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INFORMATION SHEET FOR PARTICIPANTS

Study Title: The Effects of Supervised Exercise Training in the Primary Prevention of Cardiovascular Disease in Statin and Non-Statin Users

In this research study we will use information provided by you to investigate the benefits of exercise training in the prevention of cardiovascular disease (CVD) in both statin and non-statin users.

Please take time to read the following information carefully. You do not have to make an immediate decision with regards to whether you wish to take part in the study. If you have any questions do not hesitate to discuss it with us, friends, relatives or your GP. We will do our best to explain all procedures and answer any questions that you may have now or later.

What is the purpose of the study?

CVD refers to any condition that affects the heart and/or blood vessels (e.g. heart attack, stroke) and is currently the leading cause of death and disability worldwide. The QRISK3 calculator is commonly used by GPs and healthcare professionals to identify an individual's risk of developing CVD and it is also used to help decide whether certain treatment options are necessary. You may have had your QRISK3 score calculated at a recent GP appointment, but if not, you can calculate your QRISK3 score yourself at https://qrisk.org/three/. A score of 10% means that you have a 10% chance of having a heart attack or stroke over the next 10 years. Although this risk is low, if your score is 10% or higher your GP will advise that you make lifestyle changes such as starting to regularly exercise in order to reduce your CVD risk. In addition, it is also possible that individuals with a QRISK3 score of 10% or higher will be recommended to start taking a statin by their GP. This is because both regular exercise and statin therapy can separately reduce the risk of CVD. Regular exercise provides a variety of cardiovascular health benefits and has a particularly positive effect on the health of blood vessels. Alternatively, statin therapy mainly reduces CVD-risk by lowering cholesterol in the blood stream, which may also help to improve blood vessel health. Although both therapies can separately reduce CVD risk, the interaction between exercise training and statin therapy on blood vessel function has never been directly compared in individuals with a QRISK3 score of 10% or higher, and it's currently unknown whether a combination of both therapies offers additional cardiovascular health benefits.

Therefore, this study will investigate the effect of supervised exercise training on blood vessel health in individuals with a CVD-risk score of 10% or higher and examine whether these exercise effects differ in individuals currently taking a statin compared to those not taking a statin. All participants will be randomly assigned to either 12-weeks of supervised exercise training or 12-weeks of non-exercise (conventional primary care group; maintenance of usual lifestyle). Blood vessel structure and function of the limbs and brain will be assessed using sensitive ultrasound techniques before and after the 12-week study period. The findings will highlight any similarities and/or differences between the separate effects of exercise training and statin therapy on blood vessel health; and determine whether the combination of these recommended CVD prevention pathways offers additional cardiovascular health benefits.

Why have I been invited?

As a volunteer, you have been asked to take part in this study as you have a 10-year CVD risk score greater than or equal to 10% (QRISK3 score), and you participate in minimal

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structured exercise. You are **EITHER** taking no prescribed medication **OR** you have been prescribed to a statin for a minimum of 3 months.

Do I have to take part?

Your participation in the study is entirely voluntary. This means, it is up to you to decide whether or not you wish to take part. To help you make a decision, we will describe all aspects of the study and go through this information sheet with you and will answer any questions that you may have. If you decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. You are allowed as much time as you need to consider this study and you are free to withdraw at any point without having to provide a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care that you receive.

Am I able to take part?

We are looking for males and females aged between **50 and 65 years** with a **QRISK3 score greater or equal to 10%** who **do not** engage in regular structured exercise. We are looking for individuals who are **EITHER** taking no prescribed medication **OR** have been prescribed to a statin for a minimum of 3 months.

You should **not** volunteer if you:

- Have diagnosed CVD (e.g. previous heart attack or stroke) or any other established chronic disease (e.g. diabetes, severe arthritis, cancer)
- Use any medication other than statins (e.g., fibrates, metformin, thiazolidinediones, orlistat, blood pressure medication).
- Are a smoker (or recently quit within the last 6-months),
- Are a post-menopausal female using hormone replacement therapy, or a pre-menopausal female using oral contraceptives.
- Have been advised by your GP not to undertake exercise

If you are not sure whether you are able to participate, do not hesitate to get in contact. Additionally, we will give you a questionnaire to identify any known health reasons which will prevent you from participating in this study.

