

Participant Information sheet Template



Manchester University

NHS Foundation Trust

Title of Project:

Sensations and Triggers of Coughing pre- and post-treatment in Chronic Cough

Cough Research Team,
Manchester Clinical Research Facility,
Wythenshawe Hospital
Manchester University NHS Foundation

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Invitation and brief summary

We are investigating how the sensations associated with chronic cough change after treatment, and how this relates to different measures of cough, using a newly developed questionnaire (TOPIC questionnaire). We also wish to find out whether these sensations might help us reach a diagnosis at an earlier stage.

Please take your time to read the information carefully. Discuss it with your friends, relatives, or GP if you wish to. Take time to consider whether or not you wish to take part. Your participation is entirely voluntary, so you do not have to take part if you do not want to.

What is the purpose of this research?

Cough is an important reflex which is used to clear the airways of irritating material or phlegm. However, a cough can become troublesome and coughing is the most common complaint for which people seek medical advice. Chronic cough is a cough lasting for more than 8 weeks which can have a negative effect on the individual's day to day life. At present, individuals undergo multiple investigations and trials of treatment before a diagnosis can be reached.

We know that people with chronic cough describe similar sensations associated with coughing. This research will help us understand whether treating cough alters these sensations, and whether this can be measured using the newly developed cough TOPIC questionnaire. It will also inform us whether cough improves alongside these changes in sensations. As part of the study, we will also investigate whether the sensations associated with coughing can inform us of the diagnosis.

Why have I been asked to take part?

You have been invited to take part in this research because you are a chronic cough patient in the Manchester Cough Clinic (MCC).

What would taking part involve? What happens if you agree to take part?

If you agree to take part after reading this information sheet, an experienced researcher will approach you at your first visit to the clinic. They will explain the study to you in more detail and give you the opportunity to ask any questions you may have. With your permission, your GP will be informed of your participation in the study.

Visit 1: This visit will last for approximately 1 and a half hours and will take place at either Altrincham Hospital or Withington Community Hospital, depending on where you are attending the clinic.

As detailed above, a researcher will talk through the study again with you and answer any questions you may have. If you are still happy to take part, you will be asked to sign a **consent form**. You will then be asked questions about your medical history, lifestyle and details of any medications you are taking. If you do take medications, it may be helpful to bring a prescription with you to allow us to accurately record your medications and the doses you take.

You will be asked to complete two questionnaires, one about how much you cough and how it affects your daily life and another about the sensations provoking your cough. You will also be asked to score the severity of the cough. This will include making on a line how severe your cough is at day and night (VAS) and giving a verbal (0-10) cough score.

After your clinic appointment with the Doctor, you will be fitted with a **cough monitor** which will record the number of times you cough over a period of 24 hours during the day and night. The researcher will attach a sticky pad to your chest which contains a small microphone. A clip with another small microphone will be attached to your clothing. The monitor itself will be kept in a 'bumbag' around your waist. **You must not get the monitor wet.**

Once you have been fitted with the monitor you will be able to leave the department. The cough monitor can be removed after 24 hours. This will need to be returned to Wythenshawe Hospital Clinical Research Facility (or we can arrange collection) the next day, alternatively we can give you a prepaid addressed envelope too post back the cough monitor.

The cough monitor is designed to record the number of times you have coughed during a 24-hour period (day and night). The monitor does not just record coughing sounds; it will record your activities whilst you are wearing it. For example, it will record your conversations and, in some instances, may record the voices of people around you. We do however use computer software (algorithms) to remove parts of (cut down) the recording where there is no coughing, such as some speech, when you are reading or sleeping and distant noises, such as noise from your television. In some cases the research team will have to listen to the full 24 hour recording to cough the coughs. Any conversations overheard by the researchers will be kept confidential.

The cut down recordings are listened to and analysed by a trained researcher who counts the number of times you have coughed during the day and night.

