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A research database collecting long-term behavioural data directly from participants, and health data from medical records to create a bank of data pertaining to people who have quit smoking, both with and without switching to e-cigarettes

Submission date 10/08/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 31/08/2022	**Overall study status** Completed	
Last Edited 25/03/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims

In the UK 3.6 million people use e-cigarettes (ECs). In the short-term ECs have been shown to be much less harmful than tobacco cigarettes, but there is not much data available on the long-term effects. The E-Cigarette Registry has been created to collect data on people who have quit smoking, both with and without switching to ECs, with the aim of collecting a broad range of data over a long period of time to see the long-term effects.

Over recent years ECs have become the most popular tool to help people stop smoking (cessation). Whilst studies suggest ECs are much less toxic than conventional cigarettes, there is no good quality long-term data on their effects. Compared to other nicotine replacement therapies (NRTs) we don't know very much about them. This is partly because ECs only came on to the market around 15 years ago, but also because EC trials tend to be quite short.

Smokers, healthcare professionals and regulators need more evidence on potential risks associated with long-term EC use.

A Patient and Public Involvement (PPI) Advisory Board of smokers and ex-smokers (including EC users) has been established to inform the recruitment designs, data collection, storage, data sharing and dissemination procedures. The PPI Advisory Board plays an essential role in developing and refining the project with the PMG. A participant in the Registry may be recruited to the PPI Advisory Board to give insight into Registry processes and the participant experience.

The researchers will also keep in touch with Registry participants by sending an annual newsletter to keep them informed of progress, engaged, and to thank them for their continued participation. They will also contact participants in order to recruit a participant representative to the PPI board.

Who can participate?
People aged 16 years or over who live in England or Wales, are happy to for their data to be collected, are willing to complete an annual questionnaire and are happy to communicate with the researchers in English

What does the study involve?
Participants will be sent a questionnaire once a year, to see how they are doing and what (if anything) they are smoking. The researchers will also collect information about the participants from organisations like NHS Digital. This can include but is not limited to NHS Digital, UK Health Security Agency (formerly Public Health England), the Office of National Statistics, participants' GPs, and other health data providers and research organisations.
To do this, the researchers will send them some information like participants' names and NHS numbers (so they can find them in their system). They will use the minimum number of identifiers possible to access the data, but this could also include postcodes. When they send this information they will attach a code and the information they send back will be health data and the code only, which means there will be nothing in that data which identifies participants directly, just the code.
Very few people will have access to the code and be able to link data back, this would be people like auditors who are there to make sure the researchers are protecting the data adequately and doing everything they should be to uphold the participants' rights and the integrity of the study. The data will be mixed with the other participants' data to make this resource for researchers. All information about participants will be kept confidential, de-identified (separate from their name with a code), safe and secure.
Over time, this will show if there's a difference between tobacco and vaping. Researchers may apply to use this data to improve their research. This may include commercial and overseas partners like universities abroad or companies interested in making nicotine replacement products. Participants will be emailed updates and asked if they would like to take part in any more research. If the researchers send a questionnaire and don't hear back in a few days, they will send a reminder email no more than twice.

What are the possible benefits and risks?
The researchers don't consider there to be any risk to participants as they are not asking that anyone change their behaviour or try anything new on their account, and there are no appointments to attend. There are some incentives available to participants for completing assessments. There are no other direct benefits to participants other than the knowledge that their involvement could help people in the future, and they may enjoy a sense of altruism from participation.

Where is the study run from?
The Cancer Research UK & King's College London Cancer Prevention Trials Unit (CPTU) (UK)

When is the study starting and how long is it expected to run?
February 2019 to February 2023

Who is funding the study?
Cancer Research UK

Who is the main contact?
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Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
272523

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Version 4.0 10 Feb 2022, IRAS 272523, CPMS 53821

Study information

Scientific Title
A long-term health data repository of people who have quit smoking with and without using e-cigarettes

Study objectives
The aim of the Registry is to collect prospective information on health outcomes in participants who quit smoking with and without using e-cigarettes (ECs). As the study has no pre-specified hypothesis, no formal sample size is required. Instead, the aim is to recruit as many participants as possible during the active recruitment period.

The researchers will regularly produce descriptive statistics describing changes in EC use (ex, current and never), dual use, health conditions, missing data, sample characteristics and quality control. The longitudinal design of the Registry will allow the researchers to explore trends over time to assess changes in health conditions between EC users and non-EC users.

In an interventional study, a formal sample size calculation may be required which will be dependent on the outcome, the expected effect size and prevalence of disease. This is not the case for the Registry as the results will be used to inform policy and current practice and will also be used to assess the robustness of previous studies conducted on smaller samples. The primary objective of the pilot phase is to establish and test infrastructure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Favourable opinion received 31/08/2021, Yorkshire & The Humber - Leeds East Research Ethics Committee
(NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048103; leedseast.rec@hra.nhs.uk), ref: 21/YH/0186

Study design
Open-ended prospective observational research study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
E-cigarette use

Interventions
The Registry is an open-ended, prospective observational research study (with no experimental procedure) to capture the long-term health effects of EC use. The design of the study is data linkage of individuals via national and local healthcare data repositories, with annual active data collection to ascertain relapse to tobacco or continuing use, among other self-reported data items. Data collection until pilot study end (28/02/2023).

Intervention Type
Other

Primary outcome(s)
1. Demand for Registry service measured using targeted surveys during scoping phase (pre-recruitment)
2. The availability and challenges of completing linkage for non-cancers/death particularly in primary care, assessed using quantitative and qualitative analysis at 6 monthly intervals until study end
3. Mortality and cancer incidence data collected from NHS Digital for all participants recruited at the time of application
4. Smoking/vaping status collected using automated participant surveys annually for 1 year

Key secondary outcome(s))
1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study at month 17 (recruitment end)
2. Retention rate assessed using the number of participants who consent to participate who remain in the study until the end of follow-up at month 17 (recruitment end)

Completion date
28/02/2023

Eligibility

Key inclusion criteria
1. Is 16+ years of age
2. Has a previous tobacco quit attempt
3. Consents to data linkage
4. Willing to provide annual follow-up data through direct methods (questionnaires) and indirect methods (through their health records)
5. Resides in England or Wales

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
138

Key exclusion criteria
1. Unwilling or unable to give consent
2. Cannot communicate (written and spoken) in English

Date of first enrolment

01/09/2021

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Kings College London Cancer Prevention Group
Bermondsey Wing
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet		31/08/2021	26/08/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes