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STUDY PROTOCOL

Cigarette pack size and consumption: a randomised crossover trial

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Abstract

Background

There is an absence of experimental evidence regarding the impact of cigarette pack size on consumption. Based on robust evidence from studies of food consumption, it is plausible that smaller pack sizes might reduce cigarette consumption. Those smoking from smaller packs smoke fewer cigarettes per day, but the causal nature of this association is unclear. Given that the probability of quitting increases as daily cigarette consumption decreases, capping the pack size at which cigarettes are sold is a potentially important target for tobacco control.

The aim of the current study is to assess whether capping cigarette pack sizes at 20 reduces average consumption by at least 1.5 cigarettes per day, a realistic and important effect size to detect.

Methods

We aim to recruit 210 smokers in Canada who normally purchase cigarettes in pack sizes of 25. Participants will smoke from a single pack size (i. 20, ii. 25) throughout two two-week periods in a randomised crossover study. There will be a washout period (aka usual behaviour) of at least one week in between. The primary outcome is the average number of cigarettes smoked per day.

Trial registration: to be registered on ISRCTN and OSF

Discussion

The results of this study will inform tobacco control regulations regarding the maximum pack size at which cigarettes can be sold.

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Background

There is an absence of experimental evidence regarding the impact of cigarette pack size (the number of cigarettes per pack) on consumption. Based on robust evidence from studies of food consumption (Hollands et al., 2015), it is plausible that smaller pack sizes might reduce cigarette consumption. Those smoking from smaller packs smoke fewer cigarettes per day (Hill, White & Scollo, 1998), but the causal nature of this association is unclear. Given that the probability of quitting increases as daily cigarette consumption decreases (Begh et al., 2015), capping the pack size at which cigarettes are sold is a potentially important target for tobacco control.

While there has been progress in controlling tobacco use, particularly in high income countries, the absolute number of tobacco users worldwide is not yet decreasing (World Health Organization, 2017a) and smoking remains one of the largest risk factors for global burden of disease (Gakidou et al., 2017). Cigarette pack design has been the focus of several tobacco control interventions including graphic and text warning labels (World Health Organization, 2017) and more recently, removal of branding to produce plain or standardised packs (World Health Organization, 2016). The maximum size of packs in which cigarettes are sold remains a largely unregulated aspect of the product.

The size of packs in which cigarettes are sold varies across countries, with tobacco companies using cigarette pack sizes to target particular groups of consumers and promote brand switching (Persoskie, et al., 2018). Following regulation in Australia and the UK to make cigarettes less accessible to children the minimum pack size in which cigarettes can be sold was set at 20 (Scollo & Winstanley, 2017; The Standardised Packing of Tobacco Products Regulations, 2015). To our knowledge only in Russia, and some other countries formerly part of the Soviet Union such as Georgia, are cigarettes available for sale only in a pack size of 20. In Canada and New Zealand only pack sizes of 20 and 25 are permitted, while in other countries, pack sizes range widely. For example, in Australia they range from 20 to 50, and in Ireland from 20 to 30.

Limited, non-experimental evidence suggests an association between cigarette pack size and consumption. For example, those smoking more heavily tend to purchase cigarettes in larger packs (Hill et al., 1998). In a more recent observational study, smokers wanting to self-regulate their consumption reported a preference for smaller packs (Marti & Sindelar, 2015). There is, however, a lack of experimental evidence regarding the impact of cigarette pack size on purchasing or consumption (Hollands et al., 2015; Persoskie, Donaldson & Ryant, 2018).

A policy that could balance the need to limit the accessibility of cigarettes to new smokers and promote cessation in adult smokers is to place a cap on the size of cigarette packs at 20 cigarettes per pack in jurisdictions where the minimum pack size is 20.

Reducing the number of cigarettes smoked has the potential to increase rates of smoking cessation. A Mendelian randomisation study found that smoking one fewer cigarette per day increases the odds of cessation by 9% (Taylor, Munafò, & CARTA consortium, 2014). The impact of this reduction at a population level *i.e.* the number of additional ex-smokers achieved by any policy that reduces the number of cigarettes smoked at population-level will depend on the size of the population, the prevalence of smoking, and the reduction in smoking achieved. For example, in Canada, if smoking prevalence is 13% of the adult population of approximately 29 million, a reduction of one cigarette per day would lead to an estimated increase of 4,713 ex-smokers per year if we conservatively assume an increase in the odds of cessation of 5% for each fewer cigarette smoked per day. A reduction of 1.5 cigarettes per day, representing an 11% reduction in smoking for Canadian daily smokers who currently smoke an average of 13.7 cigarettes per day (Propel Centre for Population Health Impact, 2019), would increase the number of additional ex-smokers to 7,156 per year

(Blackwell et al., 2019). The size of any effect may not be maintained after the initial introduction of the policy, but regulation that prevents the introduction of larger pack sizes may play an important role in maintaining global declines in smoking prevalence by increasing smoking cessation among those smokers who are prevented from shifting to larger pack sizes. Such larger sizes are increasingly appearing in international markets following the introduction of tobacco control policies such as standardised packaging z.