What is required at the start of the study?

If you are interested in participating in this study, you will be called by a member of the research team. A short initial screening process will be completed to ensure that you are eligible for the project and that it is suitable for you to engage with exercise training. As part of this process, you will be asked to complete a series of short questionnaires. It will also provide a great opportunity for you to ask any questions that you have about the study. If you decide to participate, you will be asked to visit the Cyncoed campus at Cardiff Metropolitan University on three occasions. During each assessment visit, you will be greeted at the University entrance by a member of the research team. You will be guided to our laboratories, where you will have time to ask any remaining questions related to the study. You will then be asked to sign a consent form that confirms that you are happy to participate in this study. If you wish, you can bring a companion with you to any of the assessment visits. Below is a detailed overview of what will take place during each visit.

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Visit 1 – Blood Vessel Assessment & Blood Sample (~3 hours)

Blood Vessel Assessment:
This visit will involve four main parts:

- **Arterial Stiffness:** Following 15 minutes of bed rest, three electrode pads will be attached to your chest and a small pen-like device will be delicately placed on your wrist, neck and upper leg to measure the stiffness of your blood vessels. An ultrasound probe will also be placed on your neck and on the upper part of your leg to allow us to image your blood vessel. This ultrasound procedure is safe and completely painless and is the same as the techniques used to scan pregnant women.

- **Flow-Mediated Dilation (FMD):** A small blood pressure cuff will be placed below your right elbow. An ultrasound probe will then be placed above your right elbow to take images of a blood vessel in your arm for 1 minute. Following this, the cuff around your arm will be inflated. After 5 minutes of cuff inflation, the cuff will be deflated and images from the ultrasound probe will be recorded for a further 3 minutes. During this test, you may feel a sensation of numbness, tightness, pins and needles or mild discomfort below the cuff during inflation. However, this sensation will disappear immediately after the cuff is released.

- **Sublingual Glyceryl Trinitrate (GTN):** Following 10 minutes of bed rest, we will again place the ultrasound probe on your arm and neck. After recording images of the blood vessels in your arm and neck for 1 minute, we will spray GTN (400µg) under your tongue. GTN is usually used to relieve chest pain (angina) in patients with heart disease, but we are using it to mimic a hormone in your body, called nitric oxide. This will cause a relaxation (widening) of your blood vessels, which allows a short-lived increase in blood flow. After the GTN administration, we will continue to image the blood vessels in your arm and neck with the ultrasound probe for a further 10 minutes. The GTN dose that we will administer is entirely safe and widely used in both clinical practice and research and its effects will wear off within approximately 15 minutes.

- **Cold Pressor Test:** Following a final 15 minute rest period, the ultrasound probe will be placed back on your neck. After one minute of ultrasound measurements at rest, you will be required to place your left hand, up to your wrist, into ice-cold (4℃) water for 3 minutes. We will continue to measure the blood vessel in your neck throughout this 3 minute period and for an additional 3 minutes once you have removed your hand from the water. During this test, you may experience some slight discomfort and numbness when their hand is placed in cold water but these sensations will typically disappear after 30-60 seconds.

Blood pressure will be measured periodically throughout each of these procedures by attaching a blood pressure cuff to your upper arm, and/or the middle finger of your left hand.

7-Day Physical Activity Monitoring: At the end of this visit, you will be fitted with an activity monitor. This is a small lightweight device that will track your daily physical activity levels. You will wear this device continuously on your waist for 7 days. During these 7-days we want you to carry out your normal daily routine so we can get an idea of your typical daily activity levels.

Visit 2 – Brain Blood Vessel & Cognitive Assessment (~2.5 hours)

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Blood Test: You will have a blood sample taken by a member of the research team who is trained in phlebotomy. The blood sample will be taken from a vein in your arm by a researcher trained in phlebotomy. No more than 30 ml of blood will be taken (equivalent to just around 2 tablespoons). Blood will be collected to look at traditional markers of cardiovascular risk (i.e. glucose, insulin, cholesterol) as well as other markers of cardiovascular risk that are not routinely assessed as part of your routine primary care.

Cognitive Assessment: You will be asked to complete a questionnaire with 30 short questions/tasks to asses multiple aspects of your thinking including your short-term memory, language, and concentration levels.

