

Comparing disability in activities of daily living over time among adults with advanced respiratory disease during the COVID-19 pandemic (DIScOVER)

Participant Information Sheet

We are inviting you to take part in a research study. Before you decide, it is important that you understand why the research is being done and how it may involve you.

Please take time to read this information carefully and discuss it with friends or relatives if you wish. We will talk through this with you and answer any questions you might have. Feel free to ask if there is anything that is unclear or if you would like more information and take your time to decide whether or not you wish to take part.

This study has been approved by the London-Camberwell St Giles Research Ethics Committee (REC reference: 19/LO/1950).

What is the purpose of this study?

We are very interested in finding out more about how people with advanced lung cancer or respiratory disease manage daily activities (e.g. washing, dressing, shopping, and walking) and how this changes over several months during the Coronavirus (COVID-19) pandemic. This is so we can identify when people with these conditions may become unable to manage everyday activities, what may cause them to have more difficulty (e.g. breathlessness) and what might help to improve their independence, in order to guide clinical practice and service provision.

Why have I been chosen to take part?

You have been chosen because of your diagnosis of either respiratory disease or lung cancer. The information you can provide about managing daily activities is very important.

What is the survey about?

The survey will be about how you manage your daily activities, and includes questions about caring for yourself, how you walk around, the symptoms you experience, services you have been accessing, the equipment you have been using to help you, and social isolation during the COVID-19 pandemic. To collect all this information, the survey will be made up of several different questionnaires. Some of the questions may appear repetitive but it is important to complete all the questionnaires in the survey as each questionnaire will tell us something different.

We will also collect information regarding your diagnosis, mobility, age, gender, ethnicity, marital-status, and health service usage such as hospital admissions. You may be asked some of these questions when you complete the first questionnaire with the researcher. We may also ask to look at your healthcare record to find out this information at the time of enrolment and at the end of the study.

What do I have to do if I agree to take part?

In this study pack you will receive this information sheet, a consent form and the first questionnaire. The researcher will contact you by telephone to explain the study and ask you for your consent to participate. You will then complete the first questionnaire with the researcher when they call and be enrolled in the study.

There will then be six identical follow-up postal questionnaires at monthly intervals for up to six months. This is so we can identify how a person's ability to perform daily activities may change over time. If you need help to complete the follow-up questionnaires this can be arranged if you let the researcher know. You will receive a telephone call a few days before each monthly questionnaire booklet is due to be sent to remind you to expect a questionnaire in the post, and to ask if you are still happy to continue in the study.

Will I be identifiable?

You will be given a unique study identification number which will be on all your questionnaires so that you are not identifiable, and your answers will be fully anonymised.

Where and when will the survey take place?

The researcher will call you at the agreed time to get your consent to participate in this study and to complete the first questionnaire over the telephone. Please have the consent form and questionnaire to hand when the researcher calls. The researcher will be available to help you and explain any questions if you wish.

Follow-up questionnaires will be posted to your desired address at monthly intervals for up to 6 months, unless other arrangements have been made with the researcher. You will be asked to return each questionnaire within the next 7 days of receipt if possible, using the pre-paid envelope provided.

How long will it take to complete?

The first questionnaire will take about 45-60 minutes. After this, the questionnaires will be shorter and will take about 30-45 minutes each.

Are there any other benefits to taking part?

This research doesn't involve any changes to your care, and so you are unlikely to benefit personally from taking part, though your participation may help us to improve the care of others in future.

Are there any risks to taking part?

The risks to taking part are very small, this research will not in any way affect the standard of care you or any person related to you might receive, care options, or any relationships you have with any staff or researchers.

Some people may find some of the questions upsetting, but you can choose not to answer questions if you do not want to. We will offer you support if you feel you need it. A telephone number for support will be available.

Do I have to take part?

No. It is entirely up to you to decide whether or not to take part. We will give you at least 24 hours to decide whether to take part, unless you wish to decide sooner.

Who will know about my involvement in the study?

All information about you will be treated confidentially and we will follow guidelines to make sure this happens. Your information will be anonymised which means no one will be able to identify you from what you have shared. The information you share will be stored in a safe place with any information that identifies you kept separately. Information about you which leaves the hospital or hospice will have your name and address removed so that you cannot be recognised. Anonymised information that you provide may also be used for education and teaching and to inform future research.

We will ask you whether you want your GP or consultant(s) to know about your involvement in this study. We can contact them on your behalf if you want them to know, but we will not tell them about your involvement if you don't want us to.

Could patient confidentiality ever be broken?

If the researcher becomes concerned about your health or welfare your clinical team or GP may be informed in order for you to receive the care you may need.

What if I decide to withdraw?

You may withdraw at any time. If you do withdraw, we will ask you if information that has already been collected may be included in the results for the study.

What happens at the end of the study?

After the study, your care will continue as normal under the guidance of your care team.

What happens to the results of this study?

The findings of this study will be published in scientific journals. A summary of the results for wider distribution will be sent to policy makers, staff, and individual users of services, their caregivers and charities. If you wish we can send you a copy of the results. Please be reminded that all personal details will be removed from the results so you and your family will not be identified from the findings.

Who is organising the study?

The study is organised by Lucy Fettes a researcher from King's College London who will be working on the study as part of a higher degree.

Who is funding the study?

This study is funded by a grant from The National Institute of Health research (NIHR).

Will I get paid?

There are no funds available for payment to those participating in the study.

Who and what is the sponsor of the study?

King's College London is the sponsor (we) for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study. This information will include your NHS number, name, and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. King's College London will keep identifiable information about you for 7 years.

To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information:

- <https://www.kch.nhs.uk/about/corporate/data-protection>
- www.hra.nhs.uk/information-about-patients/

Need more information and want to talk to someone else?

All research is looked at by an independent committee of people called a 'Research Ethics Committee', to protect your interests. However, if you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Their contact details are included at the end of this information sheet.

What if there is a problem?

If you wish to make a complaint about any aspect of the way you have been approached or treated during the study, normal NHS / local complaint procedures will be available to you. If you disclose information leading to safeguarding concerns or allegations of bad practice, action will be taken in line with the local policy where you are receiving your care. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for it.

If you wish to complain formally you can do this via the Patient Advice and Liaison Service (PALS) at:

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| • King's College Hospital, London | - Tel: 020 3299 3601 |
| • St Thomas' Hospital, London | - Tel: 020 7188 8801 |
| • Guy's Hospital, London | - Tel: 020 7188 8803 |
| • Princess Royal University Hospital, Kent | - Tel: 01689 863252 |
| • Nottingham University Hospital | - Tel: 0800 183 0204 |
| • Conquest Hospital, St Leonards-on-sea | - Tel: 01424 758090 |
| • Medway NHS Foundation Trust | - Tel: 01634 825004 |
| • Macclesfield District General Hospital | - Tel: 01625 661111 |
| • South Tyneside & Sunderland NHS Foundation Trust | - Tel: 0191 5699549 |
| • Royal Cornwall Hospital | - Tel: 01872 252793 |

Independent advice and specific concerns:

Independent advice about taking part in research can be found at:

- INVOLVE
Tel: 023 8065 1088 or Email: www.invo.org.uk

Becoming involved:

We welcome any suggestions that you have to improve this research. We are happy to share the findings of the research with you regardless of whether you participate or not.

Our contact details:

Please contact us with any questions or concerns.

Researchers:

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**Thank you very much for taking the time to read this information sheet
and consider this study**