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NUFFIELD DEPARTMENT OF CLINICAL NEUROSCIENCES

UNIVERSITY OF OXFORD

ORTU
Oxford Respiratory Trials Unit

PARTICIPANT INFORMATION SHEET

Reducing perioperative risk in chronic obstructive pulmonary disease with pre-operative pulmonary rehabilitation - A feasibility study

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 unclear, or if you would like more information, please ask us.*

Why are we doing the study?

COPD (Chronic Obstructive Pulmonary Disease) is a condition in which lung damage leads to shortness of breath and an increased risk of chest infections. Following surgery, people with COPD have more complications than healthy people because of their increased risk of chest infections. The purpose of this research is to test ways of making surgery safer for people with COPD.

Pulmonary rehabilitation is a programme of activity and education for people with COPD. It helps make people fitter, more active and less breathless. It also reduces the chances of hospitalization following a flare-up by more than 50 per cent. If it could be used to prevent complications following surgery, it would have powerful benefits for both the individual and the NHS. The intention of this research is to establish whether it would be possible to deliver pulmonary rehabilitation to patients awaiting surgery.

Currently, pulmonary rehabilitation programmes are available in most towns across the country, so if they really do help COPD sufferers recover more quickly from surgery, it would be relatively straightforward to arrange them.

Furthermore, in addition to helping individuals, if successful, pulmonary rehabilitation before surgery may lead to considerable cost savings for the NHS.

What is the purpose of the study?

This is a feasibility study that we hope will enable us to run a larger trial. Its purpose is to establish whether providing pulmonary rehabilitation to people with COPD prior to surgery reduces the incidence of complications (particularly chest infections) after surgery.

Why have I been invited?

You have been approached because you have a diagnosis of COPD and are due to have an operation in the near future. We would like to recruit 72 participants into this study.

Do I have to take part?

No, you do not have to take part. This study is entirely optional and your routine clinical care will not be affected in any way. Furthermore, if you decide to take part now but later decide to withdraw, that is also fine. However, we may ask you to consent to allowing the research team to use the data that have been collected up to the point of your withdrawal.

If you decide not to take part, we may ask you to consent to receiving a telephone call or arranging a face-to-face meeting with a member of our research team to ask a few questions about why you felt you did not want to participate.

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

If you decide to take part you will be invited to the hospital to have the study explained to you more fully and to give you the opportunity to ask questions and, if you are happy, to sign a consent form. Once you have agreed to take part, there will be four visits.

Visit 1: We will ask you questions about your health and, with your consent, will obtain further relevant information from your medical notes. You will be asked to complete several questionnaires, and do a six-minute walking test. This visit will last approximately 1.5-2 hours maximum.

You will then randomly be allocated to a treatment group, either undergoing pulmonary rehabilitation or receiving standard care. The investigators working on the study will be kept blind to the treatment you are allocated, so please remember not to discuss this with them during the study. However, your research nurse will know the group you are allocated to.

Pulmonary Rehabilitation Treatment: Those allocated to the pulmonary rehabilitation group will attend 3 sessions of rehabilitation a week in the 3–4 weeks leading up to their surgery. Pulmonary Rehabilitation is a programme of activity, education and support to help with your breathing. During the sessions, specialists will help you improve your physical condition and manage your COPD. The exercises and advice they give you will be tailored to your needs.

Each session will last approximately 2 hours and will take place in a location convenient for you. You will be enrolled onto a programme that is already running.

Standard Care: Those allocated to the standard care group will receive advice on exercise and stopping smoking. They will also be given an information sheet detailing these.

Visit 2: During your hospital stay, we will collect information from your medical notes regarding your recovery from surgery. On day 3 we will ask you to complete one questionnaire.

Visit 3: Six weeks after surgery, we will collect information from you on any post-surgery complications or COPD exacerbations. We will also ask you to complete eight questionnaires.

Visit 4: Six months after surgery, we will collect information from you on any ongoing complications or COPD exacerbations. We will also ask you to complete seven questionnaires. This is your last visit for the study.

Qualitative interview

You may also be approached by one of the researchers to have a face-to-face meeting or a telephone call to ask you about your experience of taking part in the study.

What should I consider?

You have been invited to participate because you have a diagnosis of COPD and are due to have surgery soon. You do not need to change your medications or routines in any way.

Are there any possible disadvantages or risks from taking part?

The only disadvantage is in the time that you will need to give to attend the pulmonary rehabilitation sessions, hospital visits and answering questionnaires. Pulmonary rehabilitation carries no known adverse side effects or risks.

What are the possible benefits of taking part?

Pulmonary rehabilitation might aid your recovery from surgery, but we currently do not know. Therefore, there may not be any benefit to you but this study may help us to identify how to help others with COPD in the future. With your consent, we will inform your general practitioner (GP) of your participation and which group you have been allocated to.

Will my taking part in the study be kept confidential?

Yes. All participants will be identified by a unique study number and your data will be fully anonymised.

Responsible members of the University of Oxford and the Hospital NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

We understand that transport costs can be high as well as parking at the hospital; therefore you will receive a reimbursement of £100 for your participation in the study and we will pay your travel expenses.

What will happen to my data?

All information collected about you during the study will be kept strictly confidential and stored in line with legal data protection principles and international Good Clinical Practice guidelines for medical research. All data will be pseudo-anonymised and coded only by a unique study number and initials on study documentation and electronic databases. All documents will be stored securely and only accessed by staff involved in the study and authorised personnel. Any personal information, such as phone numbers, will only be accessible to the local research teams and your verbal consent will be sought at the start of the study to use this personal information to contact you.

With your consent, your medical records may be inspected by the research study team for the purposes of monitoring or collecting information and analysing the results. Authorised personnel from the study's sponsor (University of Oxford, UK) and your local hospital may also look at the study data and your medical records to ensure the study is carried out to the highest possible standards. Regulatory bodies responsible for monitoring healthcare delivery local to you may seek permission to inspect your study data and medical records to ensure standards of medical care are maintained. All individuals or organisations with access to your study data and medical records have a duty of confidentiality to you.

The study data will be retained for at least 5 years (or longer depending on your local hospital policy) after the study has finished in a secure archive facility.

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

Your participation is entirely voluntary and you can withdraw at any time without affecting your continued clinical care.

What happens at the end of the study?

At the end of the study, the results will be analysed and shared with all healthcare professionals and other interested parties through publication in scientific journals and at conferences. In all instances, the data will be anonymous and no individual patient participating in the study will be identified in any publication. The results from this study will hopefully enable us to run a much larger study in this area.

What if we find something unexpected?

If we notice anything unexpected about your test results during the study, we will discuss it with you and your GP.

What if there is a problem?

The University of Oxford, as Sponsor, 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 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 Kyle Pattinson 01865 231 509 & email kyle.pattinson@ndcn.ox.ac.uk or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224, or the head of CTRG, email ctrg@admin.ox.ac.uk

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

If you wish to contact the PALS team please contact Oxford University Hospitals NHS Trust Foundation 01865 221473 and email PALS@ouh.nhs.uk from the PALS website http://www.ouh.nhs.uk/patient-guide/pals.aspx.

Have patients and the public been involved in this study?

Yes. We have discussed the study with members of our local Breathe Easy Group in Oxford who have helped to develop the research idea. People with COPD were also involved in reviewing the study documentation.

Who is organising and funding the study?

The study has been funded by the NIHR Research for Patient Benefit.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by XXX Research Ethics Committee

Further information and contact details:

Please contact Dr Kyle Pattinson 01865 231 509.

Thank you for considering taking part.