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STUDY PROTOCOL

The influence of different information campaigns on perceptions of e-cigarettes among smokers who are non-vapers

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Background

Smoking presents a significant and serious public health risk, with 16% of all deaths in the UK in 2018 being attributed to smoking [1]. Therefore, any method that can safely reduce smoking rates has the potential to significantly benefit public health. E-cigarettes present an effective smoking cessation tool and are estimated to be 95% less harmful than smoking combustible cigarettes [2]. Despite such benefits there is still uncertainty from both smokers, and the public, surrounding e-cigarettes. In 2015, 29% of smokers didn't know if e-cigarettes were more or less harmful than combustible cigarettes and 31% thought they were equally harmful, nearly tripling from 11% in 2012 [3]. Public Health England estimates that 40% of smokers have never tried an e-cigarette, often due to misperceptions surrounding the safety of e-cigarettes [2]. Furthermore, it is estimated that only 10% of adults understand that most of the harms from smoking are not caused by nicotine, the main ingredient present in both e-cigarettes and combustible cigarettes [2].

This study will explore the perceptions of current smokers who are non-vapers of e-cigarettes and how these perceptions differ after viewing different public information campaigns on the benefits of e-cigarettes over smoking. Furthermore, this study will examine what specific concerns underlie perceptions of harm about e-cigarettes. The aim is that by identifying which factors underlie negative perceptions about e-cigarettes, these can be specifically targeted in future public information campaigns.

Study Objective and Hypotheses:

The primary objective is to examine the effectiveness of e-cigarette information campaigns on decreasing the misperceptions surrounding the relative risks of vaping compared with smoking among current smokers.

Specifically, we hypothesise that:

- Participants who view information campaigns from a trusted source (either Cancer Research UK or a panel of scientific experts) will have fewer misperceptions about e-cigarettes than those who do not view any campaigns;
- That a video campaign with leading experts will be more effective at reducing misperceptions than a text-only animated video campaign by CRUK.

Study Design

This will be a between-subjects design, with three conditions. Participants will be current smokers who do not vape e-cigarettes and will be randomised to one of three conditions where they will either watch a video with experts talking about e-cigarettes, a short video by CRUK with key facts about e-cigarettes, or a control condition (where no video is shown). All participants will have their attitudes towards e-cigarettes measured after campaign exposure.

Study Site

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

Participants and Recruitment

Participants will initially be recruited from the current convenience sample on Prolific (<https://www.prolific.ac/>). Those who are interested in taking part will read an information statement before giving their consent to participate. Depending on the condition participants are assigned to, the experiment is expected to take between 5 and 10 minutes to complete and participants will be reimbursed £1.30 on completion. This is in line with recommended reimbursement amounts from Prolific Academic. Participants who begin the experiment but do not complete it, will not be reimbursed.

Inclusion criteria

- At least 18 years of age;
- Currently living in the UK;
- Must be a daily smoker (defined as someone who self-reports they currently smoke every day) and a non-vaper (defined as someone who self-reports they use an e-cigarette less than monthly).

The experiment will only be visible to those participants on Prolific who have previously reported that they are 18 or older and live in the UK. We also conducted a pre-screening survey (in line with Prolific requirements) to identify participants who met the smoking and vaping inclusion criteria. Of 1500 individuals who completed the screening (all of whom were smokers), 592 female and 245 males were eligible to take part in the main experiment.

Sample size determination

In the absence of other similar studies, we do not have data upon which to base a sample size calculation. We will require 390 participants (130 per group) to observe a small effect size ($f = 0.20$) with 95% power at an alpha level of 5%. This represents a difference of approximately 1 point ($SD = 2.3$) on a 7-point visual analogue scale assessing the extent to which participants agree with the statement that e-cigarettes are less harmful than cigarettes. We will recruit 450 participants (225 females, 225 males) to allow for withdrawals and excluded participants (based on failing attention checks).

