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The effect of capping cigarette pack size on consumption

Submission date	Recruitment status	[X] Prospectively registered
03/03/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
06/03/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/04/2024	Other	

Plain English summary of protocol

Background and study aims
There is a lack of evidence regarding the impact of cigarette pack sizes (the number of cigarettes per pack) on the number of cigarettes people smoke. The aim of this study is to estimate the impact of asking smokers to buy cigarettes in smaller pack sizes on how many cigarettes they smoke. The results of this study will contribute to policy questions on whether cigarette pack sizes should be capped at 20 cigarettes per pack.

Who can participate?
Adult smokers living in Canada who currently smoke factory-made cigarettes from pack sizes of 25.

What does the study involve?
Participants will be asked to purchase their usual brand variant of cigarettes in pack sizes of 20 for 2 weeks and in pack sizes of 25 for 2 weeks. Participants will be asked to attach stickers to all of the cigarette packs they finish in both of these 2-week periods and fill in information about how many cigarettes they smoked. Participants will then send photos of the packs to the researchers and fill in online surveys about their smoking.

What are the possible benefits and risks of participating?
Participants will be helping to further the understanding of the effect of cigarette pack sizes on smoking and will be able to look up the findings of the study at the research team website (http://www.behaviourchangebydesign.iph.cam.ac.uk). Participants will receive a cheque as remuneration for their time spent completing the study.

Where is the study run from?
1. University of Cambridge (UK)
2. University of Waterloo (UK)

When is the study starting and how long is it expected to run for?
June 2019 to June 2021

Who is funding the study?
The study is funded by the Collaborative Award in Science from Wellcome Trust (Behaviour Change by Design: 206853/Z/17/Z) awarded to Theresa Marteau, Paul Fletcher, Gareth Hollands and Marcus Munafò. The funder is not involved in the study design or data analysis.

Who is the main contact?
Prof. Theresa Marteau
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Contact information

Type(s)
Scientific

Contact name
Prof Theresa Marteau

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Cigarette pack size and consumption: a randomized crossover trial

Study objectives
Reducing cigarette pack sizes from 25 to 20 reduces average consumption by 1.5 cigarettes per day.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 08/11/2019, University of Cambridge Psychology Research Ethics Committee (Cheryl Torbett, Administrator of the Cambridge Psychology Research Ethics Committee, School of the Biological Sciences, 17 Mill Lane, Cambridge, UK; +44 (0)1223 766894; Cheryl.Torbett@admin.cam.ac.uk), ref: PRE.2019.068
2. Approved 30/10/2019, Human Research Ethics Committee at the University of Waterloo (Joanna Eidse, 200 University Avenue West, Waterloo, ON, N2L 3G1, Canada; +1 (0)519-888-4567 ext. 37163; jeidse@uwaterloo.ca), ref: ORE 41353

Study design
Interventional randomized crossover trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Tobacco control

Interventions
Participants will be recruited through a research agency, LegerWeb from across Canada. Participants will not be informed of the true aim of the study at the beginning.

Participants will be asked to buy their usual brand variant of cigarettes in single pack sizes of 20 cigarettes per pack for a period of 2 weeks (the intervention) and asked for a second period of 2 weeks to buy their usual brand variant of cigarettes in single pack sizes of 25 (the control).

Randomisation will occur once participants have been deemed eligible. Participants will be randomised into one of two treatment orders. Treatment order one participants will be asked to consume pack sizes of 20 cigarettes for 2 weeks, followed by a 1-week washout period, followed by 2 weeks of consuming pack sizes of 25 cigarettes (B-A, where B is the intervention and A is the control). Treatment order two participants will be asked to consume pack sizes of 25 cigarettes for 2 weeks, followed by a 1-week washout period, followed by 2 weeks of consuming pack sizes of 20 cigarettes (A-B).

Allocation of participants to the order in which they will complete the conditions will be determined using a computer-generated random number sequence prepared by the senior project statistician, using Stata version 15 (StataCorp LLC, TX, USA). Block randomisation will be used to generate an equal number of participants allocated to each treatment order and to reduce the potential of selection bias compared to simple randomisation. The random number sequence, with IDs for the sequence of potential participants, will be concealed from the research team and participant until the participant has consented to taking part in the study and shown that they are able to purchase their usual brand variant of cigarettes in packs of 20 and packs of 25. When a participant is deemed eligible for randomisation, the research team will access the next random allocation in the sequence, and this participant will be assigned the corresponding ID.

