**Patient Information Sheet**

**The PRACTICE Trial: Pulmonary Rehabilitation and ACTIvity after COPD Exacerbations**

*You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.*

**What is the purpose of the research?**

Chronic obstructive pulmonary disease (COPD) is a condition affecting the airways. The main symptom of COPD is breathlessness when doing things like walking or climbing stairs. Breathlessness leads to people being less active which can make it more likely for a person with COPD to be admitted to hospital. Patients with COPD often experience flare ups known as “exacerbations” due to chest infections, which result in worsening of their symptoms, more loss of function, and may require hospital treatment. People with COPD who have breathlessness are advised to have pulmonary rehabilitation.

Pulmonary rehabilitation (rehab) is exercise (also called physio) and education for people with breathing problems like COPD. Studies have shown that pulmonary rehab can improve breathlessness, help people do more and feel better in themselves. Pulmonary rehab can also reduce the amount of time that people with COPD spend in hospital. Many people with COPD choose not to have pulmonary rehab for many different reasons.

The purpose of this project is to assess the whether it is possible to undertake a larger study of exercise in patients who have been admitted to hospital with a flare up of their COPD. We aim to find out whether patients will be willing to participate and undertake pulmonary rehab exercise both during their time in hospital, and then immediately after they get home, and to see if this will allow patients to recover more quickly.

**What does it involve?**

If you join the study you may be asked to undertake exercises whilst in hospital, or when you get home from hospital under the supervision of a physiotherapist. The study will involve completing a number of questionnaires, and some other measurements while in hospital, the week after you go home, at a visit to hospital in about 30 days and at your follow-up hospital visit in about 90 days’ time (more detail is given on pages 3-5).

***In-hospital exercise***

This is a bedside bicycle based activity that can be undertaken whilst you are sat at the edge of your bed in hospital. It involves doing 16 rotations of the legs and arms, three times a day under the guidance of a physiotherapist or physiotherapist assistant. This will take place for 5 consecutive days while you are in hospital. You are expected to need to remain in hospital for this long, but the study would not stop you from going home if you are well enough.

***In-home exercise***

You will be visited at home by a physiotherapist within 72 hours of discharge (at a time convenient to you) and will have a total of four visits over roughly two weeks. The visits will be no more than 5 days apart. You will also be asked to complete at least one unsupervised session, a daily walking plan and an exercise diary by yourself over the two weeks. Exercise sessions will start at 20 minutes and increase to 40 minutes if you are well enough, the physiotherapist will help decide this with you.

There will be a warm up of gentle exercise, followed by more intense aerobic and resistance training involving the main muscles of the arms and legs. Exercise will be planned according to how breathless you get, and the physiotherapist may use a device to measure your oxygen levels to make sure you are ok during the exercises.

In this study, the exercise in hospital and at home will be started much earlier than the rehab classes that are currently widely available to COPD patients after a flare up (see *Usual Care* below). This study will help us to understand if exercising earlier after hospital admission has any benefits over exercising later and will help us to decide if a large study looking more closely at this is required. We will also find out why some patients do not want to take part in the research or in pulmonary rehab.

***Usual Care***

All patients admitted with a COPD flare up will be offered pulmonary rehab as part of usual NHS care whether they take part in this research or not. It is normal to have 12 group exercise sessions 4-6 weeks after leaving hospital, along with some education sessions in community venues in your area. This pulmonary rehab is usually offered twice a week, with the sessions lasting up to one hour and is similar to what is described in the in-home exercises.

**What is a pilot study and why is it being used?**

This study is a pilot study which is a small study that acts like a test run for a larger one and helps us to design it better.

Asking people to join research and undertake exercise when they do not feel well may be difficult. This may mean that a larger scale study is not possible, or will be too expensive to conduct. We will collect information on these issues by interviewing patients and professionals. We will also collect their views pulmonary rehab, as well as whether the research procedures and questionnaires are acceptable and relevant.

We won’t collect this information from enough people to know if these exercises really helps manage their condition or provides value for money. We will just collect enough information to get the design of the large-scale study right.

**Why have I been chosen?**

As someone with Chronic Obstructive Pulmonary Disease (COPD) who has been admitted to hospital and likely to stay for at least 5 days you meet the needs of the study. We are hoping to recruit 76 patients from this hospital and from [Sheffield Teaching Hospitals NHS Foundation Trust/Aintree University Hospital NHS Foundation Trust] in a 7 month period.

**Do I have to take part?**

No, it is completely up to you to decide whether or not to take part. As we need to start the in-hospital exercises as soon as possible so that we can fit them in before you go home, we will ask if you want to take part within an hour but you can have up to 48 hours from admission to make your decision if you would like longer. If you do decide to take part you will be given this information sheet to keep (and be asked to sign a consent form) and you can still withdraw at any time from the exercises or study without giving a reason. This would not affect the standard of care you receive.

**What will I have to do?**

Once you agree to take part we will ask you to sign a consent form and answer some questions about your COPD and general health, and complete other measures (detailed below). NHS staff will collect data from your notes about your COPD, medical history and basic personal data such as gender and age. Following that we will use a computer to decide whether you will have either of the two different sorts of exercise detailed above.

