



If you have any questions after reading this information please contact us at: **01865 289284** or pcshop@phc.ox.ac.uk

PARTICIPANT INFORMATION SHEET

We'd like to invite you to take part in this research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

WHAT IS THE PURPOSE OF THE STUDY?

Cholesterol plays an essential role in how every cell of the body works, and moves around your blood in 'vehicles' made of fat (lipid) and protein, called lipoproteins. The two types are high-density lipoproteins (HDL) and low-density lipoproteins (LDL). HDL cholesterol is often termed 'good' cholesterol, as it is believed to be protective. LDL is often termed 'bad' cholesterol because too much in your body may slowly build in the arteries, making them narrower which can increase the risk of heart disease.'

Many people in the UK have raised LDL-cholesterol levels, which is the type of cholesterol that increases the chances of a heart attack or stroke. Changing the type of food you eat can help reduce cholesterol levels, especially cutting down on food containing saturated fats. Saturated fats mostly come from animal sources, therefore, swapping butter for olive oil-based spreads, or using turkey mince in place of beef mince could help reduce the amount of saturated fat eaten. This will reduce LDL-cholesterol and lower the risk of heart disease.

This study will be run by the University of Oxford in collaboration with Tesco stores. Tesco's will have no input into the study design or data analysis. The study will test whether providing people with information about the saturated fat content of their usual food shopping can help them to make changes to what they eat to lower their risk of heart disease.

WHY HAVE I BEEN INVITED?

We are looking for 112 people to take part in this study. Your GP has searched in their records to see who might be eligible to take part. The result from your most recent measurement of LDL cholesterol suggests you may benefit from decreasing the amount of saturated fat you eat in order to reduce your risk of cardiovascular disease.

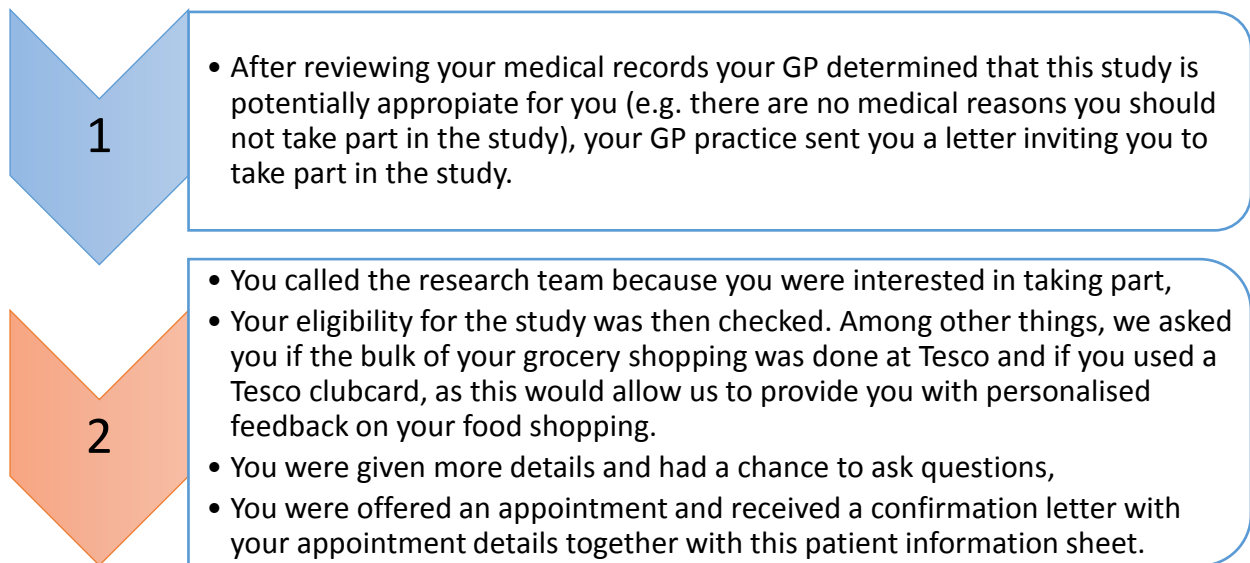
Taking part in the study will not affect the usual care you receive. The University of Oxford did not have access to any of your personal or medical information.

DO I HAVE TO TAKE PART?

