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An intervention study to improve food shopping and prevent cardiovascular disease among patients in primary care: the PC SHOP trial

Submission date
01/09/2017

Recruitment status
No longer recruiting

Registration date
21/09/2017

Overall study status
Completed

Last Edited
06/04/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Cardiovascular disease (CVD), including heart attacks and strokes, is the leading cause of death in the UK and is strongly influenced by diet. Eating too much saturated fat increases the amount of 'bad' LDL-cholesterol in the blood, which increases the risk of heart disease. Previous studies have shown that reducing the intake of saturated fat (mostly fats from animal sources such as butter or meat), by swapping some foods for others that are lower in saturated fat, can lead to big reductions in the amount of LDL-cholesterol. However, these studies have achieved success either by giving specific foods to people or by providing intensive support and advice from nutrition specialists.
The aim of this study is to develop and test the feasibility of a new intervention, involving brief oral and written advice from a health professional at the GP practice together with regular information on the saturated fat content of food purchases.

Who can participate?
Adults aged 18 and older with high LDL cholesterol.

What does the study involve?
A group of participants attend a single one-to-one appointment with a health professional where they are given advice on diet and motivations to reduce their intake of saturated fats. Another group receive the same appointment with the health professional and also receive a personalised monthly report with the nutrition and fat content on all purchases from Tesco at their follow up appointments.

What are the possible benefits and risks of participating?
Participants may benefit from receiving some information to help reduce their risk of cardiovascular disease and personalised advice on food purchases. Blood tests are also shared

with participants and their GPs may contact them to arrange any further treatment they may need if a problem is detected. There are no direct risks with participating, however participants may experience bruising and discomfort when providing blood samples.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
November 2017 to June 2019 (as of 02/10/2018)

Who is funding the study?
National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research & Care Oxford at Oxford Health NHS Foundation Trust (UK) and The National Institute for Health Research (NIHR) School for Primary Care Research.

Who is the main contact?
Dr Carmen Piernas Sanchez

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12408

Study information

Scientific Title
Primary Care Shopping Intervention for Cardiovascular Disease Prevention

Acronym
PC SHOP

Study objectives
Study aim:
This project aims to develop and test a behavioural intervention to promote reductions in saturated fat (SFA) intake among patients in primary care with raised LDL-cholesterol who are willing to change their diet.

Hypothesis:
Compared to usual care, an intervention involving health professional advice alone and/or in combination with personalised feedback and monitoring on the SFA content of food purchases, will help people reduce dietary SFA intake which, in the longer term, would be expected to lead to reductions in LDL cholesterol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central Oxford C Research Ethics Committee, 12/05/2017, ref: 17/SC/0168, IRAS project ID 214999

Study design
Current study design as of 08/02/2019:
Interventional single centre individually randomised 3 arm parallel group trial followed by a qualitative study

Previous study design:
Interventional single centre individually randomised 3 arm parallel group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Our PIS can be downloaded from this website: https://www.clahrc-oxford.nihr.ac.uk/Research/Primary-Care-Shopping-Intervention-for-Cardiovascular-Disease-Prevention

Health condition(s) or problem(s) studied
Adults with high LDL cholesterol

Interventions
Current interventions, as of 08/02/2019:
In the main trial participants are randomly allocated to either a control or intervention group.
Intervention 1: Brief advice session
This intervention consists of a single one-to-one appointment with the health professional (HP) in which they will receive advice on the importance of dietary change and motivation to reduce SFA based on the British Heart Foundation "Cut the Saturated Fat" chart, which will be provided as printed educational material. This session is aimed to inform participants about the benefits of saturated fat reduction and encourage them to attempt it. Dietary advice is particularly focused on explaining the different sources of fat and the most appropriate changes proposed in the BHF guidance to decrease SFA, primarily by substitution with lower SFA options (e.g. change from regular beef to lean beef); or with mono- and polyunsaturated fat sources (e.g. change from butter to low-fat vegetable spread).
Intervention 2: Brief advice session and shopping report
In addition to the brief advice session detailed above, participants in this intervention arm receive a personalised report with the nutritional composition of foods and beverages purchased from Tesco over the last three months (baseline) and subsequent months (monthly over the three months of follow up). This report includes information on total energy (calories) and saturated fat as a % of total energy, and the major food contributors to SFA. Participants receive monthly reports to allow them to chart their progress in reducing SFA in their grocery purchases. This information is accompanied by a list with suggestions for one-for-one swaps for foods high in SFA for lower SFA foods to support dietary change.
Control group
Participants in the control group (usual care) are recruited into the study and will be informed by post of their elevated risk and their blood tests by the study team. They are then seen again at three months for collecting outcome measures.

