CORMORANT:

COPD tRansforMation of diagnOstic pathways in pRimary cAre using N-Tidal

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PARTICIPANT INFORMATION SHEET

If you need a larger print version of this document, or a different language, please contact the study team on at cormorant@phc.ox.ac.uk

We would like to invite you to take part in our study

This Participant Information Sheet (PIS) explains why we are doing this study and what it will involve for you if you decide to take part. Please read it carefully before deciding whether you would be happy to take part. If you have any questions, please get in touch with us using the contact information at the end of this document.

Why have I been invited to take part in this study?

We are looking for people who have been referred for a spirometry test. Spirometry is a test to look at how well the lungs are functioning, particularly forced breathing. It is usually requested when people have symptoms of cough, breathlessness or frequent chest infections, to investigate the cause.

One of the conditions that spirometry looks for is COPD (Chronic Obstructive Pulmonary Disease). However, there are also other causes of the symptoms above.

You have been invited to take part in this study because you have been referred to have a spirometry test and COPD is one of the potential causes of your symptoms.

What is the purpose of this study?

COPD is common, but many people do not know they have it. In the UK almost half of people affected have not been diagnosed. Spirometry is the current standard test used by healthcare professionals to help diagnose COPD, it takes time, and requires specialist training to operate, and understand the results. At the moment spirometry testing is not available to all people around the UK, or there are very long waiting times. Prompt diagnosis of COPD is important because it means people can start treatments to reduce their symptoms, and stop them worsening, much sooner. We therefore want to research whether there are new tests which could be used to diagnose COPD instead of spirometry.

The company TidalSense has built an easy-to-use device called N-Tidal Diagnose. Patients breathe in and out normally into an N-Tidal Handset for 75 seconds, which measures a gas that everyone breathes out called Carbon Dioxide (CO_2). The N-Tidal Handset is CE marked which means that the product complies with European law with regards to medical devices. The N-Tidal Diagnose computer program can distinguish between how the changes in the level of CO_2 in the breath over time are different between those with and without and COPD. This allows us to tell how likely it is that that person has COPD.

N-Tidal Diagnose handset in use

For this study, we hope to include around 500 participants across the UK. We want to find out how accurate N-Tidal Diagnose is at diagnosing COPD compared to the usual spirometry test, as well as ask some questions about how patients and health care professionals find the experience of using the N-Tidal device and spirometry. If this study shows that N-Tidal Diagnose is sufficiently accurate to use in COPD diagnosis, patients with COPD could be diagnosed sooner and could reduce the cost to the NHS.

What will happen if I take part?

Your healthcare professional or someone from the research team will **inform you about the study** and give you the opportunity to ask any questions about taking part. This may be in-person or remote (email, text, phone call).

We will ask you to **sign a consent form** if you are happy to take part. This will be an electronic consent form and we will email you a copy.

Once you have consented to take part, **we will ask you to complete a baseline questionnaire**, including your medical history related to your breathing and general health. All of the baseline questionnaires will need to be completed at one time and should take around 20 minutes. You can ask someone else to help you with this, or complete over the phone with the study team, if you prefer.

Your spirometry test visit will take place as normal, but we will ask you to do an additional test, **using the N-Tidal Diagnose device as well**. The results from both of these tests will be recorded for the study. However, as N-Tidal is still being studied its results will not be used to influence your diagnosis. At the end of your test visit we will ask some questions about how you have found N-Tidal Diagnose and spirometry.

We will collect some information from your medical notes shortly after you enter into the study, as well as what your diagnosis from the spirometry test was once your test results have been looked at by your health care professional.

Do I have to take part?

No, you are free to decide whether or not you take part. If you decide to take part, you are still free to withdraw at any time, without giving a reason. Withdrawing or not taking part will not affect your current or future clinical care in any way.

What are the possible advantages of taking part?

The main advantage of taking part is an opportunity for you to contribute to research that may improve how COPD is diagnosed in primary care. We do not yet know whether the *N-Tidal Diagnose* will improve diagnosis and thus the care for patients with potential COPD; that is why we are doing this research.

Is it safe? Are there any disadvantages?

Participants will be asked to breathe in and out normally into the N-Tidal handset for 75 seconds. The N-Tidal handset has been used thousands of times in studies before and no safety concerns have been found. Each participant uses a clean mouthpiece so there is no additional risk of infection.

Qualitative Interview Sub-Study

There is also a smaller study nested within the CORMORANT study. We will ask around 20 of the 500 participants to take part in an additional optional interview, in the weeks after your spirometry appointment that will ask questions about your experience with N-Tidal Diagnose and spirometry. There is an option on the consent form to indicate if you are happy or not to be contacted about this optional interview. Since we need only a few participants, consenting to contact does not guarantee an interview. The research team will contact participants who have given a range of scores in relation to the device use at their appointment as well as from a range of locations, ages, and other factors in order to achieve as much diversity as possible with our feedback.