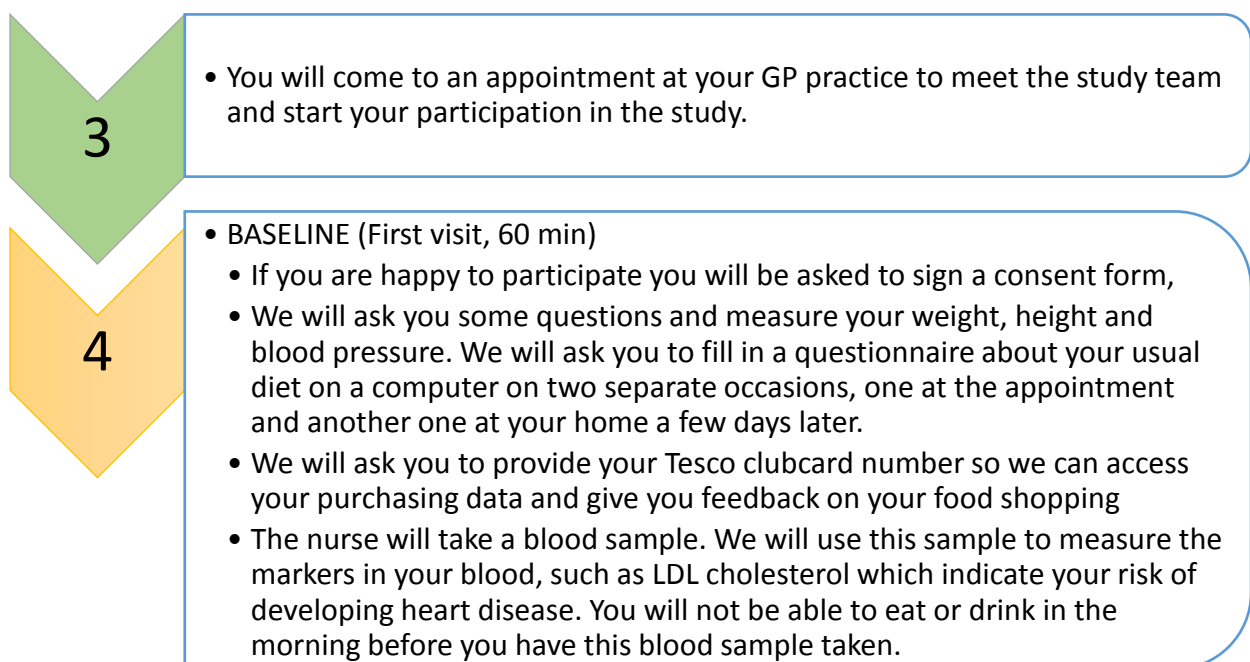
It is up to you whether you take part or not. If you do decide to take part in the study you will be asked to sign a consent form at your first appointment. You are free to withdraw at any time without giving a reason. A decision to withdraw from the study will not affect the usual care you receive from your GP.

If you decide to take part, you should be in good health, not planning to become pregnant and willing to take actions to reduce the amount of saturated fat you eat.

WHAT HAS HAPPENED SO FAR?



WHAT WILL HAPPEN NOW IF I WANT TO TAKE PART?



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- INTERVENTION (Second visit, 15 min)
 - If the blood sample confirms your LDL cholesterol levels are high, you will be randomly allocated to one of three groups to receive:
 - Advice from the practice nurse to help you make changes to your diet (15 min session); this session will be audio-recorded with your consent.
 - Advice from the nurse (15 min session) together with a paper report containing information on the nutritional content of your food shopping collected by your Tesco clubcard;
 - The usual care delivered normally at your practice for people with high cholesterol levels.
 - We will book you an appointment at the practice to receive the results of your blood test and receive the intervention you have been allocated to.
 - The group you will be assigned to is down to chance, like tossing a coin. Neither you nor the study team will know what group you will be allocated to in advance and you will not be able to choose your group because this will be decided randomly and cannot then be changed.

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- FOLLOW UP (Third visit, 45 min):
 - We will ask you to provide another blood sample after 3 months. You will not be able to eat or drink in the morning before this appointment,
 - We will ask you to fill in another dietary questionnaire on a computer on two occasions, one at the appointment and another one at your home a few days later
 - We will measure your weight and blood pressure, and ask you to complete a small questionnaire about your experiences of the study.
 - With your consent we will inform you and your GP of the results of your blood tests and blood pressure.
 - Later, by post, everyone will receive information on the nutritional content of their food purchasing in the previous 3 months.

WHAT SHOULD I CONSIDER?

To be able to take part in the study, we need to confirm that your LDL cholesterol levels are currently high. Therefore, you need to provide a small blood sample to confirm this. If your LDL cholesterol is within the normal range, you will not be eligible to take part in the study which is intended only for people with high cholesterol levels. We will provide you with your blood test information so you can keep records of your blood tests. If you wish we will also give you some information on a healthy diet and other ways to decrease the chances of heart disease as a gesture of appreciation for your time and willingness to provide a blood sample.

If your LDL cholesterol is high and you agree to take part in the study, you would need to:

- Follow your allocated treatment to the best of your ability
- Allow us to collect two small blood samples (about 1 ml)
- Complete a dietary questionnaire on a computer on two occasions, once at the GP practice and once at home, to tell us about what you usually eat
- Complete a few questionnaires we will provide at the beginning and at the end to tell us about your experience with the study
- Attend two appointments with the study team, which will need to see you at your GP practice at the beginning and 3 months after you completed the first visit.
- If you are randomly allocated to receive advice from a nurse or other healthcare professional at your GP practice, then you will be invited to attend an additional appointment, which will be recorded for quality control purposes.