Following the main trial, a qualitative study will be conducted with a sub-sample of participants from the intervention 2 arm.
A semi-structured, one-to-one, 30-minute telephone interview will be conducted to explore issues related to food purchasing behaviours, including knowledge, perceived barriers, facilitators and actions, contextual influences, and value of the healthcare advice provided.

Previous interventions:
Participants are randomly allocated to either a control or intervention group.

Intervention 1: Brief advice session
This intervention consists of a single one-to-one appointment with the health professional (HP) in which they will receive advice on the importance of dietary change and motivation to reduce SFA based on the British Heart Foundation "Cut the Saturated Fat" chart, which will be provided as printed educational material.

This session is aimed to inform participants about the benefits of saturated fat reduction and encourage them to attempt it. Dietary advice is particularly focused on explaining the different sources of fat and the most appropriate changes proposed in the BHF guidance to decrease SFA, primarily by substitution with lower SFA options (e.g. change from regular beef to lean beef); or with mono- and polyunsaturated fat sources (e.g. change from butter to low-fat vegetable spread).

Intervention 2: Brief advice session and shopping report
In addition to the brief advice session detailed above, participants in this intervention arm receive a personalised report with the nutritional composition of foods and beverages purchased from Tesco over the last three months (baseline) and subsequent months (monthly over the three months of follow up). This report includes information on total energy (calories) and saturated fat as a % of total energy, and the major food contributors to SFA. Participants receive monthly reports to allow them to chart their progress in reducing SFA in their grocery purchases. This information is accompanied by a list with suggestions for one-for-one swaps for foods high in SFA for lower SFA foods to support dietary change.

Control group
Participants in the control group (usual care) are recruited into the study and will be informed by post of their elevated risk and their blood tests by the study team. They are then seen again at three months for collecting outcome measures.

Intervention Type
Behavioural

Primary outcome measure
Change in SFA intake is measured using the 2 x 24h dietary recalls using the Web-Q instrument at baseline and 3 months (follow up).

Secondary outcome measures
Current secondary outcome measures, as of 08/02/2019:
1. Changes in SFA from total purchases and the proportion of food items with low SFA (e.g. products with ≤1.5 grams of SFA per 100 grams of the product) is measured using purchasing records obtained from the supermarket at baseline and 3 months (follow up).
2. Changes in LDL-cholesterol, HDL-cholesterol, total cholesterol and triglycerides is measured using blood samples taken at baseline and 3 months (follow up).
3. Changes in energy intake, total fat, total sugars, fibre and salt; and high SFA food groups (updated 19/03/2018) is measured using 2x24h dietary recalls using the Web-Q instrument at baseline and 3 months (follow up).
4. Changes in energy density, total fat, sugar, fibre and salt from purchases is measured using purchasing records obtained from the supermarket at baseline and 3 months (follow up).
5. Changes in systolic and diastolic blood pressure is measured using an electronic blood pressure monitors at baseline and 3 months (follow up).
6. Changes (absolute (kg) and relative (%)) in body weight is measured using a calibrated electronic platform scale at baseline and 3 months (follow up).
7. Feasibility and process measures:
7.1. Willingness of participants to take part in the study and be randomised is measured using recruitment rates at baseline.
7.2. Programme attendance and retention is measured using follow up and completion rates at 3 months.
7.3. Acceptability of the intervention for participants and health professionals; uptake of knowledge, motivation and swaps accepted is measured using non validated questionnaires at baseline and 3 months (follow up).
8. Issues related to food purchasing behaviours, including knowledge, perceived barriers, facilitators and actions, contextual influences, and value of the healthcare advice provided measured using thematic analysis (framework method) of participant interviews conducted in a subset of participants after follow-up.

Previous secondary outcome measures:
1. Changes in SFA from total purchases and the proportion of food items with low SFA (e.g. products with ≤1.5 grams of SFA per 100 grams of the product) is measured using purchasing records obtained from the supermarket at baseline and 3 months (follow up).
2. Changes in LDL-cholesterol, HDL-cholesterol, total cholesterol and triglycerides is measured using blood samples taken at baseline and 3 months (follow up).
3. Changes in energy intake, total fat, total sugars, fibre and salt; and high SFA food groups (updated 19/03/2018) is measured using 2x24h dietary recalls using the Web-Q instrument at baseline and 3 months (follow up).
4. Changes in energy density, total fat, sugar, fibre and salt from purchases is measured using purchasing records obtained from the supermarket at baseline and 3 months (follow up).
5. Changes in systolic and diastolic blood pressure is measured using an electronic blood pressure monitors at baseline and 3 months (follow up).
6. Changes (absolute (kg) and relative (%)) in body weight is measured using a calibrated electronic platform scale at baseline and 3 months (follow up).
7. Feasibility and process measures:
7.1. Willingness of participants to take part in the study and be randomised is measured using recruitment rates at baseline.
7.2. Programme attendance and retention is measured using follow up and completion rates at 3 months.
7.3. Acceptability of the intervention for participants and health professionals; uptake of knowledge, motivation and swaps accepted is measured using non validated questionnaires at baseline and 3 months (follow up).

