Imperial College London

3rd Floor Reynolds Building,
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The AHA Study

Participant Information Sheet

Title of the study: The use of AHA's Cholesterol CarePlan to be delivered as a web application on a smartphone to Patients Prescribed Cholesterol Lowering Medication

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You are being invited to take part in a research study conducted by Imperial College London. The study will involve the use of a web application on a smartphone. Participating in the study will require owning a smartphone. Before you decide if you want to participate in this study, it is important to understand what the study is, why is it being undertaken and the requirements for your involvement. Please take the time to read though the following information carefully. If you have any questions or do not understand something in the provided information, please ask the healthcare professional at the first visit. You are free to discuss the study with anyone you choose to better understand the study and your options. You do not have to sign the consent form unless your questions have been answered and you want to participate in the study. If you choose to participate, you are free to withdraw at any point in the study.

Principal Investigator: Professor Kausik Ray k.ray@imperial.ac.uk

Study Coordinator: Ms Maria Woringer m.woringer@imperial.ac.uk

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1. Background and purpose of the study

Cholesterol control is an important aspect of cardiovascular health. Physical activity, healthy diet, adherence to cholesterol lowering medication are all linked to a reduction of cardiovascular disease (CVD) events. However, these treatment therapies are limited by low patient compliance and engagement.

The American Heart Association (AHA) have developed a web application encouraging patients on cholesterol lowering medication to improve their lifestyle and regularly take medication.

This study will help to better understand if this application is the right intervention for patients to change their lifestyle and take their medication. The study will be a 12 week care plan with weekly reminders and educational videos focusing on lifestyle and medication adherence. The results collected from this study will be partly used for research towards a PhD.

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2. Why have I been invited?

You have been invited to participate as you are prescribed cholesterol lowering medication for a minimum of 30 days. You must also own a smartphone with access to internet to participate in this study.

3. Do I have to participate?

No, it is entirely up to you whether you would like to participate in this study. We will describe the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time without giving a reason. This will not affect the standard of care you receive.

4. What would taking part in this study involve?

You will be participating in a 12 week care plan on your smartphone. You will have 3 twenty minute visits with the healthcare professional at your GP clinic.

During each of your clinical visits (at weeks 1, 12 and 24) you will be asked to undergo clinical assessments of your weight, blood pressure, smoking and cholesterol, and answer some questions on the web application using your smartphone. During your 1st visit (week 1) you will meet with your healthcare professional, be asked to sign a consent form, undergo clinical measurements such as weight, blood pressure, smoking and cholesterol, be required to login to the web application using your mobile number and your date of birth and become familiar with using the web application to answer questions. You will also be given a unique ID for use in this study. During weeks 2-11, you will be sent text reminders to complete the weekly care plan on the web application. You will be prompted to answer questions, self-record your weight and blood pressure (if you have the equipment) and watch 20 seconds to 5 minute educational videos. Alternatively, if you do not have a blood pressure cuff or a scale in your home, you may skip questions pertaining to blood pressure and weight. It should take 5-15 minutes to complete weekly questions in your own time. You will have a week to answer each week's questions and may resume completing the questions at a later time by clicking on the link sent as the reminder.

5. What will I have to do in this study?

By participating in this study, you will have to attend 3 visits with a healthcare professional at the GP clinic, answer questions on your lifestyle on the web application and take some measurements including providing a total of 3 blood samples in the amount of 4 teaspoons each over 6 months. You will not need to fast to collect the blood samples. Over the 12 weeks of using the application on your phone, you will be asked some questions, watch videos and record your weight and blood pressure, if you have the equipment at your home. Alternatively, if you do not have a blood pressure cuff or a scale in your home, you may skip questions pertaining to blood pressure and weight. All of this data will be entered in to the web application.

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6. How will the data be collected and stored?

Participants will be asked a series of different questions on the application each week and also complete 4 questionnaires at week 1 and the follow-up visit (3 months after week 12). The storage and transmission of recorded responses and identifiable data will be stored in a secure digital platform and handled in accordance with Data Protection Act 1998. Anonymous data (not containing your name, mobile number nor your date of birth) will be stored in a password protected computer at Imperial College London, accessible to the research team only. To prove that research activity took place, a copy of the consent form containing your name will be given to you, stored at the general practice and mailed to Imperial College London via recorded post. Data and all appropriate documentation will be stored at Imperial College London for a minimum of 10 years after study completion including the follow-up period. The 3 blood samples collected from you will be stored in the usual manner that blood is collected and stored in GP practices and destroyed after the study is completed. Study results will only be published in aggregate form. No individual patient level data will be published. If you do withdraw from the study before it ends, then Imperial College London will keep hold of collected data and use for scientific analysis.

7. How will this information be used?

We will use the findings to look at the impact the application had on the study participant's lifestyle, medication adherence, changes to weight, blood pressure and cholesterol. We may also use the findings for other areas of research related to health promotion and CVD. The clinical measurements as well as information on medication adherence may be made available to your GP.

The results will be presented in scientific journals and conferences. Study participants will not be identified in any report or publication. Upon study completion, a summary of the study findings in aggregate form will be provided to AHA and published on the departmental web site http://www.imperial.ac.uk/school-public-health/primary-care-and-public-health/.

8. What are the potential benefits and disadvantages of participating in this study?

The benefit of this study is that it may help you understand how to better manage your cholesterol with lifestyle and medication adherence. In addition, you will be the first to trial a new digital tool for health promotion. You will have a chance to meet with healthcare professionals and discuss your progress. The results from your participation will help us to gain a better understanding of engagement with new technology and its potential to improve cholesterol management. These findings can help to deliver better patient care.

The potential disadvantages are that this requires 20 minutes of your time for 3 clinical assessments, weekly participation of 5-15 minutes and provision of 3 small samples of blood. You will not have to fast for the 3 clinical visits when bloods samples will be

collected. However, there is a potential risk of discomfort or potential bruising when the blood samples are taken.

9. What if there is a problem?

If your health professional identifies any abnormal results, your GP will be informed. Throughout the six month study period, the capacity of the participants will be monitored. If during the course of the study, loss of capacity is determined, then any data captured pertaining to that individual during the course of the study will be removed in its entirety from the relevant research database. Imperial College London holds insurance policies which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Principal Investigator (Professor Ray: k.ray@imperial.ac.uk, 020 7594 0716). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

10. Expenses and payments

We appreciate the time you will be dedicating to the study but unfortunately, you will not be compensated for any costs incurred for visiting the GP clinics during the period of the study. You will not be provided with any equipment to participate in this study such as smartphone or blood pressure monitors.

11. Who is sponsoring and funding this study?

The study is sponsored by Imperial College London and funded by the American Heart Association.

12. Who has reviewed the study?

This study was externally peer reviewed for scientific content. It is approved by the North of Scotland Research Ethics Committee to protect participants' safety, rights, wellbeing and dignity.

13. Further information and contact details

If you would like further information or have any questions about this research study, please contact the study coordinator, Ms Maria Woringer at 0207 594 0789 or via email m.woringer@imperial.ac.uk. We are happy to answer any questions you have.

We thank you for taking the time to read this information sheet and considering to participate in this research study.