

The effect of capping the size of cigarette packs on consumption

Submission date 20/12/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/01/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 27/02/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Interventional, parallel group, randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Prevention

Participant information sheet

See additional files

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 measure

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)

Secondary outcome measures

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)

Overall study start date

01/02/2018

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

250

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

Sponsor details

Cambridge Research Office, 16 Mill Lane, Cambridge, CB2 1SB
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Sponsor type

University/education

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

Publication and dissemination plan

The findings from this study will be published in at least one scientific journal in 2020 and made available open access. They will also be presented at one or more scientific meetings.

Intention to publish date

01/06/2020

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?
Participant information sheet	version V4		04/01/2019	No	Yes
Basic results		06/02/2020	07/02/2020	No	No
Results article		18/07/2021	27/02/2023	Yes	No