Oxford University Hospitals
NHS Foundation Trust

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PARTICIPANT INFORMATION SHEET part 1

Evaluation of the usefulness of adopting remote, mobile-based 6MWT among hospital outpatients (the 6-APP now Study), within the constraints imposed by the SARS-COV2 pandemic.

We would like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

Who is involved in this research?

This research is a collaboration between the Oxford University Hospitals NHS Foundation Trust and Malmö University, Sweden.

What is the purpose of the study?

Our study would like to find out whether patients are able and willing to use a smartphone app for the six-minute walk test (6MWT) to reduce time spent in hospital and to compare the number of 6MWT performed with this new method with the number of 6MWT performed before the pandemic.

Why have I been invited?

You have been invited as you are currently undertaking 6 minute walk tests as part of your outpatient assessments.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, you are free to withdraw consent at any time without giving a reason. If you decide that you no longer wish to continue with the study, we would still retain any data already obtained from you unless you request otherwise. Withdrawal from the study will not affect your clinical care.

What will happen to me if I decide to take part?

The six-minute walk test consists of walking as far you can in 6 minutes. This simple test is a standard way for measuring exercise capacity in patients with pulmonary hypertension. It is also used to optimise the use of medication.

During the study, you will be asked to download and use a smartphone app, the Timed Walk app, and use it at least once a month, and before every consultation with the Pulmonary Hypertension clinic of the John Radcliffe Hospital, either in clinic or by phone. The tests should be performed following the instructions on the app, thus strictly outdoors and walking over a straight or gently curved path. The app will use the localisation system of the phone, like the GPS, to estimate the distance walked and will store this value on its memory.

At each consultation, the clinician will ask you to read out or send the distance walked in the last 6MWT, which they will write down together with any issue you may have encountered with using the app, or if any clinical decision is taken due to a significant change in the distance you usually walk in the test.

This data will be removed of any personal information and analysed by researchers at the Malmo University, who are also responsible for the development of the app.

What should I consider?

The 6MWT is currently undertaken by most patients with pulmonary hypertension and our aim is to provide a better assessment of how much exercise you can do. If you are on long-term oxygen therapy or have difficulties walking for 6 minutes, we may exclude you from the study. You can participate even if you are involved in other research studies, and the medication you are taking will not affect the results of this study.

Are there any possible disadvantages or risks from taking part?

There are no disadvantages or risks from taking part in this study

What are the possible benefits of taking part?

The main benefit is that the clinical team in charge of following you will have additional, objective information to assess your status. The clinical team will be reviewing the data generated by the app to see if there is a change in the distance walked. If there is a change raising a medical concern, they will be in contact with you.

We also hope that the app will encourage you to walk further in your daily life, which has many health benefits.

Will my General Practitioner/family doctor (GP) be informed of my participation?

Your GP will not be informed, as the study will not affect clinical care.

Will my taking part in the study be kept confidential?

The app will collect data about the 6MWT tests you perform and keep it on your phone. If you wish, the app allows you to send a message (as an email or SMS) with the results of your tests attached. You can use this to share your results with the clinical team.

The clinical team will record events related to your 6MWT and your use of the app in a file. This will include notes like if you are using the app or if you encountered technical problems, the distance you walked in your tests and any clinical decisions made based on this distance.

The file will be stored separately on the research team's computers which are located in offices normally locked when unoccupied. The offices are in the John Radcliffe Hospital, part of Oxford University Hospitals NHS Foundation Trust. Periodically, this file will be removed of any personal information and sent to the team of researchers at the Malmö University in Sweden for analysis.

If you have technical problems and need assistance, you can contact the team in Sweden, who are responsible for the development of the Timed Walk app.

Responsible members of the University of Oxford Hospitals NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with relevant regulations.

Will I be reimbursed for taking part?

The study will not involve attending additional clinics and therefore there will be no reimbursement.

What will happen to my data?

Your anonymised information will be kept for up to 10 years after the end of the study. This anonymised data could be used in further studies, after ethical approval.

We aim to publish the results of this study in scientific journals and present them at conferences, but we will make sure to remove all identifiable information from them first.

To delete the data collected by the Timed Walk app, it is sufficient to uninstall it from your phone.

What happens at the end of the study?

The results from the study will be collected, anonymised, analysed and then will be published and presented at conferences.

What if you find something unexpected?

If there was a significant change in your walking distance, the clinical team will be in contact with you, and may ask you to attend clinic.

What if there is a problem?

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Dr Elizabeth Orchard 01865 223804 elizabeth.orchard@ouh.nhs.uk.

Please remember that there are no special compensation arrangements in this study, but the Oxford University Hospitals NHS Foundation Trust will provide indemnity if needed. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical trial as a result of negligence on the part of a member of the study team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. The Oxford University Hospitals NHS Foundation Trust, therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

You will also be able to contact the Patient Advice and Liaison Service (PALS) in the first instance (01865 221473).

How have patients and the public been involved in this study?

Patients have been involved in the study from the beginning, and have undergone preliminary testing of the app to ensure that it works. The app is the result of previous research conducted on pulmonary hypertension patients. A similar app has already been tested on 30 patients for 6 months and has proven reliable and usable.

Further general information about taking part in research can be found here:

www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

Who is organising and funding the study?

The study is being funded by the Swedish Knowledge Foundation.

Who has reviewed the study?

All research in the NHS is looked at and checked by an independent group of people, called a Research Ethics Committee, via the HRA to protect your interests. This study has been reviewed and given a favourable opinion by [**insert REC name**] Research Ethics Committee for the HRA.

Participation in future research:

We will ask if we can contact you about future studies. This is optional, you can take part in this study but decline to be contacted again. If you consent, we will keep your contact details separately from research data you have provided. Both your details and data will carry the same unique ID. This means your data is anonymised but that we can "link" details to data. In this way we can approach patients about studies relevant to their particular healthcare status. You can withdraw your consent for future contact at any time.

Further information and contact details:

Please contact Dr Elizabeth Orchard by telephone or email on 01865223084 or Elizabeth.orchard@ouh.nhs.uk

For technical enquiries, please contact Dario Salvi, on dario.salvi@mau.se

Thank you for considering taking part.

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Study Code: *Site ID Code:* *Participant identification number:*

CONSENT FORM

6APPNOW Study Part 1

Name of Researcher:

If you agree, please initial box

1. I confirm that I have read the information sheet dated..... (version.....) for this study. I have had the opportunity to consider the information, ask questions and have had 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 my medical notes and data collected during the study may be looked at by individuals from the Sponsor, from regulatory authorities and from the NHS Trust(s), where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. I understand that the data collected will be analysed, in an anonymous form, by researchers at Malmo University in Sweden.	
5. I agree to be contacted about further ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	

6. I agree to take part in this study.	

_____	_____	_____
Name of Participant	*Date*	*Signature*
_____	_____	_____
Name of Person taking Consent	*Date*	*Signature*

**1copy for participant; 1 copy for researcher site file; 1 (original) to be kept in medical notes* (if participant is a patient).