Participants will be informed of their allocation. They will subsequently be followed up with an email to check receipt of their instructions and understanding of the study procedures.

Once outcome data have been collected this will be collated and transferred to the University of Bristol. Before transfer, the field referring to allocation will be coded as X or Y according to the allocation. The data analyst who will conduct the analyses will not be informed of which of X or Y refers to participants who start with pack sizes of 20 or participants who start with pack sizes of 25.

Intervention Type
Behavioural

Primary outcome(s)
The average number of cigarettes smoked per day by participants during the two 2-week periods, calculated by adding up all of the cigarettes smoked within each study period and dividing by 14 to obtain a measure of daily consumption.
The number of cigarettes smoked will be assessed from photographs participants take of their empty cigarette packs labelled with stickers with the following information:
1. Date pack finished
2. Number of cigarettes smoked by participant from this pack (excluding those given away or not consumed by the participant for any other reason)
3. Number of cigarettes smoked by participant not from that pack while that pack has been open (e.g. given to them by a friend)

Key secondary outcome(s))
Motivation to stop smoking measured using the Motivation to Stop Scale (MTSS) with responses to the question: Which of the following describes you? Responses range from (1) I don't want to stop smoking to (7) I REALLY want to stop smoking and intend to in the next month. Assessed at two timepoints: at the end of the intervention period and at the end of the control period.

Completion date
24/06/2021

Eligibility

Key inclusion criteria
1. Aged 19 years and over
2. Smoke factory-made cigarettes
3. Have smoked at least 100 cigarettes in their lifetime
4. Currently smoke 10 or more cigarettes a day on every day of the week
5. Normally purchase cigarettes in packs of 25
6. Use a brand or brand variant in which cigarettes are available in pack sizes of 20 as well as 25 in a shop convenient to them
7. Live anywhere in Canada outside of British Columbia, Northwest Territories, Nunavut and Yukon. (The province of British Columbia only sells packs of 20 cigarettes. All other provinces sell packs of both 20s and 25s)
8. Able to read and write sufficient English to complete all study procedures
9. Willing to record on each cigarette pack dates when the pack was opened and when finished
10. Willing to send photos for 4 weeks of their completed cigarette packs
11. Willing to purchase and smoke their usual brand variant in packs of 20 for 2 weeks

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
19 years

Sex
All

Total final enrolment
254

Key exclusion criteria
1. Pregnant women and women trying to become pregnant
2. Intend to quit smoking in the next 3 months
3. Used e-cigarettes weekly over the past month, and intend to continue
4. Smoked roll-your-own (RYO) cigarettes once a week or more over the past month and intend to continue
5. Normally transfer cigarettes into a case
6. Do not usually buy their own cigarettes
7. Live in the same household as someone who has enrolled in the study

Date of first enrolment
06/07/2020

Date of final enrolment
27/04/2021

Locations

Countries of recruitment
United Kingdom

England

Canada

Study participating centre
University of Cambridge
Institute of Public Health
Robinson Way
Cambridge

United Kingdom
CB2 0SR

Study participating centre
University of Waterloo
School of Public Health & Health Systems
Waterloo
Canada
N2L3G1

Sponsor information

Organisation
University of Cambridge

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust. The study is funded by the Collaborative Award in Science from Wellcome Trust (Behaviour Change by Design: 206853/Z/17/Z) awarded to Theresa Marteau, Paul Fletcher, Gareth Hollands and Marcus Munafò. The funder is not involved in the study design or data analysis.

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data will be made available for sharing via the University of Cambridge Research Data Repository or Open Science Framework online data repository once the findings have been published. Anonymised, participant-level data will be uploaded to the University of Cambridge Data Repository (https://www.data.cam.ac.uk/repository). This website allows anyone to search for data output from studies at the University of Cambridge. Participants consent to anonymised data being made available to other researchers.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/11/2022	08/04/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results		24/01/2022	19/07/2022	No	No
Protocol file	version v1.8	03/03/2020	06/03/2020	No	No
Protocol file	version v1.9	02/07/2020	02/07/2020	No	No
Statistical Analysis Plan	version 12	30/06/2021	05/07/2021	No	No
Statistical Analysis Plan	version v13		20/07/2021	No	No