Participant Information Sheet

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The feasibility of a sedentary behaviour intervention for hospitalised chronic obstructive pulmonary disease patients following an acute exacerbation: Sitting and ExacerbAtions Trial (COPD-SEAT)

You have been invited to take part in a research study. Before you decide whether to take part 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 friends and relatives if you wish to.

Please take time to decide whether you wish to take part or not. Do not hesitate to contact a member of the usual care team and/or research team if you have any questions or would like more information. Thank you.

Background

In this research, we want to test an intervention targeting people's sitting time following admission to hospital for an exacerbation of chronic obstructive pulmonary disease (COPD). The research programme is called COPD-SEAT (Sitting and ExacerbAtions Trial) and we want to see how well an intervention aimed at reducing sitting time can be conducted in this setting. Information from this study will contribute towards PhD qualifications.

It is important for everyone to try to limit the amount of sitting in daily life. Following an exacerbation of COPD, sitting time can often increase and this may not help individuals to maintain or improve their physical capabilities and quality of life. It is therefore important to find effective ways for some people to sit less after being discharged from hospital.

Why have you been chosen?

You have been chosen because you are aged between 40 and 85 years, have a clinical diagnosis of COPD and have had fewer than 4 exacerbations requiring hospital admission. You will be amongst up to 60 patients admitted to Glenfield Hospital taking part in this research.

Do you have to take part?

No. This research is entirely voluntary. You will choose whether or not to take part. If you agree to take part, then you will be asked to sign a Consent Form, which states that you are happy to participate. You can change your mind about taking part at any time without giving a reason. Your usual care will not be affected if you decide to withdraw from the study.

If you would like any further information to help you make your decision, please do not hesitate to speak to Mark Orme or a member of the REDs team at your convenience.

What does the study involve?

Participation in the study will last for ~3 weeks, from the time a member of the research team meets you following your expression of interest to the end of the follow-up visit.

If you agree to take part, you will be randomly assigned to one of three groups. Two groups will take part in a COPD-SEAT intervention and one group will receive usual care.

You will not be told which group you will be assigned to before agreeing to take part. Whether you are in one of the COPD-SEAT interventions or the usual care group will be decided at random (a bit like picking names out of a hat). If you agree to take part, you will then be given an envelope that will tell you which group you are in. Nobody knows which group they will be in until they open their envelope.

The reason for selecting at random is so that every individual has an equal chance of being offered a COPD-SEAT programme. It also means that the groups should have an equal mix of different ages, gender, length of COPD diagnosis, and exacerbation history.

If your envelope shows that you are not in the group that receives a COPD-SEAT intervention, we will ask you to complete the baseline measures and questionnaires and take part in one interview before your discharge. We would then like you to carry out your normal daily activities after discharge and we will see you again 4 weeks later for follow-up measures and questionnaire completion. **You will have the option to receive the educational materials at the 2 week visit.**

What happens next?

We ask that you please complete the Expression of Interest form that came with this information pack indicating whether you do or do not wish to take part. Sending

back this form does not mean you agree to take part in the study - it just means we can meet you to tell you more about it.

When we meet you, we will ask you to fill in a Consent Form which states that you are happy to take part in the study. We will then ask you to fill in some questionnaires and perform the following physical measurements:

Interview One

Those Wanting to Take Part

We would like to speak to you before your discharge to talk about your COPD diagnosis, exacerbation history and how physical activity and sedentary behaviours fit into your daily life and COPD management. This information will help us to understand the role that lifestyle plays in COPD and how best we can facilitate better care. Your participation in this interview is entirely voluntary and, with your permission, we would like to audio record the conversations so they can be used as part of our research.

Those NOT Wanting to Take Part

We would like to speak to you before your discharge to talk about your reasons for not wanting to take part in the COPD-SEAT programme. We want to learn as much as we can about how best to put in place a programme to reduce sedentary behaviour after an exacerbation. Understanding why people did not want to take part will provide invaluable information and help us to design and implement better ideas in the future. Taking part in this interview is entirely voluntary and, with your permission, we would like to audio record the conversations so they can be used as part of our research.

If you agree to take part:

Please Note:
You are not required to complete any or all measurements as part of the study if you feel unable to do so. You will be asked throughout the completion of measurements if you are happy to do them or if you require rest. These measures do not have to be completed together and can be spaced apart as much as you like.