Withdrawal of participants

Participants will be informed that they are able to withdraw from the experiment at any time by leaving the experiment webpage. None of their data will be saved if they do this. However, participants who withdraw will not be reimbursed. No identifiable data will be collected from participants and 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.

Randomisation

Qualtrics will be used to evenly randomise participants into one of the three conditions. The presentation order of the questions will also be randomised by Qualtrics. We will recruit an equal number of males and females into the three conditions.

Measures and Materials

Stimuli

Existing information campaigns will be used as stimuli. This decision was taken so that a better understanding of how effective current public health advice is and so areas for improvement can be highlighted.

CRUK e-cigarette video campaign:

Participants randomly assigned to this condition will see a 30 second video published by Cancer Research UK (viewable at https://www.youtube.com/watch?v=9BEdv7UTDBA&feature=emb_logo). The video includes the following statements, alongside CRUK logos:

- Research shows vaping is far less harmful than smoking;
- E-cigarettes contain nicotine, which is addictive, but does not cause cancer;
- E-cigarettes do not contain cancer-causing tobacco;
- Passively breathing vapour from e-cigarettes is unlikely to be harmful;
- Growing evidence shows e-cigarettes are helping people to stop smoking.

Expert based video information campaign:

Participants randomly assigned to this condition will view a video (2 minutes 20 seconds) where experts address common misperceptions surrounding e-cigarettes and their relative safety over combustible cigarettes (viewable at <https://www.youtube.com/watch?v=SSn5ZZQkzKs>). The video was part funded by Public Health England and made in association with the New Nicotine Alliance.

The experts in this video are:

- John Britton, Professor of Epidemiology at University of Nottingham.
- Ann McNeill, Professor of Tobacco Addiction Kings College London.
- Linda Bauld, Professor of Health Policy University of Stirling.
- Robert West, Professor of Health Psychology University College London

and the topics discussed are:

- The different contents of e-cigarette vapour and combustible cigarette smoke,
- E-cigarette use a smoking cessation technique
- The 'gateway' theory
- The relative safety of vaping to smoking combustible cigarettes.

Measures

All questionnaire measures and response options are presented in the Appendix.

Demographics (Table 1)

Participants will report their age, location in the UK, sex, level of education, ethnicity and occupation.

Smoking and vaping behaviour (Table 2)

Participants will report their smoking status in the screening survey. In the main experiment, all participants (all daily smokers) will be asked questions about the number of cigarettes smoked per day, their use of e-cigarettes and will complete the Quitting Smoking Contemplation Ladder and Fagerström Test of Nicotine Dependence.

Attitudes to vaping (Table 3)

The primary outcome measure will be a questionnaire to assess attitudes about vaping. This will assess;

- 1) how well-informed participants perceive themselves to be;
- 2) the perceived harmfulness of e-cigarettes;
- 3) the perceived benefit to smokers;
- 4) the perceived quality of scientific evidence surrounding e-cigarettes;
- 5) participant's biggest concern regarding the sale and use e-cigarettes;
- 6) intentions to use an e-cigarette in the future.

In an exploratory effort to deconstruct the perceived harmfulness measure, we will also break down perceived harm into concerns about;

- 1) contents (of cigarettes);
- 2) contents (of e-cigarettes);
- 3) the risk of accidents;
- 4) the risk of cigarette renormalisation;
- 5) the risk to society.

Attention check

To assess attention to the stimuli and measures, two attention check questions will be used. The order of response options for each will be randomised between participants.

Immediately before completing the outcome measure, after the videos for participants in information campaign conditions, participants will be asked 'From who did you just watch a video' with the options 1) Cancer Research UK, 2) British Heart Foundation, 3) A panel of experts and 4) I did not watch a video. The correct answer will then be dependent on the participant's condition. Participants in the control group will be required to respond with 'I did not watch a video', participants in the CRUK video condition will be required to respond with 'Cancer Research UK', and participants in the expert based video condition will be required to respond with 'A panel of experts'.

Randomly presented within the questions about attitudes to vaping, participants will be asked to "respond with Strongly Agree". This question will use the same scale as the other items in the outcome measure.

