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Comparison of the standard maximal 6-Minute Walk Test against a normal-speed 6-Minute Walk Test as an alternative and more accurate assessment for ambulatory oxygen requirement.

**Chief Investigator: Dr Harry Griffin  
Principle Investigator: Dr Michael Hughes**

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| Participant Information Leaflet |
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| Participant Information Sheet and Written Informed Consent Form |

You are being invited to take part in a research study carried out by the Respiratory Physiology Department at Hampshire Hospitals NHS Foundation Trust.

Before you decide about taking part, it is important for you to understand why the research is being done, and what it will involve. Please take some time to read the following information carefully. You will have an opportunity to clarify anything you do not understand and ask any questions before deciding if you wish to participate.

This project has been granted ethical approval by the local research ethics committee (REC), project number 306758

# Thank you

**Introduction to the research**

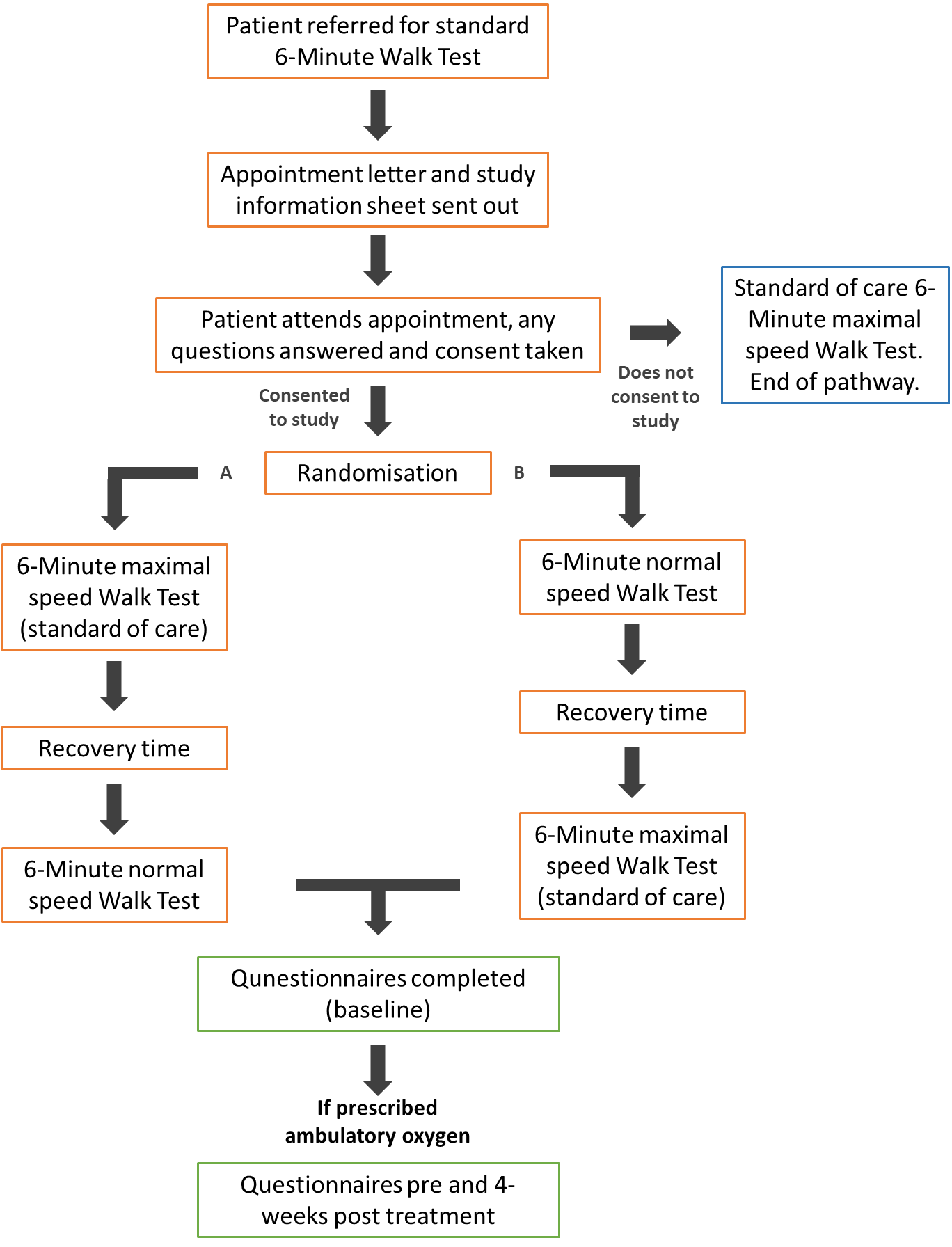
We are investigating if the standard walking test used to assess the need for ambulatory oxygen, a portable device that provides additional oxygen, is the best test to make this clinical decision.

