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The effect of capping the size of cigarette packs on consumption

Submission date
20/12/2018

Recruitment status
No longer recruiting

Registration date
04/01/2019

Overall study status
Completed

Last Edited
27/02/2023

Condition category
Mental and Behavioural Disorders

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

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 Australia who currently smoke an eligible brand-variant of factory-made cigarettes from pack sizes of 25 cigarettes or more are eligible to participate in this study.

What does the study involve?
Participants will be randomly allocated to either the control or the intervention condition. Participants in the intervention condition will be asked to purchase their usual brand variant of cigarettes in pack sizes of 20 for four weeks. Participants in the control condition will be asked to continue purchasing cigarettes in their normal pack sizes.

What are the possible benefits and risks of participating?
Participants will be helping to further our understanding of the effect of cigarette pack sizes on smoking. A summary of the research findings will be made available to participants.
Participants receive online vouchers in compensation for their time spent completing the study.

Where is the study run from?
Roy Morgan Research Ltd, Tonic House, 386 Flinders Lane, Melbourne, Australia, VIC 3000

When is the study starting and how long is it expected to run for?
The study started in September 2018 and is expected to run for nine months until June 2019.

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?
Professor Theresa Marteau, Director of the Behaviour and Health Research Unit, University of Cambridge, tm388@medschl.cam.ac.uk.

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Cigarette pack size and consumption: a parallel group randomised controlled trial

Study information

Scientific Title
Cigarette pack size and consumption: a parallel group randomised controlled trial

Study objectives
Participants smoking from pack sizes of 20 cigarettes will smoke fewer cigarettes than those smoking from pack sizes of 25 cigarettes or more.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridge Psychology Research Ethics Committee, 13/09/2018, ref. PRE.2018.037.

Amendments made to protocol in December 2018, ref. PRE.2018.125 - approval pending

Primary study design
Interventional

Study design
Interventional, parallel group, randomised controlled trial

Study type(s)
Prevention

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

Interventions
A randomised controlled trial in which smokers who routinely purchase cigarettes in pack sizes of 25 or more are randomised to one of two groups for a period of 4 weeks:
Group 1: Intervention: buy usual brand variant of cigarettes in single pack sizes of 20
Group 2: Control: buy usual brand of cigarettes in usual pack size
Participants will not be informed of the true aim of the study.
Participants will be recruited through a research agency, Roy Morgan Research Ltd from across Australia.

Participants in the intervention group will be asked to buy their usual brand variant of cigarettes in single pack sizes of 20 cigarettes per pack for a period of four weeks. Participants in the control condition will be asked to continue to purchase their usual brand of cigarettes in the usual pack size (25 cigarettes or greater) for four weeks.

Once participants have successfully completed a baseline week in which they return receipts for any cigarette packs purchased that week they are randomly allocated. Allocation of participants to purchase cigarettes in pack sizes of 20 or their usual size of pack will be determined using a computer-generated random number sequence prepared by the senior project statistician.

Intervention Type
Behavioural

Primary outcome(s)
The primary outcome measure is the number of cigarettes smoked by participants in a four-week period.
The primary outcome measure will be assessed from empty cigarette packs returned each week for four weeks, with a sticker on each pack completed by the participant stating:
1. Date pack started
2. Date pack finished
3. Number of cigarettes smoked from this pack

4. Number of cigarettes smoked by someone else from this pack
5. Number of cigarettes smoked from someone else's pack during these dates
6. Rating of warning message (to fit with cover story)

Key secondary outcome(s)
Three secondary outcome measures will be taken at the point of recruitment via telephone and two weeks after completing procedures required for the primary endpoint (returning four weeks of empty cigarette packs) either by telephone or via an online survey.
1. Nicotine dependence will be measured by the Heaviness of Smoking Index (HSI)
2. Participants' motivation to stop smoking will be measured by the Motivation to Stop Smoking scale (MTSS)
3. Participants' autonomy over their smoking behaviour will be measured by the Autonomy Over Smoking Scale (AUTOS)

Completion date
21/01/2019

Eligibility

Key inclusion criteria
1. Aged 18 and over.
2. Smoke factory made cigarettes.
3. Smoke 5 or more cigarettes a day on every day of the week.
4. Smoked at least 100 cigarettes in his or her lifetime.
5. Routinely purchase cigarettes in packs of 25 or more.
6. Use a brand or brand variant in which cigarettes are available in pack sizes of 20 as well as sizes of one or more of the following: 25, 26, 30, 35, 40, 43 and/or 50.
7. Use a brand variant that is stocked in a pack size of 20 by at least one of the two major Australian supermarkets in the month before recruitment.
8. Live anywhere in Australia.
9. Able to read and write sufficient English to complete all study procedures.
10. Willing to collect and post one week of receipts of cigarettes purchased at baseline.
11. Willing to record on each cigarette pack dates when the pack was opened and when finished.
12. Willing to post weekly envelopes – on four consecutive weeks - containing all empty packs of cigarettes smoked in the preceding week with completed forms.
13. Willing to undergo a telephone interview at the end of the study.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex

All

Total final enrolment
187

Key exclusion criteria
1. Pregnant women.
2. Intend to quit smoking in the next three 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. Don’t usually buy their own cigarettes.
7. Live in the same household as someone who has enrolled in the study.
8. Do not own a mobile phone or similar device with the ability to send photos via a text or email message.
9. Purchase their cigarettes with the intention of sharing half or more of them with another person.

Date of first enrolment
01/09/2018

Date of final enrolment
03/11/2018

Locations

Countries of recruitment
Australia

Study participating centre
Roy Morgan Research Ltd
Tonic House, 386 Flinders Lane, Melbourne, Australia, VIC 3000
Melbourne
Australia
VIC 3000

Sponsor information

Organisation
University of Cambridge

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust

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.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/07/2021	27/02/2023	Yes	No
Basic results		06/02/2020	07/02/2020	No	No
Participant information sheet	version V4		04/01/2019	No	Yes