



## **40 steps to safety – Participant Information Leaflet**

### **Exertional desaturation as a marker of risk – Validation study for the 40-steps-test**

Many thanks for your interest in this research project, investigating the effect of a simple exercise test on blood oxygen levels.

Since the start of the COVID-19 pandemic we are considering this condition in any patient presenting to hospital. Some COVID-19 patients may have “silent hypoxia” which means that their blood oxygen concentration is low, despite feeling well. Your oxygen level is currently normal, but we would like to know if this changes following a short period of exercise.

#### **Why am I being asked to take part?**

We are interested in investigating the ability of a simple exercise test to detect low blood oxygen levels in patients who appear well. We want to know whether developing low oxygen levels with exercise can be used to identify patients who are at higher risk of becoming unwell in the future.

We are asking individuals who are being considered to go home on the day of the study to take part.

#### **What does the study involve?**

You will be asked to perform a simple walking test. This will involve taking 40 steps on the spot at your normal walking speed. Your heart rate and oxygen saturation (level of oxygen in the blood) will be measured using a pulse oximeter that clips onto the end of your finger. You will also be asked to rate your level of breathlessness before and after the test on a scale of 0 to 10.

This information will help us decide whether we recommend you stay in hospital for further assessment or are discharged home.

#### **What are the benefits to taking part?**

You will be contributing to important research which could help develop a better way to identify patients who can be safely discharged from hospital. You will also be helping us to better understand the normal response to exercise, and how this is different in a range of medical conditions, including in COVID-19.

#### **What are the risks of taking part?**

We anticipate that taking part in this study is generally very safe. However, there is a small possibility of a fall, which could result in injury to yourself, whilst doing the 40-step test.

Some participants may experience symptoms such as breathlessness, light-headedness, or chest pain whilst taking part in the study. If you start to feel unwell during the test, please tell one of the researchers immediately who will stop the test. If any concerns arise during

the test about your ability to complete the exercise task safely, we may also end the study early.

### **What happens after I take part?**

We will not need to contact you following your involvement in this study.

The research team will need to access your hospital record to document whether you stayed in hospital, were readmitted, or remained at home in the 30 days after the study.

All patient data used will be anonymised, and we will not access your medical record for reasons other than those outlined.

### **If my oxygen levels drop during the study – what does this mean?**

One purpose of this study is to identify what happens to oxygen levels during the 40-step test. Therefore, we do not currently know what how much oxygen changes during this test.

There are many reasons that your oxygen level could drop during the test – this could be different according to several factors including age, and underlying medical condition(s).

If you are concerned following your participation in the study, our researchers will be happy to discuss the test with you. In some cases, the result of the test could prompt your medical team to request further investigations, either as a hospital patient or as an outpatient.

### **Expenses and payments**

There are no payments for taking part in this study.

### **What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers or the hospital concerns team who will do their best to answer your questions (Concerns office, telephone 01248-384 194).

In case of accidental disclosure of confidential details you will be informed and the disclosure will be reported in line with Standard Operating Procedures of BCUHB or your hospital.

### **Will my taking part in the study be kept confidential?**

For the study we will ask you a few questions. One copy of the answers to those questions will be added to your hospital notes and might help your doctors and nurses to look after you. All information which is collected about you during the course of the research will be kept strictly confidential. Any quotes from you will be anonymized.

Any information about you that is not in the hospital notes will have your name, address and any other personal details removed so that you cannot be recognized. Your confidentiality will be safeguarded during and after the study by the Caldicott principles and/or Data Protection Act 2018.



## **What happens if I lose my ability to consent whilst the study is ongoing?**

If for any reason you lose the capacity to consent after signing the consent form and taking part in the study today, your records will still be accessed at 30 days on the basis of the consent already provided.

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

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

This information will include your:

- Name
- Age / date of birth
- Gender
- Ethnicity
- Whether you have a diagnosis of any heart or lung conditions
- Your current medical condition
- Oxygen saturations, heart rate and level of breathlessness and the number of breaths per minute, before and after the 40 steps test
- Whether the decision to discharge you from hospital changes following the test
- The outcome of your care, including readmission to hospital in the 30 days after the test
- Whether a COVID-19 test returns a positive result (if already requested by your doctor)

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Some of your anonymous information will be shared with other NHS trusts in the UK. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

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.

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.



If you agree to take part in this study, you will have the option to take part in future research using your anonymised data saved from this study.

### **Where can you find out more about how your information is used?**

You can find out more about how we use your information

- You can find out more about how we use your information
- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- at [www.hra.nhs.uk/patientdataandresearch/](http://www.hra.nhs.uk/patientdataandresearch/)
- by asking one of the research team for a paper copies of the above leaflets
- by contacting the Sponsor, Betsi Cadwaladr University Health Board Information Governance Department 01978 727689.
- By sending an email to Our Data Protection Officer is Justine Parry and you can contact them at [bcu.dpo@wales.nhs.uk](mailto:bcu.dpo@wales.nhs.uk)

### **What will happen to the results of the research study?**

The results of the study will be published in medical journals. The research will also form part of an educational (Masters level) qualification for students (medical doctors) at Bangor University. You will not be identified in any report/publication.

### **Who is organizing or sponsoring the research?**

The study is sponsored by BCUHB. The researchers have not received extra funding for undertaking the study.

### **Further information and contact details:**

We hope that you are interested in working with us on this important project.

For more information please don't hesitate to e-mail us on [Christian.Subbe@Wales.NHS.UK](mailto:Christian.Subbe@Wales.NHS.UK), your local Principal Investigator.

### **Consent**

We ask you for your permission to participate in test and the review of your medical information.

You are free to stop participating at any time and without giving any reason to withdraw your permission. This has no negative consequences for your treatment.

If, after reading these notes questions remain unanswered, please send them directly to [Christian.Subbe@wales.nhs.uk](mailto:Christian.Subbe@wales.nhs.uk).