During this standard test (known as a 6-minute walk test), patients are asked to walk as far as they can up and down a corridor (or other flat area) for six minutes whilst their blood oxygen levels and heart rate are monitored using a pulse oximeter (finger probe). In addition, a questionnaire is used to measure their perceived breathlessness and leg muscle fatigue before and upon completion of the test (known as a Borg Score).

In this study, we want patients who have been asked to perform this standard 6-minute walk test to also perform an additional test that requires walking at their normal walking pace rather than their maximum pace to see if this provides a better indication of whether they might benefit from ambulatory oxygen.

This study is being carried out by the Respiratory Physiology Department at Hampshire Hospitals NHS Foundation Trust.

If you decide to take part, we will perform this test with you, including a modified version where you walk at your normal walking pace. On the next page, you can see an overview of what will happen during the appointment.



**Why have I been asked?**

We have identified you as someone who has been asked to have a 6-Minute Walk Test by your doctor. We would like to invite you to participate in this research during your existing outpatient appointment. We hope to use the data generated from these tests to ensure we are using the most accurate and appropriate tests to help our clinical decision making.

**Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you decide to take part, you can still change your mind later and withdraw at any time and without giving a reason. This will not affect your standard care in any way.

**What will I have to do?**

If you would like to participate, please let a member of our team know when you come to your appointment. You will have a chance to ask any questions at your appointment and if you decide to take part a member of our team will first ask you to sign a consent form. If you agree to take part we will:

* Conduct a brief medical history. This involves answering questions about your current health and problems you may have had in the past. It will include questions on medications you take.
* Ask you to perform a walking test where we will ask you to walk at your normal walking pace for 6 minutes, monitoring your heart rate and blood oxygen levels using a finger probe and asking you questions about your breathlessness and muscle fatigue before and after the test. If you usually use walking aids, such as a walking stick, you will be able to use these during the tests.
* Still ask you to perform the standard 6-minute walk test as requested by your consultant or clinical care team. This is the same test as above, but walking as far as you can in 6 minutes.
* Complete a questionnaire about your physical activity. The first will be completed at your appointment. If your medical team decide to prescribe ambulatory oxygen, we will ask you to complete two follow-up questionnaires at home – one before you begin ambulatory oxygen and another 4 week after you have started ambulatory oxygen. The research team may phone you to remind you to complete these and return them by email, or complete them over the phone with you if required.

We anticipate that agreeing to take part in this study will take around 20 minutes extra during your routine appointment and around 15 minutes to complete the associated questionnaires and send them back to us.

**What are the benefits**

The main purpose of the study is to identify the most accurate test for assessing the requirement for ambulatory oxygen. As such, there may be no direct benefit to you as a participant, but you will be involved in ensuring we are providing the best clinical care for you and other patients in the future.

**What are the risks?**

All the investigations and assessments that are taking place are routine and unlikely to carry any additional risks to your routine assessment (i.e. the additional walking test is at a slower walking pace than the routine test requested by your consultant).