Procedures:

Participants will be primarily recruited using Prolific, an online crowdsourcing platform, which provides participants with a link to the study on the Qualtrics platform. Participants who completed the pre-screening survey were reimbursed 13p and only those individuals who met the inclusion criteria of daily smokers and non-vapers will be invited to participate in the main experiment (via a Prolific 'whitelist'). We will set up separate Prolific surveys for males and females to ensure equal numbers by gender.

Once invited to the study, participants will first be presented with an information sheet explaining the experiment and what they will be required to do. Participants will be informed that the purpose of the experiment is to explore the effectiveness of public information campaigns about e-cigarettes. Participants will be informed that they are able to withdraw from the experiment at any time by closing their browser. Before commencing the experiment, participants will complete a tick-box consent page.

Participants will then be randomly assigned to one of the three conditions (with equal assignment to each) and participants in the two information campaigns will then be presented the relevant information campaign. Participants will be informed that they must pay close attention to the videos and will be tested on the content after watching it. All participants will then complete the attitudes about e-cigarettes questions (participants in the no information condition will complete this immediately after providing informed consent), demographic questions and questions about their smoking and vaping behaviour.

Participants will then be shown a debriefing sheet where all the information campaigns will be listed. Participants will be redirected to Prolific to be reimbursed.

Statistical Plan

Participant demographics and vaping and smoking behaviour responses will be used to characterise the study population (means and SD, or percentages will be reported).

7-point Likert scales will be treated as linear variables and one-way ANOVAs will be run on the mean responses to each outcome for participants in each condition, with 'don't know' responses being removed from analysis.

For the item regarding each individual's biggest concern about e-cigarettes, responses will be counted to reveal the biggest concerns about vaping. For behavioural intentions related to using an e-cigarette in the future, chi-squared analyses will be conducted to examine the difference in proportion of participants in each condition who report that they either 'probably' or 'definitely' would use an e-cigarette in the future and would use one in a future quit attempt.

We will run analyses both with and without those participants who failed the attention check questions.

Ethical Considerations and Informed Consent

Ethics approval has been obtained from the School of Psychological Science Human Research Ethics Committee at the University of Bristol (Approval Code: 98202). The study will be conducted according to the revised Declaration of Helsinki (2013) and the 1996 ICH Guidelines for Good Clinical Practice E6(R1). The study will be closed online once the required number of participants have been recruited. Therefore, 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.

Safety

As this is an online experiment, we do not foresee any risks to the participant.

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.

Anonymised study data

All study data will be anonymised by 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.

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 Open Science Framework and / or the University of Bristol Research Data Repository.

Screening documents and participant contact details

We will not collect any identifying information about participants apart from Prolific IDs. We will delete these prior to data analysis.

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.

Insurance

This study will be sponsored by the University of Bristol. The University has Clinical Research Insurance to cover the liability of the University to research participants.

Publication Policy

The findings from this research study may be published in an appropriate scientific journal (and made available via 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 the Open Science Framework and / or the University of Bristol online data repository.

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Conflicts of Interest

There are no conflicts of interest.

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Appendix

Table 1: Demographics

| Variable | Items | Response options |
|-------------------|--|---|
| Education [48] | What is the highest level of education you have obtained? | 1 = Higher Education or professional/ vocational equivalents 2 = A levels or vocational level 3 or equivalents 3 = GCSE/O Level grade A*-C or vocational level 2 or equivalents 4 = GCSE/O Level grade C or below, or qualifications at level 1 and below 5 = Other qualifications: level unknown 6 = No qualifications |
| Social grade [49] | What is the profession of the chief income earner in your household? (That's the person with the highest income, whether that be from employment, pensions, state benefits, investment or other sources) | 1 = Higher managerial/ professional/ administrative (e.g. Established doctor, Solicitor, Board Director in a large organisation (200+ employees, top level civil servant/public service employee) 2 = Intermediate managerial/ professional/ administrative (e.g. Newly qualified (under 3 years) doctor, Solicitor, Board director small organisation, middle manager in large organisation, principal officer in civil service/local government) 3 = Supervisory or clerical/ junior managerial/ professional/ administrative (e.g. Office worker, Student Doctor, Foreman with 25+ employees, salesperson, etc) 4 = Student |