Brain Blood Vessel Assessment: During 20 minutes minutes of bed rest, a headband will be fitted on your head. This will have two ultrasound probes attached to both sides for the recording of blood flow within your brain. These probes will be moved until the correct blood vessels within your brain are located. Once the appropriate blood vessels have been identified and the probes have been secured into place, we will then place a different ultrasound probe on either side of your neck to image the two blood vessels that supply blood flow to the brain. We will take resting measurements for approximately 5 minutes and then conduct the following tests:

- **Neurovascular Coupling:** You will be asked to perform a series of short sensory tasks. These will include a simple reoccurring eye opening and closing protocol, reading a short paragraph from a text book and performing a simple visualisation task involving a flashing checkerboard.

- **Dynamic Cerebral Autoregulation:** Following a period of 5 minutes of rest, you will be asked to complete 2 repeated squat to stand protocols that will last for 5 minutes. The first protocol will consist of 5 seconds of squatting followed by 5 seconds of standing. The second protocol will consist of 10 seconds of squatting followed by 10 seconds of standing. This is to assess the brain's ability to respond to changes in blood pressure.

- **Cerebrovascular Reactivity:** Following a 10 minute period of rest, you will be asked to perform a carbon dioxide breathing protocol.This will involve you wearing a facemask and breathing a fixed gas mixture of otherwise normal atmospheric air that has a slightly higher concentration of carbon dioxide (6%) for 6 minutes. This procedure is entirely safe and will allow us to measure the capability of your brain’s blood vessels to dilate (widen). During this procedure, your breathing rate may increase to a similar amount as when you perform light exercise (i.e. brisk walk).

- **Moderate Intensity Exercise:** After 15 minutes of rest, with the headband still maintained in place, you will perform a 10-15 minute bout of moderate intensity exercise on a bike.

Blood pressure will be measured periodically throughout each of these procedures by attaching a blood pressure cuff to your upper arm, and/or the middle finger of your left hand. Additionally, a mouthpiece will be used to monitor your breathing rate.

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24-hours Blood Pressure: At the end of this visit, you will be given a portable, automated blood pressure monitoring device. The device will be worn on a waist-belt connected to a small blood pressure cuff, which will be positioned on your upper arm. This device will only be worn for one full day (24 hours). Clear instructions on how to fit and position the device, as well as guidance on how long the device should be worn will be provided by a member of the research team. You will be requested to return the device during the next visit to the laboratory.

Visit 3 – Body Composition and Fitness Assessment (~1 hour)

Body Composition: Your height, weight, waist and hip circumferences will be measured. We will also use a specialised set of scales and briefly apply skinfold callipers to your upper back, chest, arm and thigh to measure your body fat percentage.

Exercise Test: You will then complete a maximal exercise test to exhaustion on a motorised treadmill. Firstly, we will place some electrode pads on your chest to monitor your heart rate and rhythm while you exercise. You will then be asked to wear a facemask that is connected to a gas analyser so that we can collect and measure your expired air at rest and during exercise. Initially, you will be asked to perform a light warm up on the treadmill for 2 minutes. At the start of the test, you will be asked to walk at a slow pace against a slight treadmill gradient for 2 minutes. Thereafter, the treadmill speed and gradient will gradually increase every 2 minutes, until you reach a point where you can no longer continue. This test will be specifically designed based on your individual ability, and typically lasts between 10-15 minutes.

What is required after the assessment visits?

After the first 3 visits you will be randomly allocated to one of two groups: a supervised exercise training (A.I) or a conventional primary care group (A.2) as shown in Figure 1. You will be required to complete a standard 3-day food diary to provide us with information regarding your normal dietary intake and fill in a brief questionnaire to highlight if any muscle discomfort develops at weeks 1, 6 and 12. In addition, if you are allocated to the conventional primary care group (A.2), you will also be asked to complete a physical activity questionnaire at weeks 1, 6 and 12. Finally, if you are a statin user, you will be asked to provide information on your statin adherence throughout the 12 weeks.