A parallel group adaptive RCT was conducted in Australia (Lee et al., under review) to assess the impact on cigarette consumption of capping cigarette pack sizes at 20. The trial was halted because it would have been unable to detect a reduction of 2 cigarettes per day within a feasible sample size. This was due to higher than expected participant drop-out, non-compliance with the intervention and larger than anticipated variation in smoking consumption between participants. The mean cigarettes smoked per day was 15.9 in participants who were asked to smoke from pack sizes of 20 and 16.8 among controls who were asked to continue smoking from their usual pack sizes of 25 or more (difference -0.9: 95% CI [-4.3, 2.6]). A study with a crossover design and improved procedures to maximise participant retention and compliance with the intervention, would provide sufficient power to detect an effect of 1.5 cigarettes per day.

Study aim

To assess whether capping cigarette pack sizes at 20 reduces consumption by at least 1.5 cigarettes per day.

Methods

Study Design

Randomised crossover trial in which smokers who normally purchase cigarettes in pack sizes of 25 will smoke cigarettes from pack sizes of 20 and 25 for two, two-week intervention periods with a washout period of at least one week in between. The study is designed to detect a reduction in daily cigarette consumption of at least 1.5 cigarettes (a reduction of 11% in cigarettes smoked per day in populations smoking an average of 14 cigarettes per day).

Primary research question

Does reducing cigarette pack sizes from 25 to 20 reduce average consumption by 1.5 cigarettes per day?

Study hypothesis

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

Setting

Canada, involving a general population of adult smokers recruited via a research agency (Legerweb).

Participants and Recruitment

Inclusion criteria

i. Aged 19 and over.
ii. Smoke factory-made cigarettes.
iii. Have smoked at least 100 cigarettes in their lifetime.
iv. Currently smoke 10 or more cigarettes a day on every day of the week.
v. Normally purchase cigarettes in packs of 25
vi. 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.

vii. 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).
viii. Able to read and write sufficient English to complete all study procedures.
ix. Willing to record on each cigarette pack dates when the pack was opened and when finished.
x. Willing to send photos for four weeks of their completed cigarette packs.
xi. Willing to purchase and smoke their usual brand variant in packs of 20 for two weeks.

Exclusion criteria

i. Pregnant women and women trying to become pregnant.
ii. Intend to quit smoking in the next three months.
iii. Used e-cigarettes weekly over the past month, and intend to continue.
iv. Smoked roll-your-own (RYO) cigarettes once a week or more over the past month and intend to continue.
v. Normally transfer cigarettes into a case.
vi. Do not usually buy their own cigarettes.
vii. Live in the same household as someone who has enrolled in the study.

Appendix 1 contains questions used to assess eligibility of participants.

Sample size determination

Based on results from a recently completed parallel group trial in Australia, we consider that a difference in the primary outcome (the number of cigarettes smoked per day) of 1.5 cigarettes would be both of importance to detect and consistent with previous research. This earlier study did not collect data on baseline consumption in a sufficiently reliable manner, but the between person SD at follow up was 7.7 cigarettes per day. The within person SD would almost certainly be less than this because of within person correlation. In addition, control group participants in Australia were permitted to purchase packs as large as 50 cigarettes per pack, suggesting that variation between participants in Canada, where only packs of 20 and 25 are available, will be lower. However, we suggest using the upper estimate of 7.7 to be conservative. With 80% power, we would detect a difference of 1.5 as significant at a 2-sided significance level of 5% with 210 participants available for analysis (105 per sequence group). Based on a small pilot study we predict that 630 participants will need to be recruited to achieve 210 participants completing the study. The participant retention rate will be monitored during the study, and recruitment of participants will stop when 210 participants have completed the study.

Remuneration

Participants will be remunerated up to Can$400 for time spent completing the study procedures. This will be paid in one instalment at the end of their participation via a cheque. If participants drop out or withdraw partway through the study, they will be remunerated based on how much time they have spent in the study as estimated by how much of the study they have completed, as follows:

Purchasing their usual brand variant of cigarettes in one pack of 20 and one pack of 25 and sending photographs of these along with the receipt to the study team: $40

Intervention period 1:
Sending photographs of cigarette packs with completed stickers:
Day 7: $50
Day 14: $50

Completion of online survey: $50

Intervention period 2:
Sending photographs of cigarette packs with completed stickers:
Day 7: $70
Day 14: $70
Completion of online survey: $70

Withdrawal of participants

Participants will be informed that they can withdraw from the study at any time.

