Centre Number:

Study Number:

Patient Identification Number for this trial:

 **C**linical **A**nd **S**ocial **C**haracteristics **A**nd **D**emographics in **E**arly **COPD**- **CASCADE II**

**A study in Chronic Obstructive Pulmonary Disease (COPD) to establish if early, personalised medical review changes disease course.**

**Participant Information Sheet**

You have expressed an interest in taking part in this research study which is being sponsored by the University of Southampton as part of the ‘Collaboration for Leadership in Applied Health Research and Care’ (CLAHRC Wessex). The purpose of this leaflet is to give you more information about why the research is being done and what taking part would mean. A summary of this study will also be available on a clinical trials register at <http://clinicaltrials.gov>.

Please ask us if anything is not clear or you would like more information. Take time to read this leaflet and decide whether or not you wish to take part. Part 1 tells you about why we are doing the study and the next steps if you choose to take part. Part 2 tells you about how the study is being conducted. One of our team will also talk through the leaflet with you before you make your final decision.

Thank you for reading.

**PART1:**

**What is the purpose of the study?**

The aim of this study is to identify Chronic Obstructive Pulmonary Disease (COPD) patients who currently have milder disease and to investigate whether a detailed, medical assessment which has time to assess all aspects of their care will improve their lung health and general wellbeing when compared to ‘usual care’ i.e. the care an individual with COPD would usually receive from their GP and practice nurse. There will be two groups of included in the study. One group will receive the detailed medical assessment from a respiratory doctor from Southampton General Hospital and one group will receive their usual care from their GP and practice nurse. We will monitor both groups over the course of a year to see if there is any difference in their lung health and general wellbeing. Patients from your GP practice are being invited to join the group receiving the detailed medical assessment by a respiratory doctor.

COPD is a condition resulting from lung damage, which, over time, causes individuals to suffer from symptoms including chronic cough and progressive breathlessness. In the UK, COPD is predominantly caused by cigarette smoking which may have occurred decades before the symptoms appear and the disease is diagnosed.

People with COPD, who have smoked in the past, are at higher risk of other medical problems such as heart disease and stroke. Being breathless and having multiple physical health problems can also lead to mental health problems such as anxiety and depression. This means it can be challenging to provide people with COPD enough time to fully assess and treat all their problems, particularly due to current pressure on the length of GP appointment times. This study investigates whether the solution to this problem may be allocating a block of time to see people with COPD routinely; early in their disease process, and ensuring if patients have these problems, they are being treated or prevented as thoroughly as possible. If this study shows a benefit to those people undergoing the detailed medical review it is something that, in the future, could potentially be included in the care of all patients with COPD.

**Why have I been invited to participate in the study and what does it involve?**

You have been invited to participate as:

* Your GP practice is one of the practices participating in the study
* You are on your GP Practice COPD Register i.e. you have a confirmed diagnosis of COPD
* Your answers to the COPD Assessment Test suggested the symptoms of COPD are affecting your life.

It is up to you to decide whether to join the study. If you chose to participate in the study you will be asked to attend the study site on three occasions over the period of a year. These visits include an initial enrolment visit, a follow up visit four to six weeks after this and a final visit twelve months after the initial visit. In addition, during the study time we will ask you to keep a record of any occasions where you have to take steroids or antibiotics for your chest.

**What will happen during the study?**

All the visits will take place either in your GP surgery or in space close to your GP surgery.

The initial visit will take about an hour and a half and we will ask you to take your inhalers as normal. If you have blue Salbutamol inhaler we would ask you to take it thirty minute before the appointment.

We will discuss the study risks and benefits in detail, answer any questions you might have and if you would like to take part we will ask you to sign a consent form which will include giving permission to access your electronic medical record at your GP Practice and giving permission for us to share any information we collect about you with your GP.

**Do I have to take part?**

Whether you decide to take part in the study is entirely up to you. If you do decide to take part you will need to sign the pages at the end of this leaflet to show you agree to participate in the study. This is called ‘giving consent’ and you should only do this if

1. A study staff member has explained the study to you
2. You understand the purpose of the study
3. You are willing to do what the study involves.

You should take as much time as you need to make up your mind. You can talk to your friends, family or GP to help you make a decision.

You can change your mind at any point in the study. You can leave the study at any point even if you have signed the form. You do not have to give a reason and it will not affect any care you receive from your GP, practice nurse, or any other NHS health professional.

**What will I have to do if I decide to take part in the study?**

At the first appointment, after you have given consent, the study doctor, who is a respiratory doctor from Southampton General Hospital, will ask you information about yourself and your disease including:

* How and when your COPD was diagnosed and what symptoms you currently have.
* Your medical history regarding any other problems or diseases you may have with you physical or mental health.
* Your medication and allergy history.
* Socio-demographic information i.e. your education, your work history, who makes up your household and whether you need any help with activities of daily living e.g. washing and shopping.

The study doctor will measure your lung function using breathing tests on a machine called a spirometer. These tests are similar to those you may have done with your practice nurse in your COPD Annual Review and are explained in more detail in the leaflet you received with your initial invitation letter from your GP practice.

You will undergo a general physical examination including measuring your height, weight, blood pressure and pulse rate. We will place a small clip over your finger, this is a painless procedure to measure your blood oxygen levels. The study doctor will also listen to your chest.

We will ask you to fill in four questionnaires about your physical and mental health and how COPD affects your life. You will be provided with a diary where you can make a note of any times you need steroids or antibiotics for your chest over the next year.