Supervised Exercise Training Group (Figure 1, A.1)

If you are randomly allocated to the supervised exercise training group you will undertake a 12-week individually tailored, progressive moderate intensity exercise intervention. This programme will be supervised by an exercise specialist at Cardiff Metropolitan University (Cyncoed Campus). Exercise training will comprise of a combination of treadmill, cross-trainer and cycling based exercise. As shown in Figure 1 (A.1) exercise will progressively increase in intensity (week 1: 40% to week 12: 60%) and duration (week 1: 3 times per week to week 12: 5 times per week) throughout the course of the intervention. A variety of flexible time slots will be available each week for the supervised exercise training sessions. These flexible slots will allow you to attend each of your exercise training sessions at a time that is most convenient to you and also allow you to reschedule a session if necessary.

Conventional Primary Care Group (Figure 1, A.2)

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If you are randomly allocated to the conventional primary care group, you will not participate in any supervised exercise training during this 12-week period. Instead, you will be asked to maintain your typical lifestyle behaviours (i.e. maintain normal dietary and physical routine) in line with your routine primary healthcare. However, at the end of the study you will be offered to enrol onto the same 12-week exercise training program as the other group.

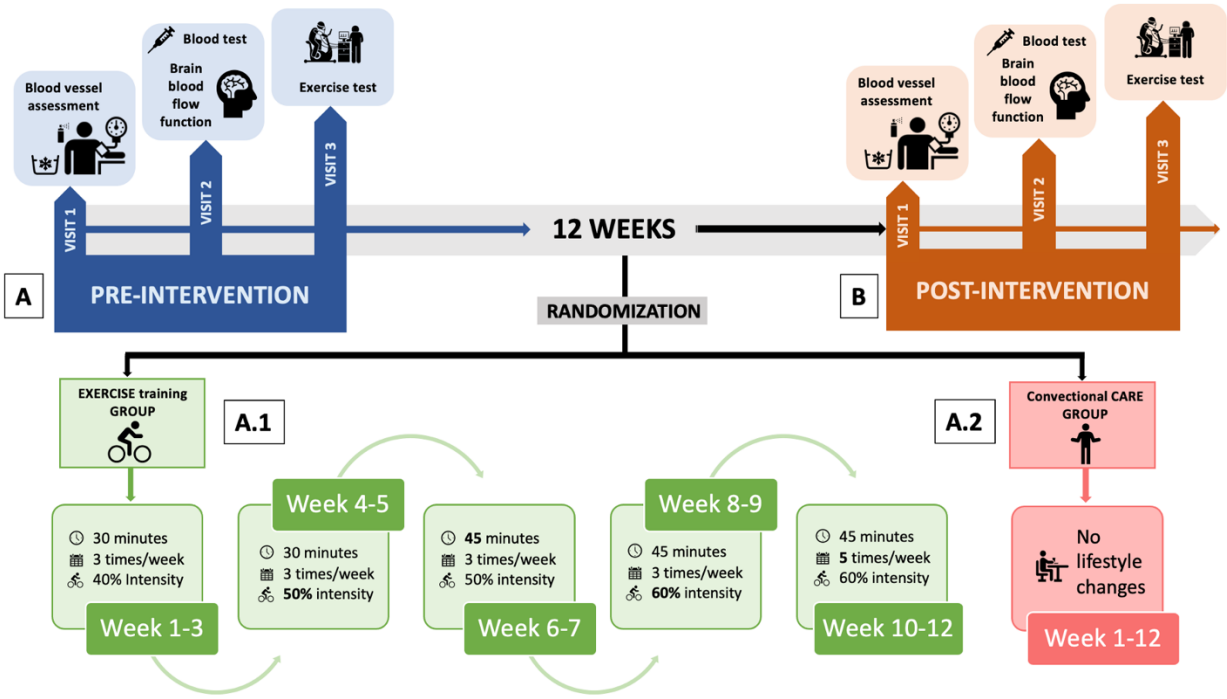

Figure 1. Diagram representing the study phases. **Part A** shows the measurements that all participants will undertake before the 12-week intervention. **Part A.1** shows the different phases of the supervised exercise intervention over the 12-weeks and **Part A.2** shows the conventional primary care group over the 12-weeks. **Part B** shows the measurements that all participants will undertake after the 12-week intervention.

What is required after the 12-week intervention?

Irrespective of whether you are assigned to the supervised exercise or conventional primary care group, after the 12-week intervention period, the initial 3 assessment visits (detailed above) will be repeated (Figure 1, B).

