If you have any questions after reading this information please contact us at: 01865 289765 or 01865 289301
tasini@phc.ox.ac.uk

The TASINI study

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?

Your doctor is taking part in the TASINI study. The study aims to help people and their doctors find out whether medicine to reduce the chance of developing heart disease or stroke helps them and whether it is suitable for them.

When people are taking medication and they develop a symptom, people often worry that the symptom is a side-effect, but another explanation is that the symptom is caused by something else. In the TASINI study, we have developed an approach to help you and your doctor be much more certain whether a medicine helps you and whether it is suitable for you following a scientific approach. The scientific approach involves testing out the medicine in you to see how it affects you and comparing that to periods when you are not using the medicine. In the TASINI study, we want to see if this helps you and your doctor decide whether to use medicine.

WHY HAVE I BEEN INVITED?

We are looking for 90 people to take part in this study. Your GP has searched in their records to see who might be eligible to take part and you contacted the research team at Oxford University to tell them you were interested. We are looking for people to take part who might benefit from lowering their cholesterol.

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

Do I have to take part?

No, 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 with the researcher. A decision to not take part, or to withdraw, will not affect your usual care in any way. You can withdraw at any time without giving a reason. If you decide not to take part, we would be interested in hearing about why not so we might be able to improve future studies (this is completely optional). If you have decided to not take part having read this information sheet then you do not have to attend the appointment with the researcher, please let us know if this is the case.

What has happened so far?

1

- After reviewing your medical records, your GP decided that the study was appropriate for you. This is because you might benefit from reducing your cholesterol.
- You may have also been to see your GP who told you that you might benefit from taking part in the study.

2

- You contacted the research team at the University of Oxford and the researchers explained the study in more detail and sent you this information sheet.

WHAT WILL HAPPEN NOW IF I WANT TO TAKE PART?

3

- If you are happy to take part, you will be invited to a 15 minute appointment at your GP practice with the researcher. At this first appointment, the researcher will answer any questions you have and then you will sign a consent form, and complete a questionnaire. The researcher will then allocate you to one of three groups. Allocation to each group is random. Neither you or the research team are able to choose what group you will be in.

4

- One of the groups is a 'control' group. If you are in this group then you will carry on as normal until a 6 month review.
- For the two treatment groups, we want to talk about one of two different ways of taking the medication which the GP will speak to you about. Please note that you do not have to take the medication if you do not want to. All you are agreeing to at this point is to have a discussion with the GP about the best ways to prevent heart disease and strokes.
- For this discussion, the researcher will book a 15 minute appointment to see your GP shortly after the visit if you are in either of the 'treatment' groups. Before this appointment you will also need to be booked to have a fasted blood test (taking about 5 minutes) to measure you cholesterol levels. You will also be asked to complete a short daily diary for one week each month for six months.

5

- People in the treatment groups will come back to see the GP 8 weeks after starting the programme to see how you are getting on. This appointment will be about 15 minutes. If you're in a treatment group, we'll also ask you to have a blood test (taking about 5 minutes) before the 8-week appointment to see what has happened to your cholesterol. For those in the treatment group, the appointments with the GP will be audiorecorded to help us design the future, bigger study.
- People in all groups will be invited to see the GP 6 months after starting for a final assessment. After this visit you will be asked to complete a short online questionnaire sent to you via a text message with a link to the survey.

Optional Discussion Group:

We want to know how people feel about the TaSINI intervention. At the end of the study, we may ask you if you would like to take part in a "focus group" (group discussion) about your experience of taking part in this study. We are looking for approximately 15 people to participate, in three groups of approximately 5 people. This would involve coming back for a 1 hour discussion group, either at your GP practice or central location along with other participants who have taken part in the study. You do not have to take part in this – it isentirely optional, and you can decide whether or not you want to take part after the main study is over, and you can change your mind at any time.

What should I consider?

When you visit the GP practice and see a researcher for the first time, we will go through a list of questions with you to make sure you are able to take part in the study.

Depending on which group you are allocated to, you will need to attend up to four appointments at your GP practice over the space of 6 months, two of which require blood tests to be taken in advance, and complete a diary card. If you are due to book your next appointment but we haven't yet heard from you (or if you miss an appointment and don't manage to contact us beforehand to reschedule), we will attempt to contact you to remind you that you are due to book an appointment (by telephone, email or post, according to what contact information you have given us). We will aim to do this up to 3 times. If we haven't managed to contact you after this we will leave it to you to contact us if you still want to continue and book an appointment.

