

## Participant Information Sheet for 11 to 15 Year-Olds (OxSOCRATES Online)

My name is Dr. Alexander Jones and I work at the University of Oxford in the Department of Paediatrics. I am inviting you to join in a research study. Please read this sheet to learn more about what it would involve, so you can decide whether you want to take part or not. You should talk to your family about it as well. We have sent some information to them too, to help you all decide together. The study team will be happy to answer any of your questions before you decide.

### Why are we doing this study?

As we get older, our heart and blood vessels change and may not work as well as they used to. Thankfully, most of us don't start having obvious problems or illnesses as a result until middle-age (about 40 years old) or older. However, we want to prevent this from happening at all, if we can.

We think this process might at least be slowed down if we do something about it when people are young. First, we need to know more about what is changing in young people as they get older and about what keeps them healthy. We already know that what we eat and how we live our lives is important. People who exercise more, eat healthily, and don't put on too much weight stay well for longer. Sadly, most people are not living as healthily as they could, including children.

We would like to investigate what happens to young people who do different amounts of exercise and eat different amounts of healthy and unhealthy foods. We also want to find out what happens when we ask some of those young people to take part in a fitness club. We think this will make their health better and we want to understand how it does that. In the end, our aim is to find a way to make sure that young people like you grow up healthily and live a long, healthy life, free of illness.

### Why have I been asked to take part?

You have been asked to take part because you are healthy, aged between 11 and 15 years, and have an activity level, height, and weight that is suitable for our study.

### Do I have to help?

No, you don't have to. It is up to you to decide with the help of your family. If you don't want to be part of the study, that's fine. It won't upset anybody or change the way you are looked after in the hospital if you are ever unwell. If you do take part, but later want to stop, you only need to tell the researcher about your decision and you do not have to give a reason. If you have dairy allergies, type 1 diabetes or there are any reasons why you cannot safely exercise or have an MRI scan, then you will not be able to take part, unfortunately. If you think you could be pregnant then you do not have to tell anyone, but please do not agree to take part.

### What does the study involve?

Depending on your school, you might take part in a fitness assessment as part of your PE lesson. If this is not possible, we will ask you and/or your parent/guardian to complete a form online instead, which will provide us with your parents/guardians contact information. We will then contact them by phone/video call to gain permission to collect information on your height, weight,

date of birth and activity levels. Depending on your results, there are two options for what happens next:

- (1) We will check your blood pressure, using a small device that attaches to a cuff worn around your arm for roughly two days and a night. This will be fitted and returned at university sites in Oxford. At these sites, we will also ask you to complete a fitness test on a running machine or exercise bike, complete a short questionnaire, stand briefly on a machine similar to weighing scales so that we can understand how your body is made up (how much muscle you have, how much fat etc.) and wear a physical activity watch for a week. Then we will ask you to visit us at the hospital for about 5 hours where you will have body scans, some blood tests and drink a rich milkshake (dairy-based). After a year, we will ask you to have another blood pressure check and wear an activity watch for a week. At the start and end of this year, we will ask you to answer questions online about your health and your diet. The diet questions will be done on three separate days each time.
- (2) Some children will be asked to do everything mentioned above in option (1) but also asked to take part in a 2-month fitness club (3x 1-hour sessions per week), where you will be supervised by our fitness experts over a video link online. Most exercise sessions will be done at home in this way but there may be an option for you to do some sessions online during normal PE lessons, depending on which school you go to. During those two months, you will complete another diet assessment and wear the activity watch again. At the end of the fitness club, they will visit the hospital again for the same tests they had before, have another 36-hour blood pressure check, visit university sites to complete another fitness test, questionnaire and body structure measurement, wear the watch and answer more online questions.

You will be able to answer the questions using a web browser in the comfort of your own home, so you can take all the time you need to fill in the form and get help from your family if you need it. We will also help you with any bits you are not sure about. To supplement your online answers, we will ask your school to tell us how you did in your exams and whether you are eligible for free school meals or not. More details on the measures summarised above are given below:

