St George's University of London

PARTICIPANT INFORMATION FOR ATHLETIC VOLUNTEERS

Research Study: The Veteran Athlete's Heart

IRAS ID: 132679 **REC ref: 13/SW/0163**

What is the purpose of the research?

The benefits of moderate exercise are well known. Individuals who exercise regularly live longer and are healthier compared to their sedentary counterparts. However elite athletes perform way beyond the recommended levels of exercise, often undertaking several hours of training per day and participating in physically gruelling events such as marathons and triathlons. There is growing controversy in the scientific community about the health implications of such high intensity exercise especially over many years. Our research team is studying effects of long-term high endurance exercise on the heart in order to establish whether there are any detrimental effects.

Who is eligible to take part?

We are interested in healthy female athletic volunteers, who are >45 years old, the so called "master athletes". Eligible participants need to be actively endurance training, and have participated in competitions e.g. marathons, ultra-marathons, cyclosportive, triathlons etc.

Are there any factors which would exclude eligibility?

Since we are interested in healthy athletes, the following factors will exclude eligibility to the study:

- Actively smoking or having smoked in the past
- A past medical history of coronary heart disease or other significant heart disease
- A diagnosis of diabetes mellitus or impaired fasting glucose
- A diagnosis of high blood pressure
- A diagnosis of chronic kidney disease
- Contraindications to an MRI scan of the heart e.g. a pacemaker implant, a metal implant, an allergy to the contrast used or kidney problems
- Contraindications to a CT scan of the coronary arteries e.g. an allergy to the contrast used or kidney problems
- Not wanting your general practitioner to be informed if an abnormality is found
- Inability to exercise on a bicycle

What would the study entail?

Having expressed an interest in the study you will be asked to complete the online health questionnaire. The questionnaire mainly focuses on heart related symptoms and a description of the

type and duration of exercise you undertake. Any information which you disclose will be entirely confidential and only be available to the researchers.

You have now been provided with this information sheet (including the sample consent form). You will be asked to sign a consent form on attending for testing and have the opportunity to discuss any queries. Prior to signing the consent form, we would encourage you to read through this information sheet in detail.

The next step will be to book the appointments for your tests using the online booking system.

You will be asked to book three hospital visits, each lasting less than 2 hours. All participants must undergo Day 1 of tests before proceeding to further testing. If you are found to have a raised cholesterol profile following blood tests on day 1 you will not be eligible to continue with the remainder of the tests i.e. CT scan and MRI. Details of the tests are given below.

Day 1: This will begin with obtaining your full consent. You will then undergo the following tests: Electrocardiogram, Echocardiogram, Cardio pulmonary exercise test (CPEX), and heart rhythm monitors and blood tests. These tests will take place at St Georges Hospital, Tooting, South London.

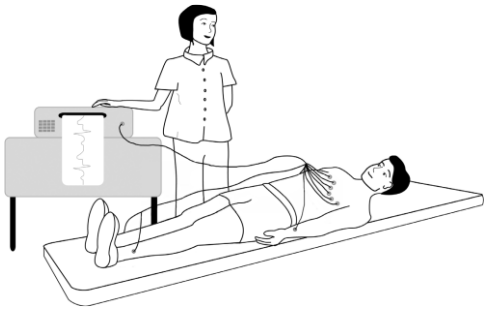
Cardiac MRI: This will take place at St Georges Hospital, Tooting, South London

CT scan: This will take at St Georges Hospital, Tooting, South London.

The final part of the study involves an annual to bi-annual follow-up phone call or email to ascertain whether you have experienced any cardiac issues since participation in the study.

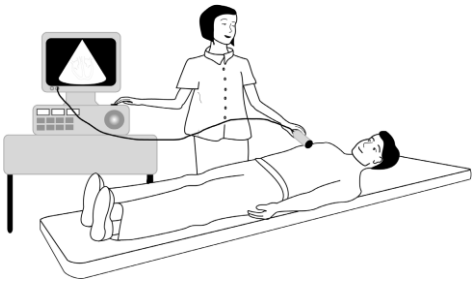
The Tests

- **Electrocardiogram (ECG)**: This is an electrical tracing of your heart. It is performed by placing wires around your heart in order to record electrical tracings transmitted by your heart. This gives an idea of the electrical structure and function of your heart. It is neither painful nor uncomfortable and involves no radiation. However, you will be asked to undress from the waist upwards. This will be in a private room or cubicle.