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| | | <p>5 = Skilled manual worker (e.g. Skilled Bricklayer, Carpenter, Plumber, Painter, Bus/ Ambulance Driver, HGV driver, AA patrolman, pub/bar worker, etc)</p> <p>6 = Semi or unskilled manual work (e.g. Manual workers, all apprentices to be skilled trades, Caretaker, Park keeper, non-HGV driver, shop assistant)</p> <p>7 = Casual worker – not in permanent employment</p> <p>8 = Housewife/ Homemaker</p> <p>9 = Retired and living on state pension</p> <p>10 = Unemployed or not working due to long-term sickness</p> <p>11 = Full-time carer of other household member</p> |
| University student | Are you currently a university student? | <p>1 = Yes</p> <p>2 = No</p> |
| University student | If 'yes', what type of course are you enrolled in? | <p>1 = Undergraduate</p> <p>2 = Postgraduate</p> |
| Gender | What is your gender? | <p>1 = Female</p> <p>2 = Male</p> <p>3 = Other (please specify)</p> |
| Age | What is your age (in years)? | <i>Number entry</i> |
| Ethnicity | What is your ethnic group? | <p>White</p> <p>1 = English/Welsh/Scottish/Northern Irish/British</p> <p>2 = Irish</p> <p>3 = Gypsy or Irish Traveller</p> <p>4 = Any other White background, please describe</p> <p>Mixed/Multiple ethnic groups</p> <p>5 = White and Black Caribbean</p> <p>6 = White and Black African</p> <p>7 = White and Asian</p> <p>8 = Any other Mixed/Multiple ethnic background, please describe</p> <p>Asian/Asian British</p> <p>9 = Indian</p> <p>10 = Pakistani</p> <p>11 = Bangladeshi</p> <p>12 = Chinese</p> <p>13 = Any other Asian background, please describe</p> <p>Black/ African/Caribbean/Black British</p> <p>14 = African</p> <p>15 = Caribbean</p> <p>16 = Any other Black/African/Caribbean background, please describe</p> <p>Other ethnic group</p> <p>17 = Arab</p> <p>18 = Any other ethnic group, please describe</p> |

Table 2: Smoking and vaping behaviour

| Variable | Items | Response options |
|-------------------------------|--|---|
| Smoking behaviour eligibility | How often do you currently smoke cigarettes? | <p>1 = Daily or almost daily</p> <p>2 = Less than daily, but at least once a week</p> <p>3 = Less than weekly, but at least once a month</p> <p>4 = Less than monthly</p> <p>5 = Not at all</p> |