Randomisation

Randomisation will occur once participants have been deemed eligible. Participants will be randomised into one of two treatment orders. In treatment order one participants will be asked to consume cigarettes only from packs of 20 cigarettes for two weeks, followed by a wash out period of at least one week, followed by two 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 two weeks, followed by a wash out period of at least one week, followed by two weeks of consuming pack sizes of 20 cigarettes (A-B).

Table 1. The two possible treatment orders to which participants will be randomised

Study allocation	Intervention period 1 (2 weeks)	1 week wash out period	Intervention period 2 (2 weeks)
Treatment order 1 (B-A)	B	✓	A
Treatment order 2 (A-B)	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 blocks will be in sizes of 2,4 and 6. Simple random sampling would allow unequal group sizes. 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. The statistician completing the analysis will be blinded to allocation throughout the study.

Measures

Primary outcome measure

The number of cigarettes smoked will be calculated from photographs participants take of their empty cigarette packs labelled with stickers with the following information:

i. Date pack finished
ii. Number of cigarettes smoked by participant from this pack (excluding those given away or not consumed by the participant for any other reason)
iii. Number of cigarettes smoked by participant not from that pack while that pack has been open (e.g. given to them by a friend)
iv. Rating of warning message (to align with the study cover story):
"The warning on this pack is effective" Scale range: 0, No to 7, Yes.

There is an additional sticker for participants to stick to any packs that they are partway through at the end of an intervention period. This is to capture accurate information regarding the number of cigarettes smoked within each intervention period. See Appendix 2 for the stickers.

The average number of cigarettes smoked per day in each intervention period will be calculated by adding up all of the cigarettes smoked within each intervention period and dividing by 14 to obtain a measure of daily consumption.

Requiring participants to take photos of their empty cigarette packs allows their compliance with the intervention to be checked and makes it less likely that participants will forget to report the cigarettes they smoke during the study.

Secondary outcome measure

Motivation to stop smoking is measured at the end of each intervention period using an online questionnaire. It is assessed using a single item measure, the Motivation to Stop Scale (MTSS; Kotz et al 2013) 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.

Additional measures

Demographic characteristics

These are recorded once participants have consented to take part in the study. Measures include age and sex, and measures of socioeconomic status including income and highest educational level achieved. See Appendix 3 for the full list of questions.

Baseline smoking characteristics

Two measures of smoking behaviour and attitudes are assessed at baseline via an online questionnaire, once participants have consented to take part in the study.

i. *Heaviness of smoking*: this will be assessed using the Heaviness of Smoking Index (HSI) assessing cigarettes smoked per day and time to first cigarette (Heatherton 1989).
ii. *Motivation to stop smoking* (see above).

Other characteristics of smoking behaviour

We ask participants three questions about their smoking behaviour in order to tailor our instructions to them during the study.

1. 'How many factory-made cigarettes do you smoke per day?'

2. ‘What brand of cigarette do you usually purchase?’ (e.g. Marlboro).
3. ‘What brand variant of cigarette do you usually purchase?’ (e.g. Marlboro Smooth Taste’)
4. ‘Do you usually purchase Regular or King Size cigarettes?

Other variables
1. The cost per cigarette of cigarettes smoked in the two intervention periods will be calculated and recorded for each participant based on the receipt(s) they send us a photo of at the start.
2. The number of cigarette packs participants have available to them on the first day of each intervention period will be assessed using a one-item survey with the question, “How many packs of 25(20) do you currently have at home?”
3. More information about participant smoking behaviour during the intervention periods will be collected at the end of each intervention period using the End of Intervention Period survey (Appendix 4).
4. Preferences for cigarette purchasing and actual cigarette purchasing behaviour during the intervention periods will be assessed at the end of the study using the End of Study survey (Appendix 5).

Procedure
Participants will be recruited from a research panel after being screened for eligibility by the research agency and the study team. Participants will be shown the participant information sheet and asked to provide confirmation of their informed consent to participate using an online form. The study will be presented to participants as investigating how pack size affects the effectiveness of health warnings to avoid participants focusing on consumption in relation to pack size.

Participants will then complete the demographic and smoking behaviour questions. To confirm that participants are able to purchase their usual brand variant of cigarettes in pack sizes of 20 and 25, participants will be asked to first purchase one pack of each size, and send the research team a photo of both packs along with their receipt(s).

Once the photo is received, participants will be randomised to one of two treatment orders (see ‘Randomisation’ section). Participants will be emailed their instructions and will be mailed the stickers they will need during the study.

Once participants have confirmed receipt of the stickers, the research team will inform them of their start date for Intervention Period 1.