Electrocardiogram (ECG)

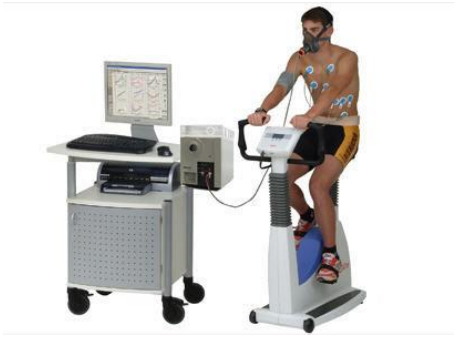
- **Echocardiogram (ECHO)**: This is an ultrasound scan of your heart, similar to that performed on pregnant women. The test provides important information on the structure, shape, size and function of your heart. Like the ECG, it is neither painful nor uncomfortable and involves no radiation.



Echocardiogram (Echo)

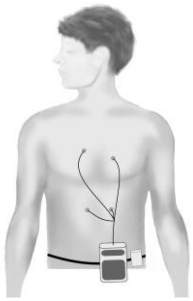
- **Blood test:** This will be done by a trained clinician and performed under sterile settings. The purpose of the blood tests is to test for raised cholesterol and raised sugar levels anaemia (as it may affect some of our results) and to check your kidney function to ensure it is safe for you to have a heart MRI and CT scan. We will ask for your consent to store the blood samples anonymously. This is so that we can do genetic tests at a later date if we find any abnormalities on your tests. These genetic tests are limited to heart diseases and will not be used for any other medical or commercial purposes. Details of the tests are strictly confidential and can only be viewed by our research team.

- **Cardiopulmonary Exercise Testing (CPEX):** This is a useful tool for evaluating the fitness of your heart and lungs. The test will be performed by a trained clinical physiologist or clinician and on average takes 20-30 minutes. Sticky electrodes will be applied to your chest to monitor your heart rate and rhythm. Your breathing will also be assessed through a tube attached to the CPEX machine. You will then be asked to cycle whilst breathing through a facemask whilst still breathing in room air. The test is designed to test your fitness and so you will undergo a rigorous work-out. It will start off relatively easy but eventually the resistance on the pedals increases gradually every few seconds. We will be monitoring you, your heart tracing and blood pressure during the entire duration of the test and so can terminate the test in the unlikely event of spotting a serious abnormality. The test is safe and there is no harm apart from the discomfort of rigorous exercise towards the end of the test. It is extremely uncommon to injure yourself or fall of the bike.



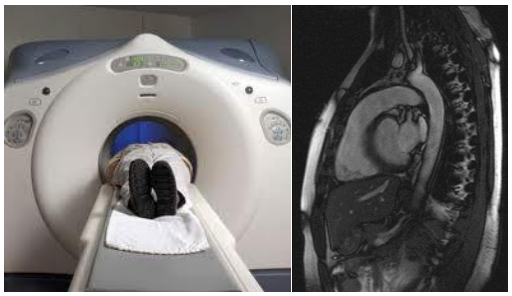
Cardiopulmonary Exercise Testing (CPEX)

- **24 hour heart rhythm monitor:** This is very similar to the ECG test except that you keep it on for a day. The machine records your heart beat over 24 hours, day and night, and during normal activities including sports. While you are having this test you must not have a bath or shower. Once the 24 hour period is complete, you can post the machine back or return it to our department. A paid envelope (addressed to the researcher) would be provided.