What do I have to do in preparation for ALL assessment visits?

IMPORTANT

For **ALL** assessment visits (pre and post the intervention) you will be required to attend the laboratory having abstained from alcohol and caffeine consumption for 12 hours, and avoided strenuous exercise for 24 hours. For **visit 1** and **2** you will be also required to attend the laboratory having fasted for 6 hours. Finally, for **visit 2** and **3** you will be required to bring a pair of trainers and suitable clothing to exercise.

For visits 1 and 2, we suggest that you bring some small snacks for after the testing sessions. Alternatively, there are a variety of food outlets and cafes onsite where you will be able to

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purchase food and refreshments. Finally, please attend all assessment visits wearing a loose fitting short-sleeved t-shirt so we can easily perform the ultrasound assessments.

What are the possible disadvantages and risks of taking part?

You will be continuously monitored by the researchers throughout all of the assessment visits and you can ask to stop an assessment at any time. None of the assessments and/or interventions conducted in this study are expected to cause any substantial side effects. The procedures have been used for research purposes in Universities and imaging centres around the world for many years. However, further specific details of any possible disadvantages/risks are given below.

Visit 1

• Blood Test: You may feel nauseous, lightheaded, or dizzy after donating blood. If this happens, it should only last a few minutes. You can lie down with your feet up until you feel better. You may also experience some bleeding at the site of the needle. Applying pressure and raising your arm for a couple of minutes usually stops this. You may develop a bruise at the site, but this will disappear within a few days. Blood sample donation is considered safe. There is no risk of contracting disease as new, sterile equipment is used for each participant and staff have undergone training on safely collecting and handling your blood.

• Sublingual Glyceryl Trinitrate: GTN is a drug that when sprayed under the tongue, causes your vessels to temporarily increase in size allowing a short-term increase in blood flow. In some rare cases (<1% of subjects), the GTN spray might cause a mild headache. In such cases, the headache typically disappears after 15 minutes and/or can be managed using paracetamol. Other rare side effects may include a slight lowering of blood pressure, which returns to normal after a short period of time (i.e. less than 10 minutes). GTN has been used for many decades in clinical and research work and the likelihood of any of these side effects occurring is extremely low.

• Flow Mediated Dilation: After the inflation of the cuff around your arm you may feel minor short-lasting discomfort, tightness and/or pins and needles in the forearm. However, after cuff release, any discomfort or sensation of 'pins and needles' will disappear immediately. In the unlikely event that you cannot tolerate the cuff inflation, the cuff will be deflated immediately, and the test will be stopped.

• Cold Pressor Test: You may experience some slight discomfort and numbness when your hand is placed in cold water. These sensations typically disappear after 30-60 seconds. In the unlikely event that you become too uncomfortable during the test, we will take your hand out of the water immediately and finish the test.

Visit 2

• Cerebrovascular Reactivity Test: There are no risks associated with breathing the slightly higher concentration of carbon dioxide (6%) as part of this test. However, you may experience a minor headache or dizziness at the beginning of the carbon dioxide breathing. These symptoms are temporary and typically decrease after 30-60 seconds. In the unlikely event that these symptoms do not decrease, and you become uncomfortable, the test will be stopped immediately.

Visit 3

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• Maximal Exercise Test: It is possible that you may find the exercise test uncomfortable as you reach volitional (voluntary) exhaustion. However, you will be closely supervised and monitored throughout the protocol and will be connected to an ECG machine to continuously monitor your heart rate and rhythm. There is a minimal risk of dizziness and/or fainting immediately after a maximal exercise effort and it is possible that participants may experience some mild muscle soreness the day(s) following the test. The risk of dizziness and fainting will be minimized by instructing the participants to perform a light-intensity 'cool down' for 3-5 minutes immediately following the test. This process will also markedly reduce the likelihood of subsequent muscle soreness on the days following the exercise test.