<u>Intervention Period 1</u>
Participants will be instructed to purchase and smoke their usual cigarette brand variant (including Kingsize or Regular) only in the allocated pack size (either 20 or 25) for 14 days.

On Day 1 participants will be sent a link to a one-item survey that will ask how many cigarette packs of the appropriate size for their condition that they currently have at home.

On Days 7 and 14, participants will be asked to send a photo to the study team of all of their empty cigarette packs with completed stickers attached. On Day 14, participants will be sent a link to the End of Intervention Period Survey.

<u>Wash-out period</u>
Participants will then have a break of at least seven days from the end of Intervention Period 1. During this time, participants can smoke from any cigarette packs they choose, including any packs leftover from Intervention Period 1. The research team will inform participants of their start date for Intervention Period 2.

Intervention Period 2
Participants will be instructed to smoke their usual brand variant of cigarettes in the alternative pack size, send photos of their completed packs and complete the online survey as in Intervention Period 1. Participants will also complete the End of Study Survey.

Debrief
The true study aim will be revealed to participants at the end of the study via a Debrief Information Sheet provided to participants in the End of Study Survey. Following debriefing, participants will be asked to provide their consent to use their data once again.

Reminders
Participants will be sent reminders to complete tasks throughout the study to optimise compliance with the study protocol.

Planned analysis

Descriptive statistics

A CONSORT flow chart will be constructed (Figure 1, p 13) to show numbers of individuals assessed for eligibility, randomised and followed up.

A table will compare demographic characteristics of participants allocated to the two possible treatment orders: means and SDs will be shown for continuous variables, with numbers and percentages within each category of nominal or ordered categorical variables.

Outcome analysis

Primary
Comparisons of primary outcomes listed above will be made by estimating the mean difference according to pack size condition, with 95% confidence interval and p-value obtained from a general linear model of the primary outcomes. This will involve a repeated measures analysis including terms for the treatment effect and order effect. Evidence for a treatment x order interaction will be examined, but this is not expected given the use of a washout period. Exact p values will be reported.

If data are shown to deviate strongly from a Normal distribution, confidence intervals and p-values will be calculated using other methods (e.g. bootstrap).

Secondary
The secondary outcome, MTSS, will be analysed in the same way as the primary outcome.

Checking assumptions
Residuals from models before and after adjustment for baseline variables will be assessed using a Normal probability plot.

Subgroup analysis
The study is unlikely to have sufficient power to detect any modest differences between demographic groups. However our earlier study (Lee et al, in preparation), suggested that heavier smoking may be associated with greater reductions in cigarette consumption as a result of the intervention, so we will test this in the current study by investigating the interaction between “treatment” and baseline consumption.

Missing data

We will account for missing data by including in our GLM analysis any variables likely to predict missingness (Groenwold, Moons & Vandenbroucke, 2014), over and above those already included because they relate to outcome. If missing data is extensive (more than 10% of participants), we will produce a Table comparing participants' characteristics between study arms for participants who have provided outcome data. These variables will include age, gender, and two measures of socioeconomic status (educational attainment and income).

Outliers
We will repeat key analyses where outcome variables differ from the median by more than 3 SDs

Non-adherence
We will repeat key analyses for the primary outcome, excluding participants deemed to have been non-adherent to the intervention. Non-adherence will be operationalised as participants smoking from packs of 25 during the two weeks when they should be purchasing packs of 20 and vice versa. Participants will be deemed to be adherent if at least 90% of the cigarette packs they use during each intervention period are of the correct size. While intention-to-treat analysis will be regarded as the primary analysis, a per-protocol analysis will be conducted as a secondary analysis to reflect the more explanatory (as opposed to pragmatic) nature of the trial.

Research Governance

In the UK, research will adhere to the Wellcome Trust Policy on Good Research Practice and the UK Policy Framework for Health and Social Care Research. Researchers also follow the principles laid out in the UUK concordat to support research integrity.

Ethical Considerations and Informed Consent

Ethics approval will be obtained the University of Cambridge Psychology Research Ethics Committee (PRE.2019.068) in the UK and through the Office of Research at the University of Waterloo (ORE#41353). As part of the recruitment process, the investigator will explain the processes and risks of the study to the participant. A cover story will be used to reduce confounding behaviours during data collection. Participants will be informed that they are free to withdraw at any time during the study. Participants will be given sufficient time to read the participant information sheet, consider any implications, and raise any questions with the investigators prior to making a decision to participate. Written consent will be obtained. After data collection, participants will be fully debriefed on the true purpose of the study and will be asked to provide their consent to use their data once again.

Sponsorship

The University of Cambridge will sponsor the study.

Insurance

The study will be insured by the University of Cambridge. The University of Cambridge arranges insurance cover for legal liability to pay damages for injury to volunteers participating in the study which has been caused by the University or its employees. Adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.