*In-hospital* *exercise* and *in-home exercise* will be under the guidance of a physiotherapist. You may be asked to take part in one of these sets of exercises, both of them or neither of them, and in all cases, you will still be referred for the standard pulmonary rehab currently offered in your area.

You have a 50/50 chance of doing *in-hospital exercise* and you have a 50/50 chance of doing *in-home exercise*. We will tell you straightaway about the *in-hospital exercises*, and these will begin on the same day. Before you leave hospital, we will let you know whether you will be doing *in-home exercises*.

The computer will randomly allocate you to these exercises, which means, neither you nor the care team will know whether you will be given the exercises in hospital or at home, both, or not at all.

Everyone will be offered *usual care* though if you receive *in-home exercises* there will be 4 less sessions of *usual care* (so there are 12 sessions overall after leaving hospital)

In addition to taking part in pulmonary rehab (either in the study exercises or as part of usual care) you will also be asked to complete questionnaires that ask about your activities at home and how your breathing problems are affecting your quality of life. Whilst you are in hospital (5 days after joining the study) a measurement of your muscle size will be done using ultrasound and you will be asked to do a short walking test (for 6 minutes).

We would like to collect information from patients who take part for 3 months. In research, this is called “follow-up” and is important so that we know about the benefits or negative effects of any treatment. Follow-up will involve you answering a number of questions about your general health, COPD symptoms and any further treatment you have had since the treatment.

As well as the measures taken before being allocated to your group, we will collect follow-up information from you as follows:

1. 5 days after joining the study, while in hospital a research nurse and/or physiotherapist will collect data from your notes and take a scan of your leg muscle using a portable scanner. They will ask you questions about your COPD and breathlessness symptoms, your health related quality of life and your beliefs about pulmonary rehab and you will be asked to do a 6 minute walking test. (TIME)
2. Before discharge you will be given a diary for completion at home and an activity monitor and shown how to use it. This is also when you will be told whether you are to have the *in home exercises*.
3. 7 days after discharge, over the phone or in person we will ask about your beliefs about pulmonary rehab again, and see if you have had any problems with your health. At this point the activity monitor should be returned, either by taxi (paid by the research team) or it will be collected at the visit.
4. 30 days after joining the study, at a research visit the research nurse and/or physiotherapist will collect data from your notes from the last month and take a scan of your leg muscle using a portable scanner. They will ask you questions about your COPD and breathlessness symptoms, your health related quality of life and your beliefs about pulmonary rehab. They will ask if you have had any problems and if you have had to seek medical help over the last month. You will be asked to do another 6 minute walking test and you will hand in one activity diary and be given another one at this visit. (TIME)
5. 90 days (3 months) after joining the study, at a routine clinic visit we will collect the same information as at the 30 day visit and you will hand in your activity diary. The visit will last TIME and it will be the last time we collect information from you for the study.

This follow-up includes an extra visit to the hospital 30 days after joining the study; you will be able to claim reasonable expenses for this visit.

To try and make sure the results of the study are as true as they can be, we want to try and hide the group you are in from the research nurse, so please try not to tell them if you have done any exercises when they ask you questions. The physiotherapist and doctors will know and they will try not to tell the research nurse too. However, we know this might be difficult and it does not matter if you or the staff do, we will just record that it happened and it will help us design the larger study.

***Activity Monitor***

The activity monitor is a small device made by McRoberts called a MoveMonitor worn with an elastic strap on your lower back. We would like you to wear it for one week, but not if you are in water (for example in the bath/shower or when swimming) as it is not waterproof. The monitor will collect data on your movement, for example how much time you spend walking, sitting or doing vigorous activity and also your movement when you are asleep. When we get the monitor back, the data is analysed using web-based software and a report is automatically produced by the company that make the monitor. This data will not include any personal information about you, just the data on your movement and sleep alongside a number that only the researchers in this trial will know.

***Interviews***

We would also like to interview 24 patients in the study to find out what they thought of the study procedures and the exercises (if they did any). This would happen 7 days after you are discharged and will be held at a convenient time and place (including over the phone or by Skype) for you and will last about 40 minutes, with a follow-up interview of 20 minutes if you are happy to. The interview will be recorded so that we document the interview accurately. The information recorded during the conversation will be written down and stored in a locked cabinet and the recording will be destroyed; any direct quotations appearing in publications will be anonymous.

You do not have to take part in the interview to take part in the study we will ask you whether you want to separately on the consent form.

**What are the alternatives for diagnosis or treatment?**

The study does not exclude you from receiving any treatment for your COPD which is otherwise available to you.

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

If the large trial finds out that the exercise in the study is more beneficial than what is currently advised, this may become the treatment of choice for people who have had flare ups of COPD in the NHS, helping future patients.