ARE THERE ANY POSSIBLE DISADVANTAGES FROM TAKING PART?

The dietary advice we provide as part of the study is consistent with recommendations from expert scientific committees in the UK and internationally. Most of the questionnaires we will use have been previously used in many other studies and we do not expect these would cause you any distress. As with any blood sample, there is a possibility that you may develop some bruising around the area and some people occasional faint while the sample is taken.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Everybody who takes part will benefit as everyone will receive some information to help reduce their risk of cardiovascular disease and we will provide personalised advice on food purchases at the end of the study to all of the participants. Your blood tests will be also shared with you and your doctor who will arrange any further treatment you may need if a problem is detected. Finally, knowledge gained in this study will help our research and in the future may help other people to reduce the amount of saturated fat in their diet in order to decrease the risk of cardiovascular disease.

WILL I BE REIMBURSED FOR TAKING PART?

You will be offered a £10 gift card at the final appointment as a way of reimbursing you for both your time and any expenses in travelling to appointments related to the study.

WILL MY GENERAL PRACTITIONER/FAMILY DOCTOR (GP) BE INFORMED OF MY PARTICIPATION?

Your GP will be notified of your participation and, with your consent, will receive copies of your blood tests at the end of the study. Taking part in the study will not affect any other care you receive from your GP.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Any information that is collected about you during the course of the research will be kept strictly confidential. We will use codes to avoid identification of participants with their names.

Responsible members of the University of Oxford and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

We need to share with Tesco your name and clubcard number so we can provide you with personalised shopping feedback. No other information will be shared with Tesco.

WHAT WILL HAPPEN TO THE SAMPLES I GIVE?

The blood samples will be analysed by the NHS laboratories which will allow us to obtain your LDL cholesterol levels together with other markers of cardiovascular disease, including total and HDL cholesterol and triglycerides. The results of the blood test will be sent to your GP and, with your consent, they will provide this information to the study team. After this, the samples will be destroyed and will not be used for other purposes.

WHAT WILL HAPPEN TO MY DATA?

Any documents holding your identifiable information will be anonymised as soon as possible so that it is not possible to know that the data came from you.

Any electronic data will be stored in an anonymised format using secure servers. Only the study team members will have access to your data. This information will be stored for 5 years after the end of the study and it will then be destroyed.

Your contact details and consent form will be stored securely in a locked cabinet, in a locked room within a restricted access building with a keypad access control system. We will need your contact information to contact you at the time points mentioned above. However at the end of the study this information will be destroyed.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

Your participation is voluntary. If you do not want to take part in the research that is fine, and you can withdraw at any time without giving a reason.

You can choose to discontinue with any of the interventions we offer but still return to be measured at the end of the study so that we can check how you are getting on.

In either of these situations your medical care will not be affected in any way.

WHAT WILL HAPPEN TO THE RESULTS OF THIS STUDY?

The overall study results may be presented at scientific meetings or published in a scientific journal. You will be not identified in the presentations and publications. We will send you a summary of the study results and also your final blood test results along with a personalised shopping report.

WHAT IF YOU FIND SOMETHING UNEXPECTED?

Your blood tests will be sent to your GP for review, and he/she will be in touch if anything unexpected was found.

WHAT IF THERE IS A PROBLEM?

The University of Oxford, as Sponsor, has appropriate insurance in place in the very unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Dr. Carmen Piernas on (01865 289284) or carmen.piernas-sanchez@phc.ox.ac.uk; or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224, or the head of CTRG, email ctrig@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to get in touch with the PALS team please contact them at 0800 0526088; or patient.services@oxfordshireccg.nhs.uk.

HOW HAVE PATIENTS AND THE PUBLIC BEEN INVOLVED IN THIS STUDY?

Members of the public helped shape the ideas for this research. In designing this study we have taken into account patient opinions on the way the study data (e.g. shopping data from Tesco) should be stored and kept confidential. Two members of the public are part of the study steering committee and will continue to be involved throughout the study.

WHO IS ORGANISING AND FUNDING THE STUDY?

The University of Oxford is responsible for the design, conduct and publication of results from this study. The study is funded by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC). No personal information about you will be shared with the funder.

Tesco is voluntarily collaborating with our research by providing us access to your shopping data with your consent, which will allow us to provide you with personalised shopping feedback.

WHO HAS REVIEWED THE STUDY?

All research in the NHS is reviewed by an independent group of people called the Research Ethics Committee, who protect your rights, safety, wellbeing and dignity. This study has been reviewed and given favourable opinion by the NRES Committee South Central – Oxford C REC Number 17/SC/0168.

FURTHER INFORMATION AND CONTACT DETAILS:

If you want to discuss the study in more detail please contact us on: 01865 289284 or pcshop@phc.ox.ac.uk.

Thank you for taking the time to read this information sheet