will then complete the screening and demographic questions. Participants
who do not meet the inclusion criteria will be taken to the end of the experiment and will not be reimbursed. Participants will complete baseline ratings of craving for tobacco cigarettes and e-cigarettes, as well as desire for other substances and experiences, and view the video as per their condition. To provide credibility to the cover story, participants will then be asked a series of questions about the videos, such as the quality of the acting, and then complete ratings again of tobacco cigarette and e-cigarette craving and desire for other substances and experiences. Current smokers will be asked about their intentions to quit smoking, while former smokers will be asked about their likelihood of remaining abstinent from smoking. Attention check questions will be hidden within the questionnaire, participants who provide unsatisfactory responses (see above) will be filtered out and not reimbursed. Finally, participants will be asked to describe the action of the actor [as per condition] and what they think was the primary purpose of the study. Participants will be asked an open-ended question about the study purpose first, and then asked separately to select from the following options: 1) to test memory for conversations, 2) to improve the quality of videos used for research, 3) to examine the impact of seeing someone smoke / vape [as per condition] on desire to smoke / vape, 4) to assess the effect of body language on desire to smoke / vape.

Participants will then be presented with a debriefing screen including information about how they can find more information if they wish to. They will also be given the Principal Investigator’s details again if they wish to contact them. The debriefing screen will also be shown to participants who start the experiment but are then ineligible to complete it based on their responses to the screening questions.

**Statistical plan**

The QSU questions will be summed to create an overall smoking urges score. Participants who fail either of the attention check questions will be removed from the principal analyses. However, these participants will be investigated separately to compare any differences they may have to participants who did not fail the attention check question. We will also check that the proportion of participants who fail the check does not differ between the intervention arms. Analyses will be run with and without participants who guess the true nature of the study. If necessary, sub-group analysis will also be run excluding any participants who did not recognise the smoking or vaping actions in the videos.

Descriptive statistics will be used to compare baseline characteristics of those allocated to each stimuli group between smoking and vaping status.

The principal statistical analysis will be to compare urge scores between all four stimulus groups (stimuli type: cigalike, tank, tobacco cigarette, control) using a General Linear Model (GLM), in relation to comparisons listed in H1-H3.

Interactions between vaping and smoking status, and the stimulus groups, will be explored. Any sociodemographic differences in urge scores between groups will also be explored.

E-cigarette craving scores, intention to quite tobacco scores (current smokers) and perceived self-efficacy of remaining abstinent from smoking (formers smokers) will also be compared between each stimuli group using a GLM model.

P-values and 95% confidence intervals (CI) will be reported for comparisons made according to experimental arm, particularly pertaining to hypotheses H1, H2 and H3.

If data are not normally distributed, the data will be dealt with accordingly (e.g., by transformation, or deriving confidence intervals and p-values using bootstrapping methods).
Study context

The results of this study will provide an estimate of the impact of viewing people using different types of e-cigarettes on tobacco smoking urges, relative to tobacco smoking or neutral cues. The results will inform current debates about the regulation of e-cigarette use in public spaces as well as informing the design of subsequent laboratory and field studies to assess the impact of shared or separate places for tobacco and e-cigarette use.

Research governance

In the UK, research will adhere to the Wellcome Trust Policy on Good Research Practice and the UK Policy Framework for Health and Social Care Research. Researchers also follow the principles laid out in the UK concordat to support research integrity.

Ethical considerations and informed consent

Ethics approval has been obtained from the Faculty of Science Research Ethics Committee at the University of Bristol (ethics approval code: 68724). The participant will receive information at the start of the survey. The study will be closed online once the required number of participants have been recruited. Participants will be given sufficient time to read the information, consider any implications, and raise any questions with the investigators prior to deciding to participate. Consent will then be obtained. Participants will be informed that they are free to withdraw at any time by closing their browser.

Sponsorship

The University of Bristol will sponsor this study.

Safety

As this is an online experiment we do not foresee any risks to participants. The University of Bristol holds appropriate liability insurance for research studies involving human participants.

If required further information can be found at the link below: http://www.bristol.ac.uk/secretary/insurance/liability-insurance/

Data management

All aspects of the General Data Protection Regulation, Data Protection Act 2018 and the Freedom of Information Act 2000 will be adhered to. All personal data will be treated as confidential.

Participant Identifiable Data (PID)

No identifiable information will be collected from participants.

Anonymised study data

All study data will be anonymised using a unique numeric identifier. Study data will be stored on an encrypted cloud server after completion. The data may only be accessed via a secure website which requires log-in credentials. Only study personnel will have access to these data.
Data sharing

Anonymous study data may be shared with collaborators for the purposes of analysis and results interpretation under appropriate collaboration agreements.

Long-term data archiving

At the end of the study, electronic study data (including finalised data sheet) will be transferred to a designated University of Bristol Research Data Storage Facility for long-term archiving. Study data will be kept for a minimum of 20 years.

Open access

At the appropriate time the data sheet will be locked and made open using the University of Bristol Research Data Repository and / or Open Science Framework.

Revoked data

Participants will not provide their name and as participants are not aware of their unique ID number, researchers will have no way to connect them with their data to revoke it. Participants will be informed of this before taking part in the study.

Quality control and quality assurance

The investigators will be responsible for data quality. After collecting approximately 5% of the data, data collection will be paused to ensure information is being collected as expected. Data will be examined prior to analysis to check that participants are answering correctly, e.g. by not giving the same answer repeatedly.

Insurance

As this is an online experiment we do not foresee any risks to participants. The University of Bristol holds appropriate liability insurance for research studies involving human participants.

If required further information can be found at the link below:
http://www.bristol.ac.uk/secretary/insurance/liability-insurance/

Publication policy

The findings from this research study may be published in an appropriate scientific journal (and made available open access), and/or presented at an appropriate meeting. Study data will be collected and held by the study investigators. The data will be made available for sharing via a University of Bristol online data repository and / or Open Science Framework.

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**Conflicts of interest**

The study investigators have no known conflicts of interest to declare.

**References**