### *Before Your Visit to the Hospital*

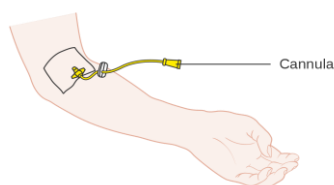
To make sure that the results of our tests are accurate, we will ask you to avoid coffee / tea, alcohol, tobacco (cigarettes) and any other recreational drugs for at least a day before your visit. We will also ask you not to exercise after 3 pm that day and to eat a standard meal (Margherita pizza) the night before your visit. If you are coming to the hospital in the afternoon, we will also ask you to eat a standard breakfast (a slice of bread or toast with butter or margarine but not other spreads) in the morning. After that, you should not eat again and should drink only water until after your visit. Before you come to the hospital we will ask you to collect a urine (wee) sample using a container that we will give to you. We will give you and your parents' instructions on how to do this. We expect that most of the time this can be done on the morning of your visit to see us at the hospital or even during the visit itself. We will test this sample to get information on what you normally eat. We would also be very grateful if you would collect a small sample of your stool (poo) before coming to the hospital. Again, this will usually be on the same day or sometimes on the day before your visit. These samples will be stored securely at the university departmental freezers and will then be analysed to help us find out whether the bacteria that live in your gut are important for keeping you healthy.

### *Your Visit To the Hospital*

We will ask you to come to the hospital in Oxford with a parent or guardian to do some tests. This is not because we think you are unwell but because that is where we do our science. The visit will last about 5 hours. The main test will be a body scan called an MRI or "magnetic

resonance” scan. The scanner is shaped like a tunnel and you lie inside it. It is safe but a bit noisy. It takes pictures of the inside of our bodies without touching us. You can have a parent or guardian with you during the scan and you can watch a movie or listen to music to pass the time. The initial scan will last for about 1 ½ hours and you will have three chances to get up and stretch your legs during this scan. After, there will be two further brief scans during the visit (about 15 minutes each).

To find out how your body reacts to a rich meal, we will ask you to drink a creamy milkshake (dairy-based). The MRI scan will show us what your heart, muscles, liver and other parts of your body do to process the meal. We will also measure how your body responds by looking, for example, at the levels of sugar and fat in your blood. We will take a sample of your blood using a cannula (a thin plastic tube) placed temporarily in a vein in your hand or arm. This is illustrated below:



We use cannulas in children of all ages every day in the hospital. The cannula is placed using just one small needle that is then removed, leaving the thin plastic tube behind. Once the tube is in place, you cannot usually feel it. You may feel a “sharp scratch” very briefly when the cannula is placed in your vein. The cannula will be removed at the end of the visit.

### *One-year Follow-up*

After a year, we will do another blood pressure check (fitted and returned at university sites), ask you to wear an activity watch and answer more questions online. This will show us whose health changed the most over the year.

### What happens to the results of the study?

We will keep your information private. This means only people with a need or right to access to it will be able to, including the research team and your parents/carers. We will only share information that has your name and address removed. Only a number will be used to identify you, and all information and results will be kept in secure computers or in locked cabinets in secured rooms in the University. We will publish our findings in scientific journals, but this may be two to three years from the end of the study. We will keep all research data and records for a minimum of 10 years after the end of the study. Third parties may be given access to research data for monitoring and/or audit of the study, or for data storage purposes.

### Is there a reward for helping?

We hope that you will find the experience interesting and we will try to make it educational. We would also like to give you a voucher (e.g. Amazon) worth £30 to thank you for your help. If you take part in the fitness club, your voucher will be worth more (£40) to thank you for the extra effort.

### What are the risks of helping with this study?

This study is safe and there are no serious risks from helping with it. However, you may experience some minor discomfort due to having the cannula (blood test). Having an MRI scan is safe but lying in the tunnel can feel a bit strange to begin with. Most people get used to it quickly.

### Who is organising and funding the research?

The research is organised by Dr. Alexander Jones of Oxford University, who is a Paediatric Cardiologist and British Heart Foundation research fellow. The study is being paid for by the

British Heart Foundation.

### Who has reviewed the study?

Before any research involving people can start, it has to be checked by a Research Ethics Committee to make sure that it is OK for the research to go ahead. This study has been approved by the University of Oxford Central University Research Ethics Committee.

### What if there is a problem or something goes wrong?

Please tell us if you are worried about any part of this study, by contacting the researcher at [OxSOCRATES@medsci.ox.ac.uk](mailto:OxSOCRATES@medsci.ox.ac.uk). You may also talk to your teacher/parent/carer who will let the researcher know. If you are still unhappy or wish to make a complaint, you or your teacher/parent/carer can write to the Chair of the Medical Sciences Inter-Divisional Research Ethics Committee at Research Services, University of Oxford, Wellington Square, Oxford. OX1 2JD, or email [ethics@medsci.ox.ac.uk](mailto:ethics@medsci.ox.ac.uk).

### Further information

We will be happy to talk to you about this study and answer your questions. If you decide you want to help us with the study, you can change your mind at any time and we won't be upset. The Principal Investigator can be contacted as follows:

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**Thank you very much for taking the time to think about our study**