Questionnaires

We kindly ask you to complete a questionnaire covering topics such as employment status, smoking history, symptoms, anxiety, depression, physical activity levels and sitting time.

Cognitive Function

A cognitive function test will be undertaken (paper-pen and verbally) with a member of the research team upon consenting to take part in the study.

Body Composition

Measurements of height and weight will be used to calculate your body mass index. You will be asked to remove your shoes, socks and personal belongings during the measurements. Weight will involve standing on a weighing scale device. Waist circumference will be measured using a tape measure and is an important indicator of abdominal body composition.

Lung Function

Spirometry will be conducted at the follow-up appointment only and will involve breathing out as hard as you can several times with recovery periods of at least a few minutes between each effort. These breathing tests may cause some temporary light headedness and coughing.

Physical Function

Please Note:
You are not required to complete any or all measurements in this section if you feel unable to do so. You will be asked throughout the completion of measurements if you are happy to do them or if you require rest. The measures do not have to be completed together and can be spaced apart as much as you like.

We will measure the strength of your upper body by performing a grip strength test which will involve you squeezing a measuring device with maximal force on three occasions with a rest period in between.

To measure your ability to rise from a chair, we will ask you to perform a five repetition sit-to-stand test. This will involve rising from a chair with your arms folded across your chest.

To look at your balance, we will ask you to complete a tandem stance test which will involve you trying to hold your balance with one foot directly in front of the other and arms out sideways for 30 seconds.

During the above physical function tests we will ask you to wear a sensor called a Physilog on your chest as well as around each foot. These sensors will not interfere

with the performance of each test and will provide very detailed analysis of your physical function levels.

In order to assess your walking speed, we will ask you to walk up to 30 metres (if possible) aiming to complete the distance in the shortest time you are able to. We will ask you to do this twice and you will be provided with a sufficient rest period between attempts.

Physical Activity and Sedentary Behaviour

You will be given a device called a LUMO which will measure your posture (i.e. sitting, lying down and standing) and an activity monitor, both will be worn on a belt around your lower back and waist. These will be worn during some of your hospital admission and for the 2 weeks leading up to the follow-up visit. You are asked to take the monitors off during water-based activities and overnight. These devices will be returned to us during your follow-up visit 2 weeks after you are discharged from hospital. We will ask you to charge the LUMO overnight. We will also provide you with disinfectant wipes so you can clean the straps as often as you like during the 2 weeks.

An information sheet about the monitors and verbal instructions will be provided before your discharge.

These devices **do not** transmit or receive information (e.g. GPS, video). They are each a 'black box' storing information about movement, activity and posture.

Participant-Researcher Interactions

In order to assess the quality of delivery and information regarding the study, we will ask your permission to audio record interactions/conversations between yourself and the researcher (Mark Orme). This information will be kept strictly confidential and destroyed following transcription. It will be used to examine the consistency and accuracy of the delivered information. You will be asked if it is okay to record at the beginning of each interaction with the researcher and saying no will not impact on your participation in the study or your usual care.

What happens in the COPD-SEAT intervention groups?

Education Group

Before you are discharged we will spend time with you, providing one-to-one education and information on what sedentary behaviour is and why it is important to reduce it after being in hospital. Ideas about how to best achieve these reductions will be discussed. You will be provided with our 'top tips' booklet and, together we will discuss ways to reduce your time spent sedentary which might work best for you. We will be contacting you during your first week to see how you are getting on, to answer any questions you might have, and to provide support and advice as needed.

Please Note:

Both the Usual Care and Education groups will receive feedback on their sedentary behaviour and walking at the end of the follow-up visit. This will include information about time spent sitting and number of steps taken.

Education plus Feedback Group

Individuals in this group will receive the exact same intervention as described in the Education Group section above but will also receive feedback and prompts (gentle vibrations) by the waist worn LUMO device which will act as a reminder for you to try to break up your sitting time if you wish to do so. After talking to you about reducing your sitting time, together, we will decide how often you would like to be reminded to try to break up your sitting time. A full tutorial on the device will be provided as well as written information for you to take home.

Interview Two

We would like to speak to you about what you thought of the COPD-SEAT programme. This will be a short interview with one of the researchers. It will take place during your follow-up visit at the end of the study. These interviews are entirely voluntary, and if you are happy with it, we would like to audio record our conversations so they can be used as part of the research evaluation. These interviews will shed light on what aspects of the programme worked well, which parts require improvement to ultimately lead to improved intervention designs in the future.