12-week supervised moderate-intensity exercise intervention

If you are randomly assigned to the 12-week supervised exercise intervention group (A.1), we can see that it is a considerable time investment for you to make. However, engaging in regular exercise will have been recommended to you as part of your routine primary healthcare and this study provides the rare opportunity to attend a free individually tailored exercise program supervised by professional exercise physiologists. Although incredibly unlikely, exercise training can potentially cause shortness of breath, dizziness, muscle injury, and in very extreme circumstances, heart disturbances. However, the chances of any of these events occurring is incredibly low, especially during moderate intensity exercise. These small risks will be minimised by ensuring that you are appropriately screened for exercise. In addition, the exercise program will be progressive in nature, specifically designed to your individual fitness levels, and fully supervised by an exercise professional, which will further reduce the likelihood of any of these very rare events. You will be advised to stop exercising if you feel unable to cope or distressed and you will be monitored throughout each exercise session. Water will be available, and the exercise sessions will be performed in a temperature controlled room.

What are the benefits of taking part?

It is well documented that regular exercise has wide-reaching health benefits and reduces the risk of cardiovascular events (e.g. heart attack and stroke). Regardless of the group you are assigned to (Group A.1: Supervise exercise intervention or Group A.2: Conventional primary care) you will be offered the opportunity to receive a structured and supervised exercise program by a qualified exercise physiologist free of charge for 12-weeks. This includes the opportunity to freely use Cardiff Metropolitan University's state-of-the-art gym equipment and exercise facilities during these 12-weeks. This is the perfect opportunity for you to incorporate regular exercise into your daily routine as an effective and personalised approach to reduce the risk of CVD.

You will also receive education on your blood vessel function, and learn about CVD risk factors, CVD prevention/treatment options and the long-term health benefits of regular exercise. We hope that the information we get from this study will help us to better understand how effective exercise training is in preventing CVD in statin and non-statins users.

What expenses will I receive?

All university site parking fees that are required to park at the University site will be covered/waived by Cardiff Metropolitan University for all testing visits and exercise training sessions throughout the study. However, it is not possible for other travel expenses to be reimbursed.

What happens if you find something unusual on my scan?

It is important to note that this study is completely research focussed, and all data collected are for specific research purposes only and not suitable for diagnosis of heart and/or blood

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vessel related conditions. Accordingly, you should not regard these research scans as a medical screening procedure. Nevertheless, occasionally when we image healthy participants, the researchers may be concerned that a potential abnormality may exist on the scan. In this case, we will raise this issue with you and suggest that the scan is reviewed by our affiliated Consultant Cardiologist. If further clinical examination is required, a direct referral to the Vascular or Echocardiography Unit at University Hospital Wales will be made, and your GP will be informed. Albeit very unlikely, any such circumstances should be considered as a positive step, as it would lead to earlier detection and subsequent treatment of the otherwise-undetected condition.

COVID-19 and your safety during your research visit

The health, welfare and safety of our participants is our number one priority. A thorough risk assessment has been conducted with regards to COVID-19 and measures have been taken and practices put in place to mitigate risk. In line with Cardiff Metropolitan University COVID-19 regulations, you will be asked to complete a remote screening questionnaire for COVID-19 symptoms via email 24 hours prior to each visit to confirm that you are symptom-free. **Please do not attend if you have any COVID-19 symptoms,** instead contact us via one of the contacts below. For all visits, you and the researchers will be equipped with any necessary personal protective equipment (PPE) and the laboratory will be adequately ventilated at all times. Our risk-mitigating procedures are directly informed by the current Welsh government COVID-19 guidelines and our University's COVID-19 risk assessments. These will be strictly adhered to throughout the study, and reviewed if/when scientific updates on risk guidelines are provided by the Welsh government.

What will happen to the results of the study?

We hope to publish the results of this study in a medical or scientific journal. We may also present the results at a scientific conference or at public health seminars that we undertake at our University. We would be happy to discuss the results of the study with you and to send you a copy of the published results. It will not be possible to identify you or images of your vessels or brain in any report or publication. Finally, we may share some of your anonymised data with other collaborating researchers at other organisations in order to conduct additional analysis in the future.

What will happen to the blood samples I provide?

It is important you understand what will happen to the blood sample you give during the study. After blood has been sampled from a vein in your arm or hand (in the same way as when you donate blood), the sample will be given an anonymised code and will be sent to the lab for processing within 24 hours. With your permission some blood will also be taken and stored for future analyses, which will examine the blood biomarkers which are likely to be important in relation to CVD and your blood vessel health. This sample taken for analysis will be stored for 10 years in the custody of the principal investigator, Dr Chris Pugh at Cardiff Metropolitan University.