Will my taking part in the study remain confidential?

Yes. It will not be possible to identify who you are from your study data. Information about you will be referred to only by a unique participant identification number. We will keep a separate record of people's real names and corresponding identification numbers. We will use as little personally-identifiable information as possible, and no personally-identifiable data will be shared with TidalSense. TidalSense will collect the test results from the device but this will not be identifiable to individuals.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from your GP and/or shared care health record in order to undertake this study and will use the minimum personally-identifiable information possible. We ask for this information in order to:

- Obtain information on any x-rays or scans you have had
- Determine whether you have received a diagnosis

The health care system records accessed will vary depending on:

- Whether you are having your spirometry appointment at your GP surgery, or elsewhere
- The arrangements for health care data sharing in your region.

Once we have obtained this information, your personally-identifiable information will be deleted.

Where will my data be kept?

We will store any research documents with personal information (such as consent forms) securely at the University of Oxford for five years after the end of the study. We will keep any other identifiable information, i.e. contact details, for less than 3 months after the study has finished.

The local study team will use your name, NHS number, and contact details, to contact you about the research study, and to oversee the quality of the study.

A copy of your consent form from this study will be kept in your medical records for as long as those records are retained.

After the end of the study, we will fully anonymise all our research data. This will mean that we can still do further analyses if needed but there will be no way of linking your data to any personal information about you.

After the five year archiving period, the study data will be destroyed. This will ensure that we have enough time to analyse it all, and to write papers and reports.

The breathing record that you produce using N-Tidal Diagnose is immediately transmitted electronically as an anonymous trace to TidalSense to be automatically analysed to produce a likelihood of COPD. This anonymous trace will be kept long-term by TidalSense, as this is compulsory as part of device regulatory requirements.

Who will be able to see my data?

Responsible members from the Universities of Oxford, regulatory authorities and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study. This is to ensure that the research is complying with applicable regulations. The only people who will have access to information that identifies you are those who need to:

- Contact you for the research study
- Collect information from your medical records
- Audit the data collection process

The people who analyse the information we collect during the study will not be able to identify you and will not be able to find out your name or contact details.

What will happen to my data if I withdraw from the study?

If you decide you no longer wish to take part in our study, please let us or your health care professional know. You can find our contact details at the end of this document. You can withdraw from the study at any time without giving a reason.

If you wish to withdraw we will:

- Still keep and use any information we have already collected about you
- Ask your permission to extract information from your medical records. If you decide not to give your permission, that is OK

If you decide to withdraw, this will not affect the standard of care you receive. The research team will respect your decision and will be happy to answer any questions you may have.

What are my data rights?

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. To safeguard your rights, we will keep the amount of information we use which could potentially identify you to a minimum.

Where can I find out more about how my data are used?

Data protection regulation provides you with control over your personal data and how it is used. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting the research team using contact details at the end of this document.

What will happen to the results of the study?

The results will be published in scientific journals and on our website X for you to read. You will not be identifiable in any reports or publications that result from this research.

Will I be reimbursed for taking part?

No, we will not be reimbursing participants for taking part in this study.

Who is organising and funding the study?

The study is funded by National Institute for Health and Care Research (NIHR). It is part of the **CO**PD t**R**ansfor**M**ation of diagn**O**stic pathways in p**R**imary c**A**re using **N**-**T**idal (**CORMORANT**) research programme. The University of Oxford is the research sponsor. This means that it is legally responsible for organising the study and overseeing the work of the researchers. The study team is led by Dr Helen Ashdown (University of Oxford), who is a GP with a special interest in respiratory disease diagnosis and health technology. The Primary Care Clinical Trials Unit at the University of Oxford has set up and is running the study. TidalSense Limited, developer of TidalSense Diagnose, contributed to study development. Therefore, some of the investigators are shareholders and/or employees of TidalSense Limited. However, no University of Oxford employees working on the CORMORANT study have received payments or support from TidalSense Limited, and the university will retain ownership and governance of research data. Additionally, no study personnel conducting visits, spirometry, or N-Tidal Diagnose tests, or analysing data, have ties to TidalSense Limited or conflicts of interest.

How have patients been involved in setting up this study?

Patient representatives were involved in reviewing this document and in the design of this study.

What if there is a problem?

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. If something does go wrong, 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. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any

complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment that is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during this study, you should contact the research team whose details are given below. Alternatively, you may contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) office on 01865616480, or email rgea.complaints@admin.ox.ac.uk .

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee (REC). The REC is there to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by South Central – Oxford A Research Ethics Committee. The reference number is 25/SC/0103.

Contact details:

Email: cormorant@phc.ox.ac.uk

Thank you for considering taking part in this research. Please ask if you have any questions.