What happens at the end of the study?

We will arrange for participants in all COPD-SEAT groups to meet us 2 weeks after discharge to complete physical measures and fill in some questionnaires. Those individuals in one of the two intervention groups will also have an interview.

If you did not receive an intervention as part of COPD-SEAT, you will be provided with the educational materials for reducing sitting time at the end of your 2 week visit. You will also receive feedback on their sedentary behaviour and walking at the end of the follow-up visit.

Those of you in the Feedback Group will also be offered the chance to continue wearing the LUMO and receive feedback for an additional 2 weeks. This is entirely optional and your decision will not affect your usual care.

What are the possible risks of taking part?

When individuals with COPD reduce their sitting time, the increased time that could be spent being more physically active may cause breathlessness and other symptoms. Planning ahead with your daily activities can help. Please do not hesitate to talk to the research team of members of REDS if you want to find out more.

Please note. This intervention will not prescribe or advise on any aspect of medication, provide information or guidance on smoking cessation, or refer individuals to pulmonary rehabilitation. These will be covered by the REDS team and clinicians as routine practice and will not affect your potential involvement in this study.

What are the possible benefits of taking part?

We cannot promise the study will have direct benefits for you, but we hope you will engage with the study and the information we get will help us to improve COPD care in the future. If you consent for us to do so, we will inform the Respiratory Discharge Service of your involvement in the study and the results of the measures will be entered into your medical records.

What if something goes wrong?

It is unlikely that anything will go wrong during this study. But if you have a complaint about anything as you go through the study, then please tell Mark or a member of the REDS team immediately. If you have reason to complain about this study, complaints should be addressed in the first instance to Prof Sally Singh whose details are at the end of this document.

If you remain unhappy and wish to complain formally, you can do this by contacting Patient Information and Liaison Service, contact 0808 178 8337 (free number).

Expenses

Travel expenses will be offered for when you travel to and from the follow-up visit to Glenfield Hospital. Expenses will cover parking and petrol or travel by bus or train. Travel by taxi will be reimbursed within a 5 mile radius of Glenfield Hospital.

Will taking part in this study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of your medical records (e.g. exacerbation and medication history) and the data collected for the study will be looked at by authorised persons from Loughborough University who are organising the research. They may also be looked at by regulatory authorities to check that the research is being conducted correctly. All will have a duty of confidentiality to you as research participants and we will do our best to meet this duty.

Personal data (e.g. address, telephone number) will be kept for 3-6 months after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain confidentiality. Only members of the research team will have access to personal data.

Whilst everything about you is kept confidential, confidentiality will have to be broken if something is mentioned that we believe puts you or someone else in danger. If we believe this to incur immediate danger, we will have to contact the police without any delay. Any non-immediate cause for concern will be discussed in confidence with the research team.

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

Your participation is voluntary and you are free to withdraw at any time, without giving a reason, and without your legal rights and usual care being affected. The treatment you receive from the REDS team and clinicians will not be affected. You should know, however, that if you withdraw then the information collected so far cannot be erased and this information may still be used in the research analysis.

What will happen to the results of the research study?

Results from this study will be used to help us understand whether the COPD-SEAT programme is acceptable for individuals with COPD following admission to hospital

for an exacerbation. The findings will be written up and presented as research publications and presentations (2016/2017) and as part of PhD theses. In the future, the COPD-SEAT programme might be used in a much larger study. The researchers will make sure all participant data is made anonymous and any identifying features will be removed before publication.

Who is organising and funding the research?

The research is organised and funded by Loughborough University and University Hospitals of Leicester.

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 your interests. This study has been reviewed and approved by Research Ethics Committee East Midland-Leicester(15-EM-0433). Study design and content has been reviewed by individuals diagnosed with COPD and members of the REDS team.

Contact for Further Information

If you would like to know more about the research, then please talk to me in the clinic or inform a member of the REDS team who will inform me of your request. My name is Mark Orme and you can contact me by phone via the Rehabilitation Office on 0116 2583652 or 0116 2583181. You will see me around the Ward as well so please do not hesitate to ask me anything about the study.

Thank you for taking the time to read this.

NHS
National Institute for Health Research