The Leeds Teaching Hospitals NHS Trust

PARTICIPANT INFORMATION SHEET

AI Analysis of Voice to Aid Laryngeal Cancer Diagnosis

You've been invited to take part in a research study

- Before deciding to participate in this study it's important that you understand the research being done and what you will need to do to participate.
- Please take the time to read the following information about the study. You may want to discuss this with friends, relatives, and healthcare staff.
- You are free to decide if you want to take part in this study and your decision will not affect the care you receive.

Important things to know

- We want to find out if laryngeal cancer can be detected using artificial intelligence (AI).
- To be able to do this we need voice recordings of patients referred to specialist clinics.
- Taking part in this study does not mean you have laryngeal cancer, we need voice recordings from all sorts of different patients.
- Taking part **will not affect your treatment or care**.
- You will be required to take part in an **interview** which will take **no more than 30 minutes** and will be recorded.
- Some information (details overleaf) about you will be taken from your medical record.
- You can stop taking part in the study at any time.

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If you have any questions about this study, please contact Mr James Moor using
Email:
j.w.moor@leeds.ac.uk
Telephone:
0113 392 8037

1. Why is this study being done?

One of the first symptoms of laryngeal cancer is a change in voice. However, this is also a common symptom to many non-cancerous diseases. In this study we aim to detect cancer patients from speech recordings using artificial intelligence (AI). In order to develop an AI system, we must collect speech recordings from both cancer and non-cancer patients with a hoarse voice or voice change. This system is being created in the hope that it will help in the early screening of high-risk patients.

2. What will I be asked to do if I take part in the study?

If you agree to participate in the study a member of the research team will ask you to read and sign a consent form. You will then be asked to attend a short interview with a member of the research team. During this interview you will be asked to perform several speech tasks. This interview will take place during your attendance at the outpatient clinic. The interview will be recorded using multiple recording devices. The interview should take around 15 minutes and no more than 30 minutes.

3. Why am I being asked to take part in the study?

You are being asked to take part in this study for one of two reasons:

1. You have been **referred on the urgent cancer referral pathway** for suspected head & neck cancer. In this work we are hoping to create a system that can detect cancer patients from the non-cancer patients referred on this pathway, therefore it's important to include as many patients referred on this pathway as possible including those who do not have cancer.
2. You are being approached as a **healthy control**. In order to fully test the system's capabilities, we need to test it on healthy controls (i.e. those with no hoarseness).

4. What are the benefits of taking part in the study?

If you decide to take part in this study, there will be no direct benefit to you. However, your participation in the study will allow work to be completed into the early screening for laryngeal cancer. It's hoped that this will allow high risk patients to be fast tracked for investigation in the future.

5. What are the risks of taking part in the study?

There are no direct risks to you taking part in the study. The interview will not include any topics that could be considered sensitive, embarrassing, or upsetting, however, you can skip any of the questions or stop the interview at any time for any reason. If during the interview you disclose any information which could be used to identify you it will be removed from the recording and not used within the study. If during the interview you disclose any information which raises welfare concerns, the interviewer will report this to your direct care team.

6. Will any of my personal information be used?

Yes. We will need to use information from your medical records for this research project. This information will include your age, gender, and medically relevant data

such as your presenting symptoms and final diagnosis. To access this data we will use your NHS number.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

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.

The audio recordings collected in the interview will be analysed by Mary Paterson, a PhD student at the University of Leeds. The people analysing the data will not have access to your NHS number, date of birth, or contact details.

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 find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to j.w.moor@leeds.ac.uk, or
- by sending an email to leedsth-tr.informationgovernance@nhs.net

7. If I change my mind, can I withdraw from the study?

Yes, you may withdraw from the study for any reason so long as the interview recordings have not been analysed. If so, they will be removed from the database alongside any information taken from your medical record. However, if the recordings *have* already been analysed it will not be possible for them to be removed from the dataset. If you wish to withdraw from the study, simply contact the chief investigator, James Moor, either by email: j.w.moor@leeds.ac.uk or telephone**:** 0113 392 8037

8. What if something goes wrong?

Every care will be taken throughout this study, however, if you have any concerns about any aspect of this research, you should ask to speak to your study doctor or nurse on: 0113 392 8037

If you wish to speak to someone independently, please contact the Patient Advice and Liaison Services (PALS) team at: 01132067168 or E-mail patient.relations@leedsth.nhs.uk

9. What will happen to the results of this study?

The results of this study may be published in journals or conference proceedings. Plain English summaries of any published results will be provided on the study website (mary-paterson.github.io/papers/). Any published work will be written in such a way that no-one can work out that you took part in the study.

10. Who is organising and funding this study?

This study is sponsored by the Leeds Teaching Hospitals Trust and funded by the University of Leeds.

11. Who has reviewed this 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 given favourable opinion by _____Research Ethics Committee.

12. Need more information?

If you have any questions about the study or need any further information, please contact the chief investigator James Moor either by telephone or email:
Email: j.w.moor@leeds.ac.uk
Telephone: 0113 392 8037
More information can also be found at: mary-paterson.github.io