Overall study start date
01/06/2016

Completion date
30/09/2019

Eligibility

Key inclusion criteria
Current participant inclusion criteria, as of 08/02/2019:
Main study:
1. Participant is willing and able to give informed consent for participation in the study
2. Male or Female, aged 18 years or above
3. With confirmed LDL cholesterol above 3 mmol/L at recruitment
4. Express a desire for support to improve the nutritional quality of their diet to reduce their CVD risk
5. Primarily responsible for household shopping (e.g. complete at least half of their household shopping)
6. Shops mainly at Tesco (e.g. at least once/week instore and/or online) using a Tesco's storecard. They need to have had a Tesco's storecard for at least 3 months before recruitment
7. Computer literate

Screening criteria:
1. Age ≥18 years with a blood test in the GP records which indicate LDL-cholesterol >3.5 mmol/L or total cholesterol >5.5 mmol/L in the past 24 months
2. Who will likely benefit from a lower SFA diet with no pre-existing conditions that warrant exclusion.

Qualitative study:
1. Participated in intervention 2 arm (brief advice plus shopping advice) of the PC-SHOP study
2. Willing to be interviewed

Previous participant inclusion criteria:
1. Participant is willing and able to give informed consent for participation in the study
2. Male or Female, aged 18 years or above
3. With confirmed LDL cholesterol above 3 mmol/L at recruitment
4. Express a desire for support to improve the nutritional quality of their diet to reduce their CVD risk
5. Primarily responsible for household shopping (e.g. complete at least half of their household shopping)
6. Shops mainly at Tesco (e.g. at least once/week instore and/or online) using a Tesco's storecard. They need to have had a Tesco's storecard for at least 3 months before recruitment
7. Computer literate

Screening criteria:
1. Age ≥18 years with a blood test in the GP records which indicate LDL-cholesterol >3.5 mmol/L or total cholesterol >5.5 mmol/L in the past 24 months
2. Who will likely benefit from a lower SFA diet with no pre-existing conditions that warrant exclusion.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
112

Total final enrolment
113

Key exclusion criteria
Current exclusion criteria, as of 19/03/2018:
1. Unable to read and understand the instructions provided in English
2. Pregnant, or planning to become pregnant during the course of the study
3. Planned or likely changes to cholesterol-lowering medication
4. Existing or recent cardiovascular conditions: heart attack or stroke within the last 3 months, heart failure of grade II New York Heart Association and more severe, or prolonged QT syndrome, angina, arrhythmia or atrial fibrillation
5. Familial hyperlipidaemia
6. Currently or recently (within the last 3 months) participating in another intervention study

which likely affects the outcomes measured in this study.
7. Patients that the GP judges not able to meet the demands of the study or unlikely to adhere to study procedures as stated in the protocol

Previous exclusion criteria:
1. Unable to read and understand the instructions provided in English
2. Pregnant, or planning to become pregnant during the course of the study
3. Planned or likely changes to cholesterol-lowering medication
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5. Familial hyperlipidaemia
6. Currently or recently (within the last 3 months) participating in another study
7. Patients that the GP judges not able to meet the demands of the study or unlikely to adhere to study procedures as stated in the protocol

Date of first enrolment
21/03/2018

Date of final enrolment
01/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Nuffield Department of Primary Care Health Sciences,
University of Oxford
Radcliffe Primary Care Building
Radcliffe Observatory Quarter
Woodstock Road
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Sponsor information

Organisation
University of Oxford

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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research & Care Oxford at Oxford Health NHS Foundation Trust

Funder Name
The National Institute for Health Research (NIHR) School for Primary Care Research

Results and Publications

Publication and dissemination plan
The investigators within the central research team will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. The main paper reporting the primary outcome will also include data on the secondary outcomes. Other qualitative outcomes, including acceptability of the intervention, may be reported in additional papers.
The trial results will be published and all who meet the criteria for authorship will be listed as authors. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

We will submit the paper to NIHR for approval before submission.

Intention to publish date

05/11/2020

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 created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version v1.0	06/03/2019		No	No
Statistical Analysis Plan	version v2.0	01/04/2019	01/04/2019	No	No
Protocol article	protocol	15/04/2019	16/04/2020	Yes	No
Results article	results	05/11/2020	12/03/2021	Yes	No
Results article	qualitative results	31/03/2021	06/04/2021	Yes	No
HRA research summary			28/06/2023	No	No