Safety

We do not anticipate any risks to the safety of participants during the study. Participants will have the contact details of the study team should they be concerned about anything related to the study.

Incident Reporting

Incident reporting will follow University of Cambridge procedures. Incidents will be documented at the end of the relevant session using an incident report. The reports will be anonymised by unique study identifier and stored securely. Incidents will be followed up until resolved if possible. At the end of the study a safety report will be compiled and sent to the Principal Investigator (PI) listing all incidents. Ethics committees will be notified of serious breaches as required.

Data Management

Personal identifiable data

University of Cambridge is the data controller for this study and will manage data in accordance with relevant legislation including GDPR guildelines. Personally identifiable information collected in this study (email address, IP address, home address, mobile number) will be stored securely so only those research team members who need to contact participants in this study have access to it. This information will be deleted when it is no longer required for data collection purposes.

Anonymous study data

Electronic data will be anonymised by a unique study identifier and the key will remain with the University of Cambridge. Anonymous study data will be held on University of Cambridge network drives and regularly backed up.

Data sharing

Anonymous study data will be shared with collaborators for the purposes of analysis and results interpretation under appropriate collaboration agreements.

Long term data archiving

At the end of the study, University of Cambridge electronic anonymous study data (including finalised data sheet) will be transferred to a designated storage facility for long-term archiving. Study data will be kept for a minimum of 20 years in line with the Wellcome Trust Award.

Collaborators may retain anonymous study data in line with the relevant collaboration agreements.

Open access

At an appropriate time, the anonymous study data sheet will be locked and made openly available on the University of Cambridge Research Data Repository or Open Science Framework online data repository.

Participant drop out

In the event that a participant drops out from the study during data collection, the investigator retains the ability to use all information collected prior to drop out unless the participant requests that their data is withdrawn.

Revoked data

If a participant decides that they do not want their data used they can request that the data are withdrawn. Data can be withdrawn up to two weeks after their participation in the study.

Quality control and quality assurance

The investigators will be responsible for data quality.

Publication Policy

The findings from this study will be published in at least one scientific journal and made available open access. They will also be presented at one or more scientific meetings. The data will be made available for sharing via the University of Cambridge Research Data Repository or Open Science Framework online data repository.

Funding Source

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.

Conflicts of Interest

The study investigators have no known conflicts of interest to declare.

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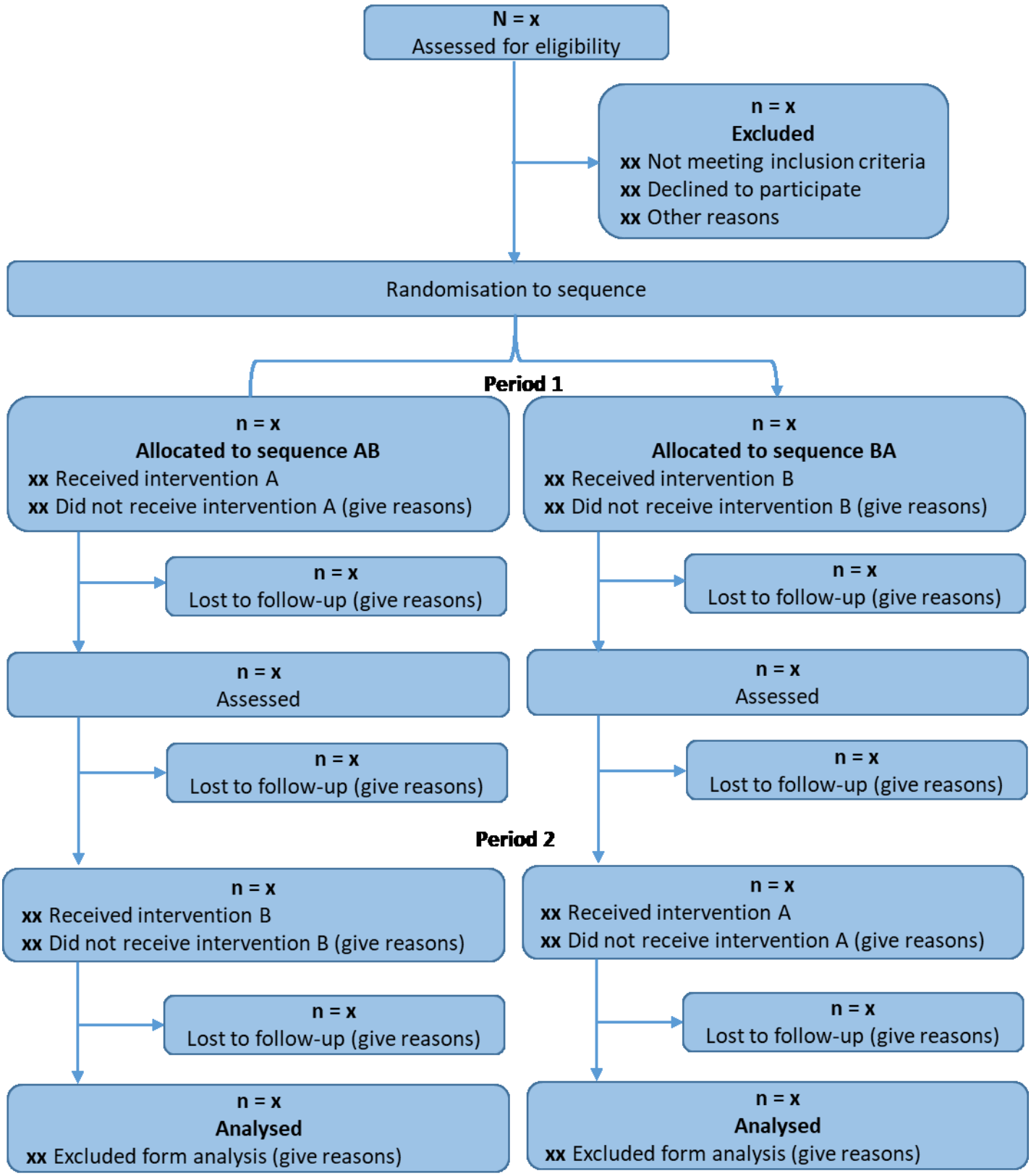
Figure 1: CONSORT Flow Diagram



