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Perceptions of harm and intentions to use e-cigarettes after viewing different e-cigarette health messages

Submission date
17/10/2018

Recruitment status
No longer recruiting

Registration date
23/10/2018

Overall study status
Completed

Last Edited
15/07/2020

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Article 20 of the EU Tobacco Products Directive (EU-TPD) states that e-cigarette packets and refill products must carry a health warning of either 'This product contains nicotine which is a highly addictive substance', or 'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'.
Given the reduced risks associated with e-cigarettes, UK health and policy makers recommend that smokers who are unwilling or unable to quit should be encouraged to switch to e-cigarettes. However, in recent years, public misperceptions of harm associated with e-cigarettes use have increased, with only 13% of survey respondents in the UK correctly believing that e-cigarettes are considerably less harmful than tobacco smoking.
The purpose of this online experiment is to investigate the potential effects of the EU-TPD health warning labels on e-cigarette products versus a newly generated comparative health message statement on smokers' and non-smokers' perceptions of harm and intentions to use e-cigarettes. Additional aims of this study are to measure the effects on smokers' intentions to quit and use e-cigarettes in quit attempts. Lastly, the potential benefits of providing a comparative harm message either in addition to the TPD warning or as a stand-alone message will be explored.

Who can participate?
Adults in the UK who are not current e-cigarette users or ex-smokers

What does the study involves?
This is an online experiment and should take approximately 10 minutes to complete.
After reading the study information and agreeing to take part, participants will be asked to provide some information about themselves and their smoking habits and e-cigarettes use. They will then be asked some questions about how harmful, addictive and acceptable e-cigarettes are and their intentions to use them in the future. This will be followed by viewing several e-cigarette package images which may include either written statements warning about nicotine addictiveness, written statements about health or no written statements at all. Participants will then be asked questions about the images, the written messages and some more questions

about their perceptions of e-cigarettes and intentions to use. Finally, participants will be presented with an on-screen debriefing letter explaining the full aims of the study and providing NHS links with useful advice on ways to quit and supporting materials including further information about e-cigarettes.

What are the possible benefits and risks of participating?
Participants will be awarded with points, which they will receive after completing the survey. The number of points can be redeemed in cash or vouchers (i.e. Amazon). Respondents can redeem their cash after cumulating 150 points or more (equating to £15).
The panel recruitment agency MRFGR, a Division of AGENTC Ltd will be responsible for the recruitment and payment of participants. Participants are awarded with points which they receive after completing the survey.
There are no known risks to participants taking part in this study. However, it is possible that the exposure of the images of e-cigarettes may induce an interest in non-smokers/never e-cigarette users to use an e-cigarette. To mitigate against this risk, participants will be fully debriefed about the relative risks of e-cigarettes and warned that these products are not recommended for non-smokers.

Where is the study run from?
London South Bank University (UK)

When is the study starting and how long is it being run for?

Who is funding the study?
Cancer Research UK (UK)

Who is the main contact:
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CRUK Grant Number: 25855; Open Science Framework: osf.io/ta4vx

Study information

Scientific Title
The effects of the European e-cigarette health warnings and comparative health messages on non-smokers' and smokers' risk perceptions and behavioural intentions

Study objectives
This Cancer Research UK (CRUK) funded study will investigate the effects of the TPD e-cigarette health warnings and a comparative harm message on smokers' and non-smokers' perceptions of harm, addictiveness and social acceptability of e-cigarettes. Additional aims are to evidence the potential effects of the TPD warnings, as they are implemented, on smokers' intentions to purchase and use e-cigarettes in future quit attempts. Lastly, the potential benefits of providing a comparative harm message either in addition to the TPD warning or as a stand-alone message will be explored.

Hypothesis 1:
Participants exposed to the TPD health warning will rate e-cigarettes as more harmful and addictive compared to those exposed to the TPD warning combined with a comparative message (TPD+) the comparative health message (COMP) alone and the no message control condition

Hypothesis 2:
For participants exposed to the TPD health warnings, post-exposure scores on intentions to purchase and use e-cigarettes will decrease compared to those exposed to the COMP alone, the TPD+ messages, or no message (control)

Hypothesis 3:
TPD health warnings will decrease quit intentions in smokers and the comparative health message (COMP and TPD+ conditions) will attenuate this effect

For hypotheses 1 and 2 we will explore differences between smokers and non-smokers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London South Bank University Ethics Committee, 04/07/2018, reference SAS1815

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Smoking-related behaviours

Interventions
Block randomisation will be used for allocation of conditions and demographic variables (including smoking status) will be stratified so that the sample of smokers is representative of the target population in line with ONS data. Each participant will be assigned to one of the six conditions to obtain equal group sizes using IBM SPSS. Participants will be exposed to one of six stimuli displayed on screen for a standardised period of 30 seconds. Message statements will be displayed on e-cigarette package images as per the current EU-TPD warning labels on e-cigarette products. Warning label stimuli are:
1. TPD1: TPD health warning as per currently implemented in the UK. “This product contains nicotine which is a highly addictive substance"
2. TPD2: TPD longer health warning as currently implemented in many EU countries: "This product contains nicotine which is a highly addictive substance. It is not recommended for non-smokers"
3. COMP: Comparative health message as generated in the pilot study (using the same parameters used for the TPD warning labels; font, font colour, size and placement on the pack)
4. TPD1+: The TPD health warning (TPD1) in combination with the comparative message (using the same parameters above)
5. TPD2+: The TPD longer health warning (TPD2) in combination with the comparative message (using the same parameters as above).
6. No message: A no message condition using the same e-cigarette packages
There will be no follow-up period and the study experiment will take approximately 10 minutes.

Intervention Type
Behavioural

Primary outcome measure
Smokers’ and non-smokers’ perceptions of e-cigarettes associated with:
1. Harm
2. Addictiveness
3. Social acceptability
4. Effectiveness
5. Intention to purchase
6. Intention to use e-cigarettes
This will be assessed at the baseline and at the end of the intervention (after exposure to messages) using a 7-point Likert rating scale with the anchors "Extremely" to "Not at all"

Secondary outcome measures
N/A

Overall study start date
01/04/2018

Completion date
31/01/2019

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Resident in the UK
3. Fluent in English

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2400 participants will be recruited (1200 smokers and 1200 non-smokers)

Total final enrolment
2495

Key exclusion criteria
1. Current e-cigarette users (including dual users, those who smoke tobacco cigarettes and use e-cigarettes)
2. Former smokers

Date of first enrolment
12/11/2018

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Addictive Behaviours Research, London South Bank University
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/02vwnat91

Funder(s)

Funder type
Not defined

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We will disseminate a lay summary, explaining our findings and their importance. The findings will be disseminated via open access peer-review publication, conference presentations and press releases, and shared with a number of charities, practitioners and public health and policy organisations via presentations, briefing papers and web-based material. We expect the dissemination of the data to occur some time around end of March, beginning of April.

Intention to publish date
31/01/2021

Individual participant data (IPD) sharing plan
The study will use a panel agency that is GDPR (General Data Protection Regulations) compliant. All data will be kept in accordance with the study protocol and with GDPR's requirements under password protected networked PCs and any documents on hard copies in locked filing cabinets in a locked office. Once finalised, anonymised data will be deposited on the University's open data repository. The data collected are intended to benefit the general public and to inform policy decision making; we will therefore preserve all data resulting from the study (with the exception of personal data) and make it publically available with as few restrictions as possible. The data will be given a CC-BY license which will require any future users to acknowledge the investigators in any subsequent publications arising from use of the data

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/11/2018		Yes	No
Results article	results	01/02/2020		Yes	No