Health warning labels and alcohol selection study

Submission date	Recruitment status No longer recruiting	[X] Prospectively registeredProtocol		
11/12/2019				
Registration date	Overall study status	Statistical analysis plan		
21/01/2020	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
19/04/2021	Mental and Behavioural Disorders			

Plain English summary of protocol

Background and study aims

Many people exceed the current recommended guidelines for alcohol consumption in the UK. As well as immediate health effects, drinking too much alcohol has been linked to long term illnesses such as liver diseases (e.g. cirrhosis) and cancers (including breast cancer and bowel cancer). We know that warning labels on cigarettes can increase awareness of the health hazards of smoking, increase beliefs about the risks associated with smoking, decrease cigarette consumption and motivate quit attempts. Therefore, warning labels on alcoholic drinks could also help reduce alcohol consumption and improve the health of the general population but we need to test this before any decisions to use such labels are made. The aim of this study is to estimate the impact on selection of alcoholic drinks displaying image-and-text and text-only HWLs describing adverse health consequences of excessive alcohol consumption.

Who can participate?

Adults over the age of 18, who drink beer or wine at least weekly and shop in a physical supermarket for food and drink regularly (at least monthly).

What does the study involve?

Participants from the research agency's (Blue Yonder Research Ltd) panel of participants will first be contacted by email and invited to complete the initial screening questionnaire and given information on the study. The study is described broadly as an experiment on 'shopping habits and behaviour' to disguise the true aim. If eligible, participants will be randomised to a specific group (image-and-text HWL, text-only HWL or no label) and an appropriate time will be arranged. Participants will be invited to attend a study session and are given information on the study again before providing consent to take part.

Participants will then complete a shopping task in a room set up to look like a real supermarket, with shelves displaying a variety of alcoholic and non-alcoholic drinks and snacks. Participants are asked to do their weekly shop (for drinks and snacks) and are given a shopping trolley to put the selected items in. Depending on their allocated condition the alcoholic drinks will display an image-and-text HWL, text-only HWL or have no labels. Participants leave behind the items they have selected and these items are recorded and returned to the shelves. After the shopping task participants rate both an image-and-text and a text-only HWL presented on a beer or wine

bottle on negative emotional arousal to the HWL and acceptability of the HWL. Finally, demographic measures are taken. The study will take approximately 20 minutes to complete. Following completion of the study, participants are asked questions on what they thought the aim of the study was and how 'typical' the shop felt before being debriefed, which includes giving information about the study and the health consequences of consuming excess alcohol.

What are the possible benefits and risks of participating? Participants will be paid standard market research panel rates for participating in this study. There are no known risks of participating in the study.

Where is the study run from?

Behaviour and Health Research Unit, University of Cambridge (UK) and Blue Yonder Research Limited, Leeds (UK)

When is the study starting and how long is it expected to run for? August 2019 to February 2020 Data collection will take place over a two week period in February 2020

Who is funding the study? Wellcome Trust (UK)

Who is the main contact? Dr Natasha Clarke ncc42@medschl.cam.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Natasha Clarke

ORCID ID

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Health warning labels and alcohol selection: an experiment in a semi-naturalistic shopping laboratory

Study objectives

Image-and-text and text-only health warning labels (HWLs) placed on bottles and cans of beer and wine will reduce their selection

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 27/08/19, Cambridge Psychology Research Ethics Committee (School of the Biological Sciences, University of Cambridge, 17 Mill Lane, Cambridge CB2 1RX; +44 (0)1223 766894; Cheryl. Torbett@admin.cam.ac.uk), ref: PRE.2019.058

Study design

Between-subjects randomised experimental study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Excess alcohol consumption

Interventions

Participants from the research agency's (Blue Yonder Research Ltd) panel of participants will first be contacted by email and invited to complete the initial screening questionnaire and given information on the study. The study is described broadly as an experiment on 'shopping habits and behaviour' to disguise the true aim. If eligible, participants will be randomised to a specific group (image-and-text HWL, text-only HWL or no label) and an appropriate time will be arranged. Participants will be invited to attend a study session and are given information on the study again before providing consent to take part.

Participants will then complete a shopping task in a room set up to look like a real supermarket, with shelves displaying a variety of alcoholic and non-alcoholic drinks and snacks. Participants are asked to do their weekly shop (for drinks and snacks) and are given a shopping trolley to put the selected items in.

Participants will be randomly assigned to one of three groups and requested to select drinks from a range of alcoholic and non-alcoholic drinks, varying in the labels on the alcoholic drinks: Group 1: image-and-text HWL; Group 2: text-only HWL; Group 3: no label (control).

Participants leave behind the items they have selected and these items are recorded and returned to the shelves. After the shopping task participants rate both an image-and-text and a text-only HWL presented on a beer or wine bottle on negative emotional arousal to the HWL and acceptability of the HWL. Finally, demographic measures are taken. The study will take approximately 20 minutes to complete. Following completion of the study, participants are asked questions on what they thought the aim of the study was and how 'typical' the shop felt before being debriefed, which includes giving information about the study and the health consequences of consuming excess alcohol.

Intervention Type

Behavioural

Primary outcome measure

Proportion of total drinks selected that are alcoholic in the pseudo-purchasing task

Secondary outcome measures

- 1. Pseudo-purchasing indices:
- 1.1. Total spend on alcoholic drinks
- 1.2. Spend on alcoholic drinks as a proportion of total spend
- 1.3. Number of alcohol units selected: the total number of alcohol units will be calculated from the selected alcohol.
- 2. Post intervention:
- 2.1. Negative emotional arousal generated by health warning labels, assessed using a four-item measure, previously used to assess the impact of warning labels on cigarette packages
- 2.2. Acceptability of health warning labels, assessed using one item, adapted from previous research assessing the impact of sugar tax

Overall study start date

01/07/2019

Completion date

16/02/2020

Eligibility

Key inclusion criteria

- -1. 18+ years old
- -2. Able to read and write in English
- -3. Regular drinkers (i.e. consume beer or wine at least once a week)
- -4. Purchases supermarket products (food and drink) for household at least monthly
- -5. Shops regularly (at least monthly) in a physical supermarket store
- -6. Available to attend at least one time slot for each of the study arms (one each for Group 1, Group 2, and Group 3 session). This means that when participants are randomised to one of the arms, it is certain that they will be able to attend at least one time slot for that session.

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

435

Total final enrolment

399

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/02/2020

Date of final enrolment

16/02/2020

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Blue Yonder Research Ltd

4325 Park Approach Leeds United Kingdom LS15 8GB

Sponsor information

Organisation

University of Cambridge

Sponsor details

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Madingley Rd
Cambridge
England
United Kingdom
CB3 0TX
+44 (0)1223333543
Research_Governance@medschl.cam.ac.uk

Sponsor type

University/education

Website

http://www.cam.ac.uk/

ROR

https://ror.org/013meh722

Funder(s)

Funder type

Charity

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

- 1. Planned submission of the main results of this study for publication in a peer-reviewed journal
- 2. Dissemination of the results to the public, policy makers and other researchers through targeted social media

Intention to publish date

31/08/2020

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details		Date added	Peer reviewed?	Patient-facing?
Preprint results	non-peer-reviewed results in preprint	18/09/2020	12/02/2021	No	No
Results article		01/04/2021	19/04/2021	Yes	No