Appendix 1 - Screening questionnaires

The table below contains the questions used to assess whether participants meet the eligibility criteria for the study.

Criteria	Research agency	Research team
i. Aged 19 and over.	How old are you? (text response) Screen out under 19	What is your age in years? Under 19 19-40 41-6- 61-80 Over 80 Screen out Under 19
ii. Smoke factory-made cigarettes.	Covered in multiple other questions	Covered in multiple other questions
iii. Have smoked at least 100 cigarettes in their lifetime.	In your lifetime, have you smoked at least 100 cigarettes (manufactured or roll-your own), or the equivalent amount of tobacco? Yes No Screen out No.	In your lifetime, have you smoked at least 100 cigarettes (manufactured or roll-your own), or the equivalent amount of tobacco? Yes No Screen out No.
iv. Currently smoke 10 or more cigarettes a day on every day of the week.	On average, how many factory-made cigarettes do you smoke per day? Text response Screen out below 10.	How many factory-made cigarettes do you smoke per day? 0-9 10-20 20-30 30+ Screen out 0-9.
v. Normally purchase cigarettes in packs of 25.	What pack size of cigarettes do you typically purchase? 20 25 Screen out 20	What size of cigarette pack do you normally buy? 20 25 Both Screen out 20 and 'Both'
vi. 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.	If needed, would you be able to purchase your usual brand variant of cigarettes in a pack size of 20 at a convenient location? Yes No Screen out 'No'	Would you be able to purchase your usual brand variant of cigarettes in pack sizes of 20 at a convenient location? Yes No Screen out 'No'.

vii.	Live anywhere in Canada outside of British Columbia, Northwest Territories, Nunavut and Yukon.	In which of the following do you currently reside? British Columbia > screens out Alberta Saskatchewan Manitoba Ontario Quebec New Brunswick Nova Scotia Prince Edward Island Newfoundland Northwest Territories > screens out Yukon > screens out Nunavut > screens out	In which province or territory do you live? British Columbia > screens out Alberta Saskatchewan Manitoba Ontario Quebec New Brunswick Nova Scotia Prince Edward Island Newfoundland Northwest Territories > screens out Yukon > screens out Nunavut > screens out
viii.	Able to read and write sufficient English to complete all study procedures.	Compared to the average or typical Canadian adult, how would you rate your own reading and writing skills in English? Screen out below 5	Compared to the average or typical Canadian adult, how would you rate your own reading and writing skills in English, using a scale from 0 to 10, where 5 means 'about average', 0 means 'very poor' and 10 means 'very good'? Screen out below 5
ix.	Willing to record on each cigarette pack dates when the pack was opened and when finished.	Bullet point confirmation at the end of screening survey	Are you willing to record the date on which you finish every cigarette pack for four weeks? Yes No Screen out No
x.	Willing to send photos for four weeks of their completed cigarette packs.	Bullet point confirmation at the end of screening survey	Are you willing to send photos of every cigarette pack you finish for four weeks? Yes No Screen out No
xi.	Willing to purchase and smoke their usual brand variant in packs of 20 for two weeks.	Bullet point confirmation at the end of screening survey	Would you be willing to purchase your usual brand variant of cigarettes in pack sizes of 20? Yes No Screen out No
Exclusion criteria:			
i.	Pregnant women and	Are you currently pregnant or trying to become pregnant?	Are you currently pregnant or trying to become pregnant?

