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PARTICIPANT INFORMATION SHEET
Exploring the opinions and potential impact of unflavoured e-liquid on smoking cessation among smokers and smoking relapse among e-cigarette users

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Before you decide if you would like to participate in this research study, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully. Take time to decide whether or not you wish to take part and remember that your participation is voluntary.

What is the purpose of the study?

It is important to consider what factors influence current cigarette smokers to switch to using e-cigarettes, and what keeps current vapers from returning to smoking cigarettes. The use of flavoured e-liquid may be an important factor when considering smoking cessation and initiation of e-cigarette use in adults. Many people use vaping as a way to begin the process of quitting smoking, but it may be the availability of different flavours that allows so many to use this as an effective method. This study aims to look at the impact that unflavoured e-liquid has on current smokers and current vapers.

Am I eligible to take part?

Please note you must be aged over 18 to volunteer. Please read all of these criteria very carefully and contact the researcher if you have any doubts regarding your eligibility. If you do not pass the screening on the study day, you will not be able to take part, and we cannot offer reimbursement for screening failures.

In order to take part, you should:

- Be at least 18 years of age
- Currently live in the UK
- EITHER be a daily smoker* OR a daily e-cigarette user** who has quit smoking in the last 12 months
- Be willing to try an e-liquid and e-cigarette (provided by the research team)
- Be willing to self-administer a urine test (provided by the research team) to check for cotinine and pregnancy (if female)

- Speak English as a first language (or equivalent level of fluency)
- Be able to give informed consent as judged by the investigator
- Be able to attend two online study sessions using a virtual meeting platform (Zoom)
- Have not had, or been in contact with anyone who has had, any flu-like or coronavirus (COVID-19) symptoms in the last 10 days***

***In order to take part as a smoker, you must also:**
- Have smoked 5 or more cigarettes per day for the last 3 or more months
- Not be currently attempting to quit (i.e., not currently using nicotine replacement products or in active smoking cessation treatment), and not currently using an e-cigarette

****In order to take part as a daily vaper, you must also:**
- Have vaped 5 or more times a day for the last 3 months at least
- Have recently quit smoking (defined as previously met the definition of a current smoker above within the last 12 months, but have since replaced smoking with use of an e-cigarette for at least 1 month)
- Only currently use non-tobacco/non-menthol flavoured e-liquids (e.g., fruit flavoured)
- Use nicotine-containing e-liquids

***Participants who have received their e-cigarette and e-liquid will be able to reschedule their study session if they develop symptoms prior to their study session

You would **not** be able to take part in the study if you;
- Have any known allergies to the e-liquid ingredients
- Have a current/past significant physical illness, including lung conditions such as asthma
- Have a current/past significant psychiatric illness (excluding mild conditions that have not required medication)
- Have uncorrected visual or hearing problems
- Have any current sensory problems (loss of sense of smell or taste)
- If female, are currently pregnant or breastfeeding or planning to become pregnant during the study period.

Smoking/e-cigarette use (i.e., nicotine use) will be assessed via a self-administered urine test to detect cotinine (a biproduct of nicotine). Females will be additionally required to take a self-administered pregnancy urine test. You will not be enrolled onto the study until the test results have been confirmed by the research coordinator via a virtual meeting platform (Zoom).

Expenses and reimbursement

Participants who are ineligible on the testing day based on the criteria described above, will not be reimbursed. To reimburse you for your time, you will receive a £20 Love2shop voucher, and you can keep the e-cigarette and remaining e-liquid at the end of the study. Participants who withdraw from the study after experiencing an adverse reaction will receive full reimbursement (£20 Love2shop voucher). Participants who withdraw prior to study completion for any other reason will receive no reimbursement.

How much time will the study take?

In total, we expect that you will spend less than 30 minutes completing screening procedures and less than 5 hours participating in the study (including a 4-hour vaping period).

What will I have to do?

Telephone Screening:

A researcher will arrange a telephone screening with you in which you will be assessed for your eligibility for the study. This information is for screening purposes only. All of this information will be kept strictly confidential. Only your gender, age, and smoking/vaping habits, will be used as study data. If you would rather not give this information, this is fine, but we may not be able to decide whether you are eligible to participate. The telephone screening will last approximately 20 minutes.

Remote Screening:

If you pass the telephone screening, we will ask you to complete an online consent form and will ask you for your home postal address, which we will send an e-cigarette and bottle of unflavoured e-liquid to along with the urine test(s). You will be asked to complete the urine test(s) on the morning of your remote screening (approximately one week after telephone screening). In the remote screening you will show the researcher the result of the urine test(s). The remote screening will last approximately 10 minutes.

Online Survey and Vaping Period:

If you pass the remote screening, you will be asked to complete a short online survey which will take approximately 10 minutes. When you have completed the survey, you will be asked to use the e-cigarette and e-liquid we have provided instead of smoking or using your own e-cigarette until your online interview (approximately 4 hours later).