Participants may benefit from being in the study as exercise has been shown to help with recovery following COPD flare ups, and it is recommended that this activity starts within a month of being in hospital. However, in this study the exercise will happen in hospital and straight after discharge, which is earlier than what currently happens. There is the possibility that doing the exercise earlier may not be beneficial, and could cause some problems which are detailed below but the activity will be supervised a trained physiotherapist who is aware of these risks and will be looking out for them.

COPD is a condition associated with decreased survival. Many previous studies have shown the exercise training improves peoples function and quality of life at home. However, one recent study of unsupervised exercise immediately after being in hospital has suggested that more patients may have died in the following year. It is unclear as to why this might have occurred, but for this reason any exercise you do after your time in hospital will be supervised by a trained physiotherapist and you will be monitored closely throughout the study.

***Possible side effects of the exercises***

There are possible risks associated with pulmonary rehab, especially after being in hospital from a flare up. You may feel physically and mentally tired, have aching muscles and it may cause problems with your breathing.

**What if something goes wrong?**

You will receive proper health care by your consultant whether you choose to participate in the study or not. We do not think that taking part in this research will be different to receiving treatment outside the study but if you have a concern about any aspect of this study, you should ask to speak to the care team or the research nurse who will do their best to answer your questions, or contact the study team (contact details below).

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital. 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 Sheffield Teaching Hospital NHS Foundation Trust [or Aintree University Hospital 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 [Patient Services/Advice Team local details].

**What if I don’t want to take part?**

It is important that we know more about why people do not want to have pulmonary rehab or take part in the research so we would like to interview you if you do not join the study to find out when you are discharged. The research nurse will ask you if you want to take part in the interviews and give you more information.

If you do not want to take part in the research or in the interview that is fine too and it will not affect the care you receive.

**What if new information becomes available?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the care team or research team will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information your doctor might consider it to be in your best interests to withdraw you from the study. They will explain the reasons and arrange for your care to continue.

If the study stops for any reason while you are taking part in it we will let you know and explain why either through your care team or the research team.

**What will happen if I don’t want to carry on with the study?**

You can withdraw from the study at any time, but you will still need to attend clinical appointments so that you can be monitored as part of your usual care. We will keep your data up until the point that you withdraw and we will not collect any more information from you.

**Will my taking part in this project be kept confidential?**

All information that is collected about you will be kept strictly confidential and will be held securely in line with the Data Protection Act. Members of the local research team and the research team at the University of Sheffield will have access to your personal details so that you can be contacted over the telephone and sent questionnaires. Consent forms may be sent by post to the University of Sheffield for monitoring. If you participate in the trial, we will notify your GP, and if appropriate your consultant.

Data will be stored securely at [Sheffield Teaching Hospital NHS Foundation Trust or Aintree University Hospital NHS Foundation Trust] and the University of Sheffield. Access will be restricted to authorised individuals from the research team. Data for all participants in the study, including those who withdraw, will be kept for a minimum of 5 years.

An anonymous copy of the research data (with any personal details that might identify participants removed) will be retained and made available to other researchers for use in future studies.

If you join the study, some parts of your medical records and the data collected for the study may be looked at by authorised persons from Sheffield Teaching Hospitals NHS Foundation Trust and the University of Sheffield. They may also be looked at by representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant.

**Will I be recorded, and how will the recorded media be used?**

The audio and/or video recordings of the interviews made during this research will be used only for analysis and for illustration in conference presentations and lectures and any direct quotes used from the interviews will be anonymous. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.

**Involvement of the General Practitioner/Family doctor (GP)**

Your GP (and respiratory consultant if appropriate) needs to be notified of your participation in the study, and we ask for your permission.

**What will happen to the results of the research project?**

The results of the study will be used to see whether a large scale trial can be conducted and how to design it.

These findings will also be published in scientific journals and presented at scientific meetings. The findings will be made available to patients through patient organisations, health information websites that are open to the public and the media where possible and appropriate. You will not be identified in any report or publication.

The study website (TBA) will publish a summary of the results following completion of the study. This will be published in spring 2018; please check the website for details.

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

The study has been designed by UK respiratory doctors, physiotherapists and researchers. It is sponsored by Sheffield Teaching Hospitals NHS Foundation Trust, and managed by the Clinical Trials Research Unit at the University of Sheffield. Patients will be recruited in Sheffield and Liverpool. The study is being funded by the UK National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme.

**Who has ethically reviewed the project?**

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by South Yorkshire Research Ethics Committee (Reference: 15/YH/0259).

**Contact for further information**

Your physiotherapist will be contactable on NUMBER, CONTACT TIMES should you have any concerns about the exercises. Please note however that this is not an emergency contact number. If you should experience any increased breathlessness or other symptoms requiring urgent attention please contact your GP or ring 999 as appropriate.

**Thank you**

Patients and doctors rely increasingly on the results of clinical studies, such as the large scale version of PRACTICE, to make sure they are making the right decisions about treatment. Thank you for taking the time to read this information sheet, we hope that it has been helpful in enabling you to decide if you would like to participate in the PRACTICE study.

The PRACTICE Trial, Chief Investigator: Rodney Hughes

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