24 hour heart monitor

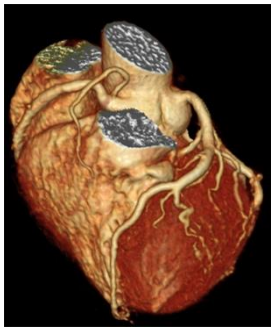
- **Cardiac Magnetic Resonance Imaging (MRI) Scan:** Cardiac MRI uses magnets, and a computer to create detailed pictures of your heart. It is safe, useful and accurate and doesn't involve any radiation. During the 60 minute test, you lie in a short 'tunnel', which holds a large magnet that acquires images of your heart. The magnet can be fairly loud and so protective headphones are worn throughout which music of your choice can be played (you can bring your own music). We will remain in communication with you throughout the scan. Some people might feel uncomfortable lying in the MRI Tunnel and it is important that if you suffer from claustrophobia to not take part in the study. During the scan, an MRI contrast medication will be injected into a vein in your arm in order to give us better views of your heart. This medication is washed away by your kidneys within hours of having the test and rarely causes long term side effects. In exceptional cases (less than 1%) there is risk of allergy or kidney damage.



Cardiac MRI (CMR)

- **A Computerized Tomography (CT) coronary angiogram**: This is an imaging test to look at the arteries that supply the heart muscle with blood, demonstrating the presence/absence of coronary artery disease. It relies on an X-ray machine and a computer to create pictures of the heart and heart vessels. The time required for the scan is approximately 20mins. A cannula (a thin plastic tube, similar to a flexible needle) will be inserted into a vein in the arm which will later be used to inject X-ray dye during the scan so that your arteries become visible. This dye is washed away by your kidneys within hours of having the test and rarely causes long term side effects. In exceptional cases (less than 1%) there is risk of allergy or

kidney damage. In addition, you will receive a spray of GTN (Glyceryl Trinitrate) under the tongue. The GTN works to increase the size of arteries so that they are better seen on the scan. It is a safe and commonly used medicine. Side effects are rare and temporary and include dizziness, or a mild headache.



CT Coronary Angiogram

Are there any risks to my health as a result of taking part?

Most of the tests are completely safe and are not detrimental to your health. The contrast agent used in the MRI scan and CT scan can, in rare circumstances, cause an allergic reaction or lead to kidney dysfunction (less than 1% risk). Allergies can be a mild itchy rash which is easily treated or in extremely rare cases (0.01%) an anaphylactic reaction which is a medical emergency requiring prompt treatment and hospitalisation. The CT coronary angiogram will expose you to a small amount of radiation. The radiation dose from the CT coronary angiogram on our CT scanner is very low as we employ all the dose reduction techniques available. The fact that athletes tend to have relatively low body mass index, allows us to lower the dose further. The total radiation dose is equivalent to that received by the average UK resident from natural sources over approximately 4 years. It corresponds to a lifetime risk of induced fatal cancer of approximately 1 in 2000 although this is age dependent. The natural lifetime risk of fatal cancer in the UK currently stands at approximately 1 in 3 to 1 in 4. Therefore, a risk of 1 in 2000 represents an increase of approximately 0.2% over the natural risk which is very small.

Who is organising the research?

The test is being carried out by the Centre for Inherited Cardiovascular Conditions and Sports Cardiology at St George's Hospital in Tooting, London. It is being funded by a charity called Cardiac risk in the Young (CRY) which raises awareness of sudden cardiac death in young adults and provides support for families (C-R-Y.org.uk). The research is being coordinated by Dr Uchenna Ozo (Cardiology Research Fellow for CRY) and Professor Sanjay Sharma (Professor of Inherited Cardiac Diseases and Sports Cardiology, Consultant Cardiologist and Medical director of the Virgin London Marathon)

Would I receive any compensation for taking part?

The research will provide a free and detailed evaluation of your heart. Some of these tests form part of the routine screening for serious heart conditions. Other tests are on the cutting edge of cardiology and are not ordinarily offered by a GP or a general cardiologist because of cost and other

constraints. If all the tests are normal, then this will be an immense reassurance to you. If there is an abnormality, then we will inform you (in verbal and written form) and organise a referral to your GP.

