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Does the bottle size for cola drinks influence how much people drink at home? A feasibility and acceptability study

Submission date
12/05/2015

Recruitment status
No longer recruiting

Registration date
18/05/2015

Overall study status
Completed

Last Edited
22/06/2017

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
People in the UK consume far too much sugar, exceeding recommendations, with the largest source in the diet being sugar-sweetened beverages (SSBs). SSB consumption has been linked with health problems, including the development of obesity (being very overweight), metabolic syndrome (where someone is obese, has diabetes and high blood pressure), diabetes, and dental disease. It also contributes to health inequalities given that people who are more socially deprived consume more SSBs. One possible way of reducing SSB consumption is to reduce the sizes of the containers (i.e. bottles and cans) in which these drinks are available. However, there is currently no evidence that this would reduce SSB consumption. The aim of this study is to find out whether placing a fixed volume of SSBs in smaller bottle sizes reduces consumption at home.

Who can participate?
Households (defined as people who live together, who may or may not be related but who share all or most drink and food within the house) that buy at least 2 litres of week of regular (i.e. not diet or low sugar) cola drinks and live in Cambridge, UK

What does the study involve?
Each week, for four weeks, the research team give each participating household a set amount of a carbonated cola drink based on how much cola they typically buy in a week. The total amount of cola is split into bottles of one of four sizes: 1500ml, 1000ml, 500ml or 250ml. All the cola delivered in a week to particular household is in the same sized bottle. Each household is also given their cola in each of the four bottle sizes over the 4-week period of the study.

What are the possible benefits and risks of participating?
The findings from this preliminary study will help to design a larger study to test whether giving a fixed amount of SSBs in smaller bottle sizes reduces consumption at home. The results are expected to contribute to ongoing scientific and policy discussions about effective methods for reducing sugar intake in the general population. This study is considered to be low risk. No adverse consequences are expected.

Where is the study run from?
The Behaviour and Health Research Unit at the University of Cambridge (UK)

When is the study starting and how long is it expected to run for?
May 2015 to June 2016

Who is funding the study?
Department of Health Policy Research Programme (Policy Research Unit in Behaviour and Health [PR-UN-0409-10109])

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Impact of bottle size on in-home consumption of sugar-sweetened beverages (SSBs): a feasibility and acceptability study

Study objectives

The impact on consumption of altering the available sizes of the containers in which SSBs are presented is not known. We are planning a cross-over randomised controlled trial to assess the impact of presenting a fixed volume of SSBs in different bottle sizes on consumption within homes. This will provide evidence to assess the potential of reductions in package size to decrease consumption and test the hypothesis that smaller package size reduces consumption. Prior to conducting this trial we need to reduce some key uncertainties related to the study design. The aim of this study is to assess the feasibility and acceptability of the procedures for recruitment, allocation, measurement, retention and intervention delivery of the aforementioned randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Cambridge Psychology Research Ethics Committee, 15/03/2015, ref: Pre.2015.20

Study design
Feasibility cross-over randomised controlled trial using a mixed methods design conducted in home settings

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
High consumption of sugar-sweetened beverages (SSBs), which has been associated with weight gain and the development of non-communicable diseases including diabetes and poor oral health.

Interventions
Receipt of a given quantity of a carbonated cola sugar-sweetened beverage for consumption at home but sub-divided into bottles of one of four different sizes:
1. In 1500 millilitre bottles
2. In 1000 millilitre bottles
3. In 500 millilitre bottles
4. In 250 millilitre bottles

In any one week households will receive cola in just one size of bottle, with the number of bottles being determined by the total volume of cola each household receives; this will be fixed

across all four intervention periods. This fixed volume will be determined with reference to the volume of cola households purchased during a two-week baseline period, as assessed by till receipts and by self-report, rounded up to the nearest multiple of three litres. Volumes consisting of multiples of three litres are needed to avoid the total quantity varying systematically between intervention periods, thereby confounding the effect of altering the bottle size with volume. During each intervention week, households will be given the opportunity to receive additional deliveries should they want these. All participating households will receive all interventions according to a pre-specified random order.

Intervention Type
Behavioural

Primary outcome measure
This feasibility study is not powered to detect changes in outcome measures but to assess feasibility and acceptability of procedures planned for a full-scale trial.

Feasibility outcomes:
1. Recruitment rates
2. Number of households discontinuing participation at follow-ups
3. Awareness of the study aim, assessed through i) questionnaire and ii) qualitative interviews
4. Practical problems associated with:
4.1. The randomisation procedure
4.2. Delivering the intervention
4.3. Collection of consumption-related data

Acceptability outcomes assessed through qualitative interviews
1. Acceptability of the:
1.1. Interventions
1.2. Study procedures
1.3 Assessment procedures

Other outcomes:
1. Characteristics of participating households, assessed through questionnaire:
1.1. Index of Multiple Deprivation scores (derived from postcodes)
1.2. Total household income
1.3. Household composition (number of adults; number of children)
1.4. Highest education qualification obtained by any person within the household
1.5. Gender of all household members
1.6. Age of all household members
2. Volume of cola in millilitres consumed by the household during each of the week-long intervention periods, measured:
2.1. Objectively, by recording the numbers of empty and remaining full bottles. The remaining volume of partly consumed bottles will be measured using a measuring jug.
2.2. Subjectively, through self-report via questionnaire

Secondary outcome measures
N/A

Overall study start date
15/05/2015

Completion date
15/06/2016

Eligibility

Key inclusion criteria
Participating households will be of any size or composition. Households are defined as people who live together, who may or may not be related but who share all or most drink and food within the house. This includes households consisting of:
1. Single members
2. Couples (married or cohabitating)
3. Families with school age children
4. Single parents with dependent children
5. Families with extended family members living in the house (e.g. grandparents)

Multi-occupancy households comprising non-related individuals are excluded. Inclusion criteria for participating households are as follows:
1. Purchase regular (not low sugar) Coca-Cola® or Pepsi Cola® at a minimum rate of two litres a week
2. Reside in or near to Cambridge, UK, within 10 miles of the research team base
3. Do not plan to be away from home for longer than seven days during the study period

Participant type(s)
Healthy volunteer

Age group
Mixed

Sex
Both

Target number of participants
100 eligible households will initially be approached with the aim of assessing (a) how many are interested in taking part in the study and (b) how many complete a one-week run in period (an indicator of active participation for one week). Of the households completing the run-in period and expressing a willingness to continue with the study, 16 will be invited to continue their participation. If fewer than 16 households complete the run-in period, additional households will be approached. One individual will be recruited from each eligible household to act as a household representative, who will consent to participation in the study on behalf of all household members and provide all necessary data.

Key exclusion criteria
1. Households not located in Cambridge, UK
2. Households consuming less that two litres of cola per week
3. Households consuming cola brand other than Pepsi Cola® or Coca-Cola® or diet/sugar free versions of the included brands.

Date of first enrolment
15/05/2015

Date of final enrolment
15/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Behaviour and Health Research Unit
University of Cambridge
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Sponsor information

Organisation
University of Cambridge

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Research Operations Office
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Sponsor type
University/education

ROR
https://ror.org/013meh722

Funder(s)

Funder type

Government

Funder Name
Department of Health Policy Research Programme (UK)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Saphsa Codling (sc701@medschl.cam.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/11/2015		Yes	No
Results article	results	07/04/2017		Yes	No