	women trying to become pregnant..	Yes/No Screen out Yes.	Yes/No Screen out Yes.
ii.	Intend to quit smoking in the next three months.	Motivation to stop scale (MTSS) Which of the following describes you? a. "I don't want to stop smoking" b. "I think I should stop smoking but I don't really want to" c. "I want to stop smoking but haven't thought about when" d. "I REALLY want to stop smoking but I don't know when I will" e. "I REALLY want to stop smoking and hope to soon" f. "I REALLY want to stop smoking and intend to in the next 3 months" g. "I REALLY want to stop smoking and intend to in the next month" ANSWERS e-g screened out	Motivation to stop scale (MTSS) Which of the following describes you? a. "I don't want to stop smoking" b. "I think I should stop smoking but I don't really want to" c. "I want to stop smoking but haven't thought about when" d. "I REALLY want to stop smoking but I don't know when I will" e. "I REALLY want to stop smoking and hope to soon" f. "I REALLY want to stop smoking and intend to in the next 3 months" g. "I REALLY want to stop smoking and intend to in the next month" ANSWERS e-g screened out
iii.	Used e-cigarettes weekly over the past month, and intend to continue.	Do you currently smoke any of the following? • Factory made cigarettes • e-cigarettes • roll your own cigarettes • none of the above screen out 'none of the above' How often have you smoked roll your own cigarettes in the past month? • Every day • Most days • Once a week • Less than once a week Do you intend to continue smoking e-cigarettes/roll your own cigarettes?	Do you currently smoke any of the following? • Factory made cigarettes • e-cigarettes • roll your own cigarettes • none of the above screen out 'none of the above' How often have you smoked roll your own cigarettes in the past month? • Not at all • Less than once per week • Once per week or more Do you intend to continue smoking e-cigarettes/roll your own cigarettes?

		Yes/No If they smoke e cigarettes or roll your own cigarettes more than weekly and intend to continue, they are screened out.	Yes/No If they smoke e cigarettes or roll your own cigarettes more than weekly and intend to continue, they are screened out.
iv.	Smoked roll-your-own (RYO) cigarettes once a week or more over the past month and intend to continue.	Same as above	Same as above
v.	Normally transfer cigarettes into a case.	Do you typically transfer your cigarettes into a case for storage? Yes No Screen out Yes	Do you typically transfer your cigarettes into a case for storage? Yes No Screen out Yes
vi.	Do not usually buy their own cigarettes.	Do you typically purchase your own cigarettes? Yes No Screen out No	Do you typically purchase your own cigarettes? Yes No Screen out No
vii.	Live in the same household as someone who has enrolled in the study	Bullet point confirmation at the end of screening survey	Do you live in the same household as anyone else who as enrolled in the study? Yes No Screen out Yes.

Appendix 2 – Stickers

Label to be used on all cigarette packs.

Participant ID:	
Pack number:	
Date pack finished:	
The warning on this pack is effective No 1 2 3 4 5 6 7 Yes	
How many of these cigarettes did you smoke yourself?	
How many cigarettes from OTHER packs did you smoke while this pack was open?	

Label to be used on cigarette packs that have been started but are unfinished at the end of each intervention period.

Last day of Study Period	
How many cigarettes are left?	

Appendix 3 – Demographic measures

Which of the following categories best describes your ANNUAL household income, that is the total income before taxes, or gross income, of all persons in your household combined, for one year?
01 Under $10,000
02 $10,000-29,999
03 $30,000-44,999
04 $45,000-59,999
05 $60,000-74,999
06 $75,000-99,999
07 $100,000-149,999
08 $150,000 and over
77 Not Applicable
88 Prefer not to answer
99 Don't Know

What is the highest level of formal education that you have completed?
1 Grade school/ some high school
2 Completed high school
3 Technical/ trade school or community college
4 Some university, no degree
5 Completed university degree
6 Post-graduate degree
7 Not applicable
8 Prefer not to answer
9 Don't know

Thinking about your family's income, how difficult or easy is it to make ends meet?
1= Very difficult
2= Difficult
3= Neither easy nor difficult
4= Easy
5= Very easy
-77= Don't know
-88= Prefer not to answer

What sex were you assigned at birth, on your original birth certificate?
1= Female
2= Male
-77=Don't know
-88= Prefer not to answer

Are you an Aboriginal person, that is, First Nations (North American Indian), Metis or Inuk (Inuit)?
Note: First Nations (North American Indian) includes Status and Non-Status Indians.
1= No, not an Aboriginal person
2= Yes, First Nations (North American Indian)
3= Yes, Métis
4= Yes, Inuk (Inuit)
-88= Prefer not to answer

People in Canada come from many racial and cultural groups. Choose the group(s) that best apply/applies to you.
SELECT ALL THAT APPLY.