The study doctor will look at all aspects of your health and ensure that you are on the right treatment to keep you in the best health possible. If the study doctor feels you would benefit from any addition treatments or investigations these will be discussed with your GP and arranged. As with all medical treatments these are only recommendations and you do not have to take these recommendations up.

The second appointment with the study doctor will take place four to eight weeks after the first and will take approximately an hour. It will be a follow up appointment to the previous review to see how you are doing with any changes that might have been suggested in the previous appointment.

After this review, the study doctor may contact you by phone or by email if there are investigation results we need to let you know about or if you need any other input for your COPD.

The final appointment with the study team will take place approximately twelve months after the initial appointment and will take approximately an hour. This will involve reviewing the information in the diary you have kept and repeating the blowing tests (spirometry) and questionnaires. We will also look through your GP record to see how many times you have needed to use your GP service over the last year.

Throughout the study you will still have access to your GP and practice nurse as normal and all information you give to the study doctor will be shared with your GP.

**How will being part of this study affect my lifestyle?**

You will need to have the time and transport to be able to attend the three study appointments. It could be that the study doctor recommends additional investigations or treatments which might require more time and transport.

You will need to fill in the diary we give you each time you take steroid or antibiotics for your chest.

**What are my alternatives to taking part in the study?**

You can choose to continue to receive your normal care from your GP and practice nurse. Whether or not you choose to take part in the study does not alter how you can access your GP, practice nurse or any other health professional.

**What side effects or risks can I expect from the study?**

When you are participating in spirometry you will need to have taken you blue (salbutamol) inhaler. If you do not have one of these then one will be provided by the study team. Allergic reactions to salbutamol and possible side effects (shakiness, increased heart rate, headaches) are rare and should go away within several minutes.

Some of the questionnaires deal with how you feel about your life. Occasionally, if people are feeling down or depressed, they can find this upsetting. If this is the case we could talk to you about this is more detail at the time or we can make an appointment for you to talk to your GP or Practice nurse if you would prefer.

**What are the possible benefits of taking part?**

Taking part in this study may not have a direct benefit for you.

Some possible benefits to you are:

* The study doctor is a respiratory doctor so you will receive specialist review of your COPD.
* The study doctor may be able to adapt your treatment to better suit your disease

Whether or not you choose to take part in the study, all patients with COPD in your GP practice will be invited to attend a patient education session to learn more about COPD at the end of the study period.

**What happens when the research study stops?**

You will continue to access your GP practice as normal during the study, so when the study finishes your care will continue as normal with your GP and practice nurse. The results of the study will be sent to you in the form of a summary sheet as well as being available on the CLAHRC website.

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

Yes. We will follow ethical and legal practice and all information about your participation will be kept confidential.

**What if there is a problem?**

You can contact the study doctor Dr Lucy Rigge or study nurses Mrs Kate Lippiett and Mrs Kate Gillett about any questions or concerns you have about the study on:

07833482100 or UHS.COPDstudy@nhs.net

**PART 2**

**Do I have to stay in the study?**

You may choose to leave the study at any time, without giving a reason. Please call or email the study doctor or nurse if you change your mind and decide you no, longer wish to participate. This will not affect your future medical care.

We may ask you leave the study if:

* You find cannot understand or follow instructions for follow up visits
* The study doctor thinks it is in your best interests to stop.

**What happens if I leave the study?**

No more information about you will be collected. Any information you gave us before you left the study will still be used.

**What if there is a problem?**

If you have a concern about any aspect of this study, you can speak to the study researchers on 07833482100 or UHS.COPDstudy@nhs.net who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do so via the NHS Complaints Procedure. Details can be obtained from INVOLVE a government funded organization to support active public involvement in NHS research. INVOLVE can be contacted on 02380 651088 or at admin@invo.org.uk.

Any concerns can also be raised to the University of Southampton on 02380595058 or at rgoinfo@soton.ac.uk.

**Will my information be kept private?**

Personal information about you such as your name and address will be kept confidential and kept in a secure file that can only be accessed by members of the study team. Your study information will be labelled with a code number which will not include your name or address so will not identify you. The study team will be free to use this coded information in publications such as journal articles to share the results of the study with other doctors, health professionals and members of the public to try to better understand COPD, other diseases and conditions. Neither you, nor your GP surgery would be named in any publication.

Sometimes government, hospital or university officials check to see research studies are being run properly. Your study information may also be checked by these people, they will keep all information confidential.

Your personal information will be kept for ten years in accordance with policy of the University of Southampton. After this time it will be destroyed in a secure manner.

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

The research is funded by the Wessex CLAHRC- this is a government funded, five year research and implementation programme with the aim of improving the health of the people of Wessex.

**Who has reviewed the research?**

All research in the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed by the Wessex CLAHRC and approved for conduct in the NHS by the National Research and Ethics Committee.

Centre Number:

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**CONSENT FORM**

Title of Project: **C**linical **A**nd **S**ocial **C**haracteristics **A**nd **D**emographics in **E**arly **COPD**- **CASCADE II**

Name of Researcher:

Please initial box

1. I confirm that I have read and understand the information sheet dated 02/07/2015

(version 2) for the above 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 regulatory authorities or from the

University of Southampton, 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 agree to my GP being informed of my participation in the study.

5. I agree to take part in the above study.

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Name of Patient Date Signature

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Name of Person Date Signature

taking consent

When completed: 1 for participant; 1 for researcher site file; 1 for GP notes