Unfortunately, there will be no travel expenses provided for attending study appointments and there will be no financial incentive to take part.

What if things go wrong or you want to leave the study?

As mentioned above, the risk of adverse effects from the tests are very low. However, if something does go wrong then we will inform you, and treat the problem promptly. Where necessary, we will make the necessary referral to your GP or specialist for follow up/treatment of any side effect.

As a volunteer, you are entitled to leave the study at any time and withdraw your consent. If you're not happy about the conduct of the study or research team then you have the right to complain, have your complaint investigated, and be given a full and prompt reply. Advice about how to complain and the complaints procedure can be obtained from the patient advice and Liaison service at St. George's hospital (contact details below). This organisation is independent of the research team. If you're not satisfied with the way the NHS has dealt with your complaint, then you can take your complaint to the independent Parliamentary and Health Service Ombudsman. You also have the right to claim for compensation if you've been harmed.

Patient Advice and Liaison Service
St George's Hospital, Blackshaw Road, London, SW17 0QT
Email: pals@stgeorges.nhs.uk, Number: 020 8725 2453

The study has been ethically approved by a research ethics committee (Committee South West - Central Bristol) which is part of the national research ethics service (NRES). The study is fully insured in the unlikely event of anything going wrong (NHS indemnity scheme and St Georges University of London Indemnity scheme).

What will you do with private information about me?

***Please add in details from transparency supplement**

All the test results and information from your medical questionnaire and investigations will be kept confidential and only be seen by designated healthcare professionals of the research team. The blood samples, as mentioned above, will be stored with your consent

What happens if a serious heart abnormality is found?

We expect the majority of participants to have normal investigations or have subtle abnormalities which do not warrant any further medical attention. In a few cases, however, we might pick up an incidental serious abnormality which may require you to have specialist referral and/or treatment. If such an eventuality arises you will be immediately informed and a letter will be sent to your GP advising him or her to start treatment and/or make a referral to a cardiologist. It is important to note that being diagnosed with a heart condition may have implications on your lifestyle and may affect things such as obtaining various forms of insurance. However, picking up an abnormality early will clearly be advantageous in starting early treatment or lifestyle interventions.

Where can I obtain further information?

Further information about the study can be obtained by contacting the principal investigator,

Dr Uchenna Ozo
Department of Cardiovascular Sciences, St George's University of London
Cranmer Terrace, London SW17 0RE
Number: 02087254721 Email: masterathletes@sgul.ac.uk

St George's University of London

CONSENT FORM

Title: The Veteran Athletes Heart

IRAS ID: 132679 **REC ref: 13/SW/0163**

Name of Researcher: Dr Gemma Parry-Williams
Department of Cardiovascular Sciences,
St George's University of London

Participant Identification Number:

Please initial box

1. I confirm that I have read and understand the information sheet (Version 7, date 19/10/2017) for the above study and have had the opportunity to consider the information, ask questions and have these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from St George's University of London (SGUL) and/or St George's University Hospitals NHS Foundation Trust (SGHT) or from the regulatory authorities. I give permission for these individuals to have access to my records. ☐
4. I understand that should a heart abnormality be identified, my GP will be informed so as to arrange further tests, treatment, and/or follow-up. I am aware that being diagnosed with a heart condition may have implications on my lifestyle and may affect me obtaining some forms of insurance. ☐
5. I give consent for blood samples to be taken, stored and analysed ☐
6. I accept that if I previously took part in one or more tests described in this study (in the last 2 years) then I give consent for the researchers to access these records for the purpose of avoiding duplication of investigations and unnecessary waste of resources. ☐
7. I agree to take part in the above study. ☐
8. I agree to contact being made with my GP and if necessary use of my NHS number to achieve this during the follow-up period, should I be uncontactable using the other forms of contact I have provided. ☐
9. I agree to the storage and use of my anonymised samples or of my anonymised data for the purposes of future research. ☐

_____	_____	_____
Name	Date	Signature
_____	_____	_____
Name of person taking consent	Date	Signature

Consent Form, Version 5-19/10/2017