Please be aware that we could rarely hear information or conversations on the recording. This is very unusual as in the majority of cases the recording is reduced to a compressed (coughs only) recording. Very occasionally however a full 24hr audio recording is needed to analyse the cough frequency. Very rarely we could hear something on this recording which might place either yourself or another person in danger. We have specific procedures in place to deal with situations where sensitive, personal or potentially incriminating information is heard.

Visit 2 (6-12months after visit 1): At visit 2 the study procedures at visit 1 will be repeated.

You will be asked to complete the same questionnaires and cough scores **as visit 1**.

As with the previous visit, you will be fitted with a cough monitor to be worn for 24 hours to record how often you cough. This will need to be returned to the Wythenshawe Clinical Research Facility (or we can arrange collection) the next day.

What are the possible benefits of taking part?

Taking part in this study will not benefit you directly. However, we hope that the results of this study will help us to understand more about chronic cough and improve treatments in the future. We will be able to compensate you with £25 per visit. This is to compensate you for your time and travel expenses to/from the hospital.

What are the possible disadvantages and risks of taking part?

We do not anticipate any risks to yourself from taking part in this study.

Do I have to take part?

No, you do not have to take part if you do not wish to, and your decision will not affect any standard of care you receive at Manchester University NHS Foundation Trust.

What happens if I change my mind?

Taking part in this study is completely voluntary and if you decide at any point you no longer want to take part you can withdraw from the study and you will continue to receive standard care within the NHS. You do not need to give a reason and your decision will not stop you from taking part in other studies in the future if you want to. The study doctor may also withdraw you from the study early if it is necessary for your health.

You will be compensated for your time for all completed visits.

What happens if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with the lead researchers who will do their best to answer your questions (**Paul Marsden or sub-investigators (address provided at top of information)**). If you remain unhappy and wish to complain formally, you can do this by contacting local NHS Patient and Liaison Service (PALS) by email pals@mft.nhs.uk or call 0161 276 8686.

The hospital is insured to carry out clinical research through the NHS Indemnity scheme, however the normal National Health Service complaints procedures should be available to you. 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 Manchester University NHS Foundation Trust but you may have to pay your legal costs

What will happen with the results of the study?

It is intended that the results of the study will be published in medical journals so that we can explain to the medical community what our research results have shown. Your name will never appear in any report or publication arising from this study.

We intend to share a fully anonymised final data set, so people will not be able to identify you, for future research which may be carried out by researchers other than those who ran the first project, including researchers working for private companies.

We will also write about the research findings in the chronic cough newsletter, which is sent to every participant who takes part in our research studies. You can request on the consent form if this is sent in the post or via email.

Who is organising and funding the research?

This research is sponsored by Manchester University NHS Foundation Trust and being carried out by experienced research staff at the North West Lung Centre, Wythenshawe Hospital. The study is funded by an Investigator initiated grant from Merck Sharp & Dohme Ltd.

How will we use information about you?

We will need to use information from you from your medical records for this research project. The research team will have access to the following to your medical records in clinic, but the research record will only include your initials, study ID, demographics, medical history and research specific material (questionnaires and cough scores).

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. 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.

Access to data will be restricted to members of our research team. Data will be stored within a locked office (paper) on a secure server (electronic) which only members of the research team have access to.

Paper documentation, electronic files and cough recordings will be retained for a maximum of 5 years as per local procedures on research documentation archiving. The cough recordings will be stored until the study documents are destroyed, 5 years after the end of the study. Cough recordings entered into RaDar will be stored in accordance with the RadaR protocol. Research data collected during the study can be stored for up to 25 years.

Should you lose capacity during the study, any data that had already be obtained would be kept, but no further procedures or data collection would be carried out.

What are your choices about how your information is used?

- 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.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. [This includes Radar, an anonymised database of 24 hour cough recordings.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at <https://research.cmft.nhs.uk/getting-involved/gdpr-and-research>

- by asking one of the research team
- by sending an email to cough.research@manchester.ac.uk or
- by ringing us on 0161 291 5879

Thank you for reading this information. We hope this research will be of interest to you.