If you withdraw from the study after providing the sample, your blood sample with be processed in the same way as detailed above, unless you decide that you want the sample to be withdrawn from the study and disposed of. Finally, the venous blood sample you provide at Cardiff Metropolitan University will be anonymised and may be transferred to other collaborating institutions for specific analysis.

Will my personal information collected as part of this study be kept confidential?

Principal Investigator: Dr Chris Pugh,

Cardiff Metropolitan University, Cardiff, CF23 6XD

Email:cjpugh@cardiffmet.ac.uk Tel: 02920 205293

All information that is collected about you during the course of the research will be kept strictly confidential and secure under the direction of the Principal Investigator. Any information about your identity obtained from this research will be kept private and all data will be fully anonymised. Your personal information will be kept strictly confidential at all times and access to this information will be restricted to those few members of the research team that really need it to conduct the study.

We may share the anonymised data we collect with researchers at other institutions including Universities and commercial research organisations for similar future research. However, any information that is shared will have your name and address removed to ensure confidentiality at all times. We will use your anonymised data to publish scientic reports and research articles, but again, these documents will not include information that will make it possible for other people to know your name or identify you in any way. If you join the study, some parts of your personal records and/or study data may be reviewed by authorised individuals from the University, for the purposes of monitoring and audit. Data will be kept securely for a minimum of 10 years in accordance with good research practice and data protection regulations imposed by Cardiff Metropolitan University and the Data Protection Act 1998 and GDPR regulations.

What will happen if I don't want to carry on with the study?

You are free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not negatively affect you in any way. If you lose the capacity to consent to take part in the study you will be withdrawn, but your anonymised data will still be used.

Who is organising and funding the research?

This research study has been organised by Cardiff Metropolitan University in order to fulfil educational qualifications (PhD: Miss Xela Dafauce Bouzo & Miss Jemima Benson) and is funded by the Welsh Government; (Ser Cymru; Health and Care Research Wales) through a grant managed by the PI, Dr Chris Pugh.

How will we use information about you?

Information collected as part of this research study and information from your medical records / GP will be used for this research project. This information will include your initials/ NHS number/ name/ contact details. Only the principal researchers will be provided with this information. Once we have checked that you are suitable for this study your identity will be fully anonymised by a code number for the duration of the study and for all of our reports. All your information will be safe and secure at all times in password protected files.

Can I choose how my information is handled from the study?

You can withdraw from the study at any time, without giving a reason, but we will keep any anonymised data that we have already collected from you.

Where can I find out more about how my information is being used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to CCR-I@Cardiffmet.ac.uk or

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- by ringing us on 029 2041 6305.

Who has reviewed the study?

This study has been reviewed and approved by a Local Research Ethics committee (insert REC number here when approved).

What if new information becomes available during the course of the study?

If the new information is related specifically to your health, you will be informed, and continued inclusion in the research will be discussed.

Will my General Practitioner be notified of my participation in the research?

Yes, your GP will be notified of your involvement in the study. For this reason, we ask you to provide details (name and address) of the GP with which you are registered.

What if I am feeling unwell when I have returned home?

If you are feeling unwell when you have returned home or have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Please contact a member of our research team any of the contacts below.

What if there is a problem?

Cardiff Metropolitan University have suitable indemnity insurance if you are harmed due to someone's negligence. However, there are no special compensation arrangements for non-negligent harm. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

What if I am unhappy about some aspect of the study?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, please contact the office detailed below. In addition, should you wish to withdraw consent for storage and use of your samples, please contact:

Research & Enterprise Support Services
Cardiff Metropolitan University School of Health Sciences
Room D3.18
Llandaff Campus
200 Western Avenue
Cardiff
CF5 2 YB
Tel: 029 20416747, E-mail: researchadmin@cardiffmet.ac.uk

Contact for further information

PI: Dr Chris Pugh, Cardiff School of Sport and Health Sciences,
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If the information has interested you and you are considering participation, please contact Miss Xela Dafauce Bouzo & Miss Jemima Benson on st20112487@outlook.cardiffmet.ac.uk, st20191506@outlook.cardiffmet.ac.uk and/or 02920 416503

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THANK YOU FOR READING THIS INFORMATION SHEET AND CONSIDERING TAKING PART IN THE STUDY.