1= White
2= South Asian (e.g., East Indian, Pakistani, Sri Lankan, etc.)
4= Chinese
5= Black
6= Filipino
7= Latin American
8= Arab
9= Southeast Asian (e.g., Vietnamese, Cambodian, Laotian, Thai, etc.)
10= West Asian (e.g., Iranian, Afghan, etc.)
11= Korean
12= Japanese
13= Other _____
-77= Don’t know
-88= Prefer not to answer

Appendix 4 – End of Intervention Period survey

At the end of each of the two intervention periods, the following questions will be asked to each participant using an online survey:

1. How effective did you find the warning labels on your cigarette packs over the last two weeks? (Rating from 1 (Not at all) – 7 (Extremely)
2. How many cigarettes do you think you smoked in the last two weeks compared to the number you usually smoke?
    a. Fewer
    b. About the same
    c. More
    d. Don't know
3. In the last 2 weeks, have you changed how much smoke you inhale from each cigarette, by changing the number of puffs or how deeply you inhale?
    a. Less smoke than usual
    b. About the same
    c. More smoke than usual
    d. Don't know
4. Is there anything that affected your usual pattern of smoking over the last two weeks?
5. Did Covid-19 affect the number of cigarettes you bought in the last two weeks?
    a. No
    b. Yes – I bought more cigarettes in the last two weeks because of Covid-19.
    c. Yes – I bought fewer cigarettes in the last two weeks because of Covid-19.
6. Did Covid-19 affect the number of cigarettes you smoked in the past two weeks?
    a. No
    b. Yes – I smoked more cigarettes in the last two weeks because of Covid-19.
    c. Yes – I smoked fewer cigarettes in the last two weeks because of Covid-19.

Appendix 5 – End of Study survey

At the end of the study (the end of Intervention Period 2), the following questions will be asked to each participant using an online survey:

1. Do you try to make your usual pack of 25 cigarettes last a certain amount of time?
    d. Always
    e. Sometimes
    f. Never

    If you answered (a) or (b), please answer Questions 2 and 3 below:

2. How long is this? …..days or …….hours
3. Did you try to keep to the same amount of time for pack sizes of 20?
    a. Yes
    b. No

    Thinking about the two weeks when you were smoking from packs of **20 cigarettes**, please answer the following questions…

4. When you finished a pack did you usually:
    a. have another pack ready to start
    b. go out to buy another pack

    If you answered (b), please answer question 5 below.

5. When did you usually go out to buy another pack:
    a. Immediately, or as soon as I realistically could e.g. first thing in the morning if I finished the pack at night
    b. I waited

    If you answered (b), how long did you try to wait? ……hours

6. How did you buy your cigarettes when you were buying them in packs of 20?
    a. in individual packs as I needed them
    b. in multiple packs of 20s
    c. in a carton containing multiple packs of 20 cigarettes
    d. other (please specify)
7. How often did you buy cigarettes when you were smoking from pack sizes of 20 compared to packs of 25?
    a. Less often
    b. More often
    c. The same

    Thinking about the two weeks when you were smoking from packs of **25 cigarettes**, please answer the following questions…

8. When you finished a pack did you usually:
    a. have another pack ready to start
    b. go out to buy another pack

    If you answered (b), please answer question 9 below.

9. When did you usually go out to buy another pack:
    a. Immediately, or as soon as I realistically could e.g. first thing in the morning if I finished the pack at night
    b. I waited

    If you answered (b), how long did you try to wait? ……hours

10. How did you buy your cigarettes when you were buying them in packs of 25?
    a. in individual packs as I needed them
    b. in multiple packs of 25
    c. in a carton containing multiple packs of 25 cigarettes
    d. other (please specify)

11. Which is better value for money for you:
    a. Buying cigarettes in pack sizes of 20
    b. Buying cigarettes in pack sizes of 25
    c. No difference
    d. Don't know

12. Thinking about your experiences of the two cigarette pack sizes (20 and 25), please indicate in the box below which size you preferred, and why.
13. Why do you normally purchase cigarettes in packs of 25?
14. Thinking again about your experiences with each cigarette pack size, please indicate in the box below which size you would prefer to buy from now and why.
15. Please use the space below to briefly tell us what you think the study was about
16. Thinking about your experiences with each cigarette pack size, do you think the different pack sizes had any impact on your smoking or how much you smoked, and if so why?
17. Please use the space below to make any other comments about this study.
18. [After participants have been debriefed on the study purpose] Now you know what the study was about, are there any comments you would like to make?