Online Interview:

You will then complete an online video interview via a virtual meeting platform (Zoom), in which you will be asked for your opinions of the e-liquid and how your behaviour would be affected if other e-liquid flavours were unavailable. You will receive both a debrief form and your reimbursement voucher via email. The interview will last approximately 40 minutes.

What are the possible disadvantages and risks of taking part?

As a current smoker/vaper, you may already know the risks associated with vaping. If you are a smoker who is new to vaping, it can take around three days to adjust to e-cigarette use, with some potential side effects including a dry cough, mouth and throat irritation, headache, dizziness, and light-headedness. If you are a vaper, you should not experience any side effects as you regularly use e-cigarettes. It is possible that the ingredients in the e-liquid may cause an allergic reaction - please review the ingredients of the e-liquid to ensure that you are not allergic to any of the ingredients. Stop vaping and inform the researcher if you have a reaction to the e-liquid. Please ensure you follow Public Health England's advice surrounding the risks of coronavirus (COVID-19). This includes washing hands regularly, using antiseptic wipes provided to keep the e-cigarette clean and not sharing the device with others. Your life insurance or private medical insurance could be affected by taking part and if you have private medical insurance you should check with the company before agreeing to participate. The e-cigarette you receive will be fully charged. Should you choose to keep it, please ensure that you only use the provided charger to charge it. Failure to do so could result in injury.

What are the possible benefits of taking part?

Although this study may help us to understand the importance of flavours in e-liquid, you would not directly benefit from taking part in this research study and your participation is voluntary.

What if there is a problem?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for it. Regardless of this, if you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, please contact Angela Attwood (angela.attwood@bristol.ac.uk).

Will my taking part in this study be kept confidential?

Yes. Your identity and personal information that could identify you (e.g., name, email address, postal address) will be kept securely by the study team and will not be shared publicly or with other research groups. On occasion this information may be made available to university research staff and government bodies which monitor whether research studies are performed properly. However, this will only be in the context of monitoring and this information will not be used to contact you or to make your participation in this study known. This research study will adhere to General Data Protection Regulation (GDPR) and the Data Protection Act (DPA) 2018. We will be using information from you in order to undertake this study and will act as the data controller for this. This means that we are responsible for looking after your information and using it properly. We will keep identifiable information about you (name, email address) until one year after the study, but this will not be shared or be part of your study data. If you agree to take part in a study, data about you will be processed for a task in the public interest, which is consistent with the University Charter for scientific research.

What would happen to the results of the research study?

During the study, we will collect two types of data: screening data and study data. Both types of data are anonymised. This means we give the data a unique identification number and your personal information (e.g., name, email address) is removed, so that you cannot be identified by this information. Screening data are collected before you are fully enrolled onto the study. They identify whether you are eligible for the study, but they are not part of the study data. We keep these data securely within our research group but do not share it. Study data refer to the information gathered once you are enrolled onto the study. These data are collected to answer our research questions. Interviews will be audio recorded and stored on a secure drive (in a folder only accessible by the research team) until they are transcribed. Once transcribed and identifiable information has been removed, original audio files will be deleted, and the transcription will be labelled using an anonymised unique identification number. When the study has been completed, we would analyse the study data we have collected and report the findings. This would be reported in an appropriate scientific journal or presented at a scientific meeting. You would not be identified in any way and if you would like a copy of the final paper, you may request this. As your study data are anonymised, it would not be possible to identify you by name from any aspect of documentation or reporting for this research study. Your rights to access your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally identifiable information possible. At the end of the study your data would become “open data”. This means that it would be stored in an online database so that it is publicly available. Your screening data would not be shared.

What is open data?
Open data means that study data are made available, free of charge, to anyone interested in the research, or who wishes to conduct their own analysis of the data. We would therefore have no

control over how these data are used. However, all data would be anonymised before being made available and therefore there would be no way to identify you from the study data.

Why open data?
Sharing research data and findings is considered best scientific practice and is a requirement of many funding bodies and scientific journals. As a large proportion of research is publicly funded, the outcomes of the research should be made publicly available. Sharing data helps to maximise the impact of investment through wider use and encourages new avenues of research.

Can I withdraw my study data after I have participated in the study?

Yes. If you decide that you do not want your data to be used, you can contact the study team and request that your data are withdrawn. You can do this up to one year after the study ends or up until the point the data are shared as "open data" (whichever comes first). At this point links between your identity and your anonymised data set would be destroyed, and therefore we would no longer be able to withdraw your data as we would no longer be able to identity which data set is yours.

Who is organising and funding the research?

The study is being organised by the authors listed, at the University of Bristol. It is funded by Public Health England (PHE).

Who has reviewed the study?

This study has been reviewed by the School of Psychological Science Human Research Ethics Committee, a subcommittee of the Faculty of Life Sciences Ethics Committee (reference: 010421116008).

Who can I contact for further information?

If you have any questions about this study or you would like to take part, please contact Jasmine Khouja (jasmine.khouja@bristol.ac.uk).