ISRCTN52982308 https://doi.org/10.1186/ISRCTN52982308

Examining smoking behaviour over a 24 hour period

Submission date
01/05/2013

Recruitment status
No longer recruiting

Registration date
27/06/2013

Overall study status
Completed

Last Edited
20/03/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
In countries like UK, where other formal marketing channels are prohibited, the cigarette pack itself is the main way in which the tobacco industry can promote their products. Standardised (plain) packaging would require all cigarettes to be sold in packs with a standard pack shape, colour and method of opening, removing all branding and leaving only the brand name in a standard font and location. In December 2012, Australia was the first country in the world to introduce plain packaging and other countries are either considering, or are already following suit. Research shows that plain packaging makes the cigarette pack less appealing, both in terms of the pack itself and the taste and quality of the cigarettes they contain, prevents the use of misleading pack features and increases attention to health warnings in the pack. Research has also shown that using plain packs has increased the number of people who avoid smoking or stop smoking, particularly female daily smokers. This previous research was the first to test the impact of using plain cigarette packaging on attitudes to smoking, although it relies on self-report measures. Therefore, this project aims to see the effect that plain packaging of cigarettes has on actual smoking behaviour in a real-world setting over a 24-hour period.

Who can participate?
The study will recruit daily cigarette smokers from the general population who report smoking within one hour of waking and smoking between 5 and 20 cigarettes a day.

What does the study involve?
On two test days, spaced 48 hours apart, participants will complete paper-based questionnaires regarding their smoking status and attitudes to smoking. On test day 1, participants will be randomly allocated to receive either a branded or a standardised pack of cigarettes, which they will use for all of the following day. Smoking behaviour will be assessed using a hand-held smoking topography device. On test day 1, taste ratings of two cigarettes, one taken from a branded pack and one from a standardised pack of cigarettes will be completed by participants. On test day 2, participants will complete taste ratings for the cigarettes in the packs provided to them the previous day, paper-based questionnaires testing attitudes to smoking and their perceptions of the packs provided to them, and a computer task assessing the rewarding value of cigarettes.

What are the possible benefits and risks of participation?
Participants would not directly benefit from taking part in this research study. However, the information from this study may help governments worldwide to decide whether plain packaging will be an effective tobacco control measure. If effective, plain packaging may prevent many people from starting smoking, effectively saving millions of lives.

Where is the study run from?
The study will be run in the School of Experimental Psychology, University of Bristol, UK.

When is the study starting and how long is it expected to run for?
The study is expected to run from March 2013 to March 2014.

Who is funding the study?
The study is being organised by the University of Bristol and is funded in part by an Economic and Social Research Council (ESRC) (UK) PhD studentship.

Who is the main contact?
Ms Olivia Maynard
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Study website
http://www.bristol.ac.uk/expsych/research/brain/targ/participants/smokingbehaviour.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Standardised packaging of cigarettes and smoking behaviour: a randomised controlled study

Study objectives
We propose a randomised controlled trial to assess the impact of standardised packaging, as compared with branded packaging, on cigarette smoking behaviour over the course of a typical smoking day. We hypothesise that participants randomised to receive standardised packs will smoke fewer cigarettes and will have reduced exposure to cigarette smoke than those randomised to receive a branded pack. We also hypothesise that participants in the standardised pack condition will report more negative perceptions about the pack, the cigarettes and their smoking experience and more positive attitudes to standardised packaging legislation than those in the branded pack condition. Finally, we will investigate the effects of packaging on tobacco choice in a task where participants are required to choose between earning two distinct rewards: tobacco and chocolate. We hypothesise that there will be reduced tobacco choice amongst those participants assigned to the standardised packaging condition compared to those assigned to the branded pack condition. For all analyses, we will explore whether these effects are most pronounced among female smokers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Faculty of Science Human Research Ethics Committee, 5th February 2013, Reference: 310113607

Study design
Randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
http://www.bristol.ac.uk/expsych/research/brain/targ/participants/expsych/research/brain/targ/participants/maynardsmoking2.docx

Health condition(s) or problem(s) studied
Daily cigarette smokers

Interventions

Participants will be randomised to use for a whole day either a fully branded pack of UK cigarettes, or a standardised pack of Australian cigarettes.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Smoking behaviour across a 24 hour period, defined as:
1. The number of cigarettes smoked (measured by self-report)
2. Average volume of smoke inhaled per cigarette (measured by smoking topography device)

Secondary outcome measures
1. Smoking urges: Questionnaire of Smoking Urges (QSU-Brief) (Test Day 1 and 2)
2. Motivation to quit smoking: Contemplation Ladder (Test Day 1 and 2)
3. Cigarette taste: (Test Day 1 and 2)
4. Experience of smoking from the cigarette pack: (Test Day 2)
5. Experience of smoking: (Test Day 2)
6. Attributes of the cigarette pack: (Test Day 2)
7. Perceptions of the on-packet health warning: (Test Day 2)
8. Behaviour changes: (Test Day 2)
9. Views on standardised packs: (Test Day 2)
10. Concurrent choice/transfer task: (Test Day 2)

Overall study start date
04/03/2013

Completion date
04/03/2014

Eligibility

Key inclusion criteria
1. Participants smoking daily (between five and 20 cigarettes per day and first smoking within one hour of waking)
2. Participants who predominantly smoke the specific brands of cigarettes available in the study (Marlboro Gold, Marlboro Red, Dunhill Grey, Dunhill Red, Dunhill Blue, Benson and Hedges Gold, Benson and Hedges Silver)
3. Participants aged between 18 and 40 years
4. English as first language or equivalent level of fluency
5. Able to give informed consent as judged by lead researcher

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
128

Key exclusion criteria
1. Participants not in good physical health
2. Participants not in good psychiatric health
3. Participants currently taking psychiatric medication (e.g., antidepressants)
4. Participants currently using illicit drugs (except cannabis)
5. Females who are pregnant
6. Participants planning on quitting smoking in the next month
7. Participants who in opinion of the lead researcher are not appropriate to participate
8. Participants who develop or engage in of any of the above during the course of the study would be removed from the final analysis

Date of first enrolment
04/03/2013

Date of final enrolment
04/03/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Experimental Psychology
Bristol
United Kingdom
BS81TU

Sponsor information

Organisation
University of Bristol (UK)

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Sponsor type
University/education

Website
http://www.bris.ac.uk/

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Research council

Funder Name
The study is being organised by the University of Bristol and is funded in part by an Economic and Social Research Council PhD studentship. It is envisaged that this protocol will form part of a programme of work within the MRC/University of Bristol Integrative Epidemiology Unit, which is due to commence in June 2013. Full confirmation of the funding of this Unit is expected in May 2013. O.M.M., M.R.M. and L.B. are members of the UK Centre for Tobacco Control Studies, a UK Public Health Research Centre of Excellence. Funding from British Heart Foundation, Cancer Research UK, Economic and Social Research Council, Medical Research Council and the UK National Institute for Health Research, under the auspices of the UK Clinical Research Collaboration, is gratefully acknowledged.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/06/2014		Yes	No
Results article	results	13/03/2015		Yes	No