**What happens if I do not wish to take part?**

The study is entirely voluntary and if you do not wish to participate it will not affect your current or future care. It is important to emphasize that your overall management by your usual doctor and clinical care teams will not be affected regardless of the decision you make.

**How will we use information about you?**

We will need to use information from you, your medical records and letters from your GP for this research project.

If you decide to take part you will be allowing us access to your medical records, however, the research team will already be part of your standard care team so no additional access will be required.

This information will include your name, NHS number, HHFT hospital number, contact information and details of your medical history. People will use this information to do the research or to check your records to make sure that the research is being done properly.

They may additionally be looked at by the hospital Research and Development department and by regulatory authorities who check that the study is being carried out properly. People who do not need to know who you are, including our academic collaborators at the University of Winchester and Manchester Metropolitan University, will not be able to see your name or contact details. Your data will have a code number instead (known as pseudo-anonymisation).

We will keep all information about you safe and secure.

Once we have finished the study, we will keep all the clinical information in your medical record as they may be needed for your future medical care (and will not be subject to archiving or deletion following the study). Any reports written after the study will be done in a way that no-one can work out that you took part in the study.

By signing the specific consent form for this study, you are giving permission for this to be done. We will also ask your permission to inform your GP you are participating in the study and pass on any relevant clinical information as necessary to assist in your ongoing medical care.

The data controller will be the Data Protection officer at Hampshire Hospitals NHS Foundation Trust and can be contacted at: information.governance@hhft.nhs.uk.

You can find out more about how your information is being used at www.hra.nhs.uk/information-about-patients or by asking a member of the research team using the details at the end of this leaflet.

**What happens if I change my mind during the study?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. It will not affect your current or future medical care.

We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

**What if there is a problem?**

In the event that something does go wrong and you are harmed during the research and this is due to someone‘s negligence then you may have grounds for a legal action for compensation against Hampshire Hospitals NHS Foundation Trust, but you may have to pay your legal costs.

The normal National Health Service complaints mechanisms will still be available to you; in the first instance we suggest that you contact the local Customer Care and Patient Advice and Liaison Services (PALS) office on 01256 486766 or email customercare@hhft.nhs.uk and they will be able to provide independent advice and direct you appropriately.

**Complaints**

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; their contact details are at the end of this sheet. If you remain unhappy and wish to complain formally, you can do this via the NHS Complaints Procedure. You can contact Customer Care and Patient Advice and Liaison Services (PALS) office on 01256 486766 or email customercare@hhft.nhs.uk.

If you would like to discuss this research with health care professionals not involved in the project, you could discuss this with members of the Customer Care and Patient Advice and Liaison Services (PALS) office on 01256 486766 or email customercare@hhft.nhs.uk.

**What happens at the end of a study?**

At the end of the study, all the results will be anonymously collated into a final study report. The results may be published in a scientific journal, shared with other hospital sites and presented at conferences. This will allow our findings to help guide clinical decisions both within Hampshire Hospitals NHS Foundation Trust as well as other sites across the country.

It is our intention to also notify you about the results of the study either in person at one of your appointments, or via email or phone if this is more suitable. Regardless, the final report from the study (that does not contain any personal identifiable information or individuals’ results) will be made available in the public domain that you will be free to view at any point.

**Who is organising and funding the research?**

The research is being organised by the Respiratory Physiology Department at Hampshire Hospitals NHS Foundation Trust. The Chief Investigator is Dr Harry Griffin. It is funded internally by the hospital and is completely independent of any third party.

**What expenses and reimbursements am I entitled to?**

As the study will occur during a routine outpatient appointment, there is no reimbursement for travel or participation in the study.

**What if I have more questions or do not understand something?**

The researchers involved in the study will happily answer your questions. You will have an opportunity to clarify anything you do not understand and ask any questions before deciding to participate in the study.

**Contact Details**

You can email the team conducting this research at respphysresearch@hhft.nhs.uk

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