As part of your discussion with the GP about the way to reduce the risk of heart disease, it may be necessary to stop one of your current medications if you choose to take the medication being offered. You don't need to decide this now though, and can discuss this with the doctor as part of the research study.

Are there any possible disadvantages or risks from taking part?

You will be asked to give some of your time to attend up to four study visits and, if randomised to the right group, complete a daily diary (taking about 5 minutes) for a week each month for the next six months. You will need to fast in advance of the blood samples for this study (more detail will be provided by your practice depending on when the sample is to be given) and all blood tests come with a risk of bruising and pain. Each sample will require up to 8ml of blood (about 1.5 teaspoons).

What are the possible benefits of taking part?

You may have the opportunity to speak to the GP about the best way to reduce your cholesterol and try a new approach to test whether the medicine suits you.

Will I be reimbursed for taking part?

We will reimburse you with a £20 gift card at your final study visit for your time and effort.

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 code numbers to avoid identification of participants with their names.

Responsible members of the study sponsor, the University of Oxford, may be given access to data for monitoring and/or audit of the study. This will ensure that the research is complying with the appropriate regulations.

We will let your GP know that you are taking part in the study unless you would prefer us not to.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest'. The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records and will use the minimum personally-identifiable information possible. We will store any research documents with personal information, such as consent forms, securely at the University of Oxford for up to 5 years after the end of the study. We will keep any other identifiable information about you for up to 1 year after the study has finished. The appointments with your GP (for those in the treatment groups) will be audiorecorded and then transcribed. The audio recorder will be stored in a locked filing cabinet at the Univeristy of Oxford. A professional transcription company will be used and a confidentiality agreement is in place to ensure all data is kept confidential. The transcriptions will be de-identified and the original recording will then be deleted. The blood samples that you provide will be processed by NHS laboratories and will be recorded in your clinical medical records in the same way that they would do if you had a blood test as part of your usual care at the surgery.

The daily diaries are done through a web-based programme, and before the data is downloaded to Oxford it will be stored on the host's system. This will not include any identifiable information.

Your GP practice will use your contact details to contact you about the research study and make sure that relevant information about the study is recorded for your care, and to

oversee the quality of the study. They will keep identifiable information about you from this study for up to 1 year after the study has finished. A copy of the consent form will be stored in your medical records permanently.

If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate.
Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/

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

Your participation is voluntary. If you decide you do not want to take part in the research at any point that is fine, and you can withdraw at any time without giving a reason. We will give you the opportunity to tell us the reason for withdrawing if you would like to. We will use the data that has been collected up to the point at which you decide to withdraw from the study.

It is important to understand that when you are saying yes to take part in the study, you are agreeing to have a discussion with the GP about the medication. You are not saying yes to taking the medication. When the GP gives you more information about how you will experiment with the medicine, you can decide whether or not to follow this plan.

If, after giving informed consent to take part in the study, you lose capacity to consent during the study, you will be withdrawn from the study. Identifiable data already collected with consent would be retained and used in the study. However, no further data would be collected or any other research carried out on or in relation to you.

WHAT WILL HAPPEN TO THE RESULTS OF THIS STUDY?

The results of this study will help us to design other, bigger studies to help reduce the chance people have heart attacks or stroke. These studies may help to change guidelines for patients and their healthcare professionals, about the different ways to help people decide whether a medicine is suitable for them or not.

The overall study results may be presented at scientific meetings or published in a scientific journal. Anonymous data will be part of the presentations and publications and may be shared with other researchers for future projects. You will not be identifiable in any presentation or publication.

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. Kate Tudor 01865 289301 or tasini@phc.ox.ac.uk; or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrg@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 to shape the ideas for this research, and also helped to design the study. We have asked patient representatives what they think would work well with the study and they also advised on parts of the study that may pose a challenge. Patients have also advised us what questions to ask in the optional focus group. One of our patient representatives has become a member of the study steering committee and will continue to be involved throughout the study. We also spoke to 200 GPs before desigining the study to see if they thought it was a beneficial study for their patients.

Who is organising and funding the study?

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

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 North of Scotland Research Ethics Committee.

Further information and contact details:

If you want to discuss the study in more detail please contact us on: 01865 289765, 01865 289301 or tasini@phc.ox.ac.uk.

Thank you for taking the time to read this information sheet