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|---|--|--|
| Smoking behaviour eligibility | On a typical day, how many cigarettes do you smoke? | Text (integer) |
| | In a typical week, how many cigarettes do you smoke? (<i>screening only</i>) | Text (integer) |
| Vaping current use | How often do you currently use an e-cigarette or vaping device? | <p>1 = Daily or almost daily</p> <p>2 = Less than daily, but at least once a week</p> <p>3 = Less than weekly, but at least once a month</p> <p>4 = Less than monthly</p> <p>5 = Not at all</p> <p>6 = Don't know</p> |
| Quit intentions | <p>Quitting Smoking Contemplation Ladder</p> <p>Which of the statements below sounds most like you?</p> | <p>1 = I have decided not to quit smoking for my lifetime. I have no interest in quitting.</p> <p>2 = I never think about quitting smoking, and I have no plans to quit.</p> <p>3 = I rarely think about quitting smoking, and I have no plans to quit.</p> <p>4 = I sometimes think about quitting smoking, but I have no plans to quit.</p> <p>5 = I often think about quitting smoking, but I have no plans to quit.</p> <p>6 = I definitely plan to quit smoking in the next 6 months.</p> <p>7 = I definitely plan to quit smoking in the next 30 days.</p> <p>8 = I still smoke, but I have begun to change, like cutting back on the number of cigarettes I smoke. I am ready to set a quit date.</p> <p>9 = I have quit smoking, but I still worry about slipping back, so I need to keep working on living smoke free.</p> <p>10 = I have quit smoking.</p> |
| Fagerström Test for Nicotine Dependence | How soon after you wake do you smoke your first cigarette? | <p>1 = Within 5 minutes</p> <p>2 = 6 to 30 minutes</p> <p>3 = 31 to 60 minutes</p> <p>4 = After 60 minutes</p> |
| | Do you find it difficult to refrain from smoking in places where it is forbidden, e.g. in church, at the library, in cinemas etc.? | <p>1 = Yes</p> <p>0 = No</p> |
| | Which cigarette would you hate most to give up? | <p>1 = The first cigarette in the morning</p> <p>2 = Any other</p> |
| | Do you smoke more frequently during the first hours after waking than during the rest of the day? | <p>1 = Yes</p> <p>0 = No</p> |
| | Do you smoke if you are so ill that you are in bed most of the day? | <p>1 = Yes</p> <p>0 = No</p> |

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| Quit attempts | In your best guess, about how many times in your lifetime have you made a serious attempt to stop smoking? By serious attempt we mean that you decided that you would try to make sure that you never smoked another cigarette. | Text (integer) |
| Minimum CPD | What is the MINIMUM number of cigarettes that you have smoked on any day in the last two months? | Text (integer) |
| Maximum CPD | What is the MAXIMUM number of cigarettes you have smoked on any day in the last two months? | Text (integer) |

Table 3: Outcome measures

| Variable | Item | Response option |
|--|---|--|
| Perceived informed | I know enough about e-cigarettes to have formed accurate opinions. | 7-point scale (SA-SD) |
| Perceived harm | e-cigarettes are harmful. | 7-point scale + Don't know (SA-SD) |
| | e-cigarettes are less harmful than combustible cigarettes. | 7-point scale + Don't know (SA-SD) |
| Benefit to smokers | e-cigarettes are a helpful tool for people who want to quit smoking. | 7-point scale + Don't know (SA-SD) |
| Quality of evidence | There is convincing scientific evidence that e-cigarettes are safe. | 7-point scale + Don't know (SA-SD) |
| | There is convincing scientific evidence that e-cigarettes are safer than smoking. | 7-point scale + Don't know (SA-SD) |
| Biggest concerns | My biggest concern about e-cigarettes is... | their harmful contents / their addictiveness / the potential for freak accidents / their harm to others/ they are normalising smoking for young people / other (please elaborate). |
| Behavioural intentions | Do you think that you will try an e-cigarette / vaping device soon? | Definitely yes Probably yes Probably not Definitely not |
| | My future quit attempts will involve an e-cigarette / vaping device | Definitely yes Probably yes Probably not Definitely not |
| Perceived harm: Contents cigarettes | The health risks of smoking come from the tar in combustible cigarettes. | 7-point scale + Don't know (SA-SD) |
| | The health risks of smoking come from the nicotine in combustible cigarettes. | 7-point scale + Don't know (SA-SD) |
| Perceived harm: Contents e-cigarettes | E-cigarettes often contain tar. | 7-point scale + Don't know (SA-SD) |
| | E-cigarettes often contain chemicals that are harmful to the user's health. | 7-point scale + Don't know (SA-SD) |
| Perceived harm: Risk of accidents. | There is a high risk of harmful accidents when using e-cigarettes. | 7-point scale + Don't know (SA-SD) |
| Perceived harm: Risk to society. | Second-hand e-cigarette vapour can expose others to harm. | 7-point scale + Don't know (SA-SD) |
| Perceived harm: Risk of renormalising. | E-cigarettes normalise smoking, making more young people take up smoking. | 7-point scale + Don't know (SA-SD) |