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NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

Primary Care Clinical Trials Unit

UNIVERSITY OF BATH

University of BRISTOL

UNIVERSITY OF Southampton

The University of Nottingham

Determining the Effectiveness of a FeNO-guided asthma management INtervEntion in primary care (DEFINE)

DEFINE

www.define-study.com

Lead investigator: Dr Kay Wang

Participant Information Leaflet for patients aged 16 years and older

We would like to invite you to take part in our study.

This information leaflet explains why we are doing this study and what it will involve for you if you decide to take part. Please read it carefully before deciding whether you would be happy to take part. If you have any questions, please get in touch with us using the contact details at the end of this leaflet.

Why have I been invited to take part in this study?

We are looking for people with asthma aged 12 years and over who have their asthma reviewed at their GP surgery. You have been invited to take part in this study because you are due for your routine asthma review.

What is the purpose of the study?

We want to find out whether using the FeNO test during asthma reviews can help improve care for asthma patients and reduce costs to the NHS.

What is the FeNO test?

The FeNO test is a breath test which measures the amount of nitric oxide in the air you breathe out. Nitric oxide is an indicator of possible inflammation in the airways, which can sometimes be found in people with asthma. Everyone breathes out some nitric oxide but people whose airways are inflamed breathe out more nitric oxide than people whose airways are not inflamed. Many asthma medications aim to reduce inflammation to help prevent asthma attacks.

The FeNO test is safe and non-invasive. It involves blowing out into a mouthpiece in one long, slow breath. You can watch a short video on how to do the FeNO test here: http://tinyurl.com/fenodemo

*Please note that the nurse in the picture above is not wearing a face mask because this photograph was taken before the start of the Covid-19 pandemic. However, your health care professional will take the necessary steps to protect you from Covid-19 infection where required.

What will happen if I take part?

Your health care professional or someone from the research team will **talk to you about the study** and ask if you have any questions about taking part.

We will ask you to complete a **consent form** to say you are happy to take part. You may complete these forms in person, online or over the telephone.

You will then be randomly allocated to either having your asthma reviewed **with the FeNO test** or having your asthma reviewed **without the FeNO test** over the next year. Half of people in the study will have the FeNO test; the other half will not. This will be decided at random, like tossing a coin, to make sure the results are fair. Neither your health care professional nor the research team will have any control over whether or not you will have the FeNO test.

We will ask you to measure your **peak flow** when you enter the study and again one year later.

We will ask you to **fill in some questionnaires** about your asthma and general health when you enter the study and every three months after that for a year. Most of the questionnaires will need to be filled in when you enter the study. Filling in each set of questionnaires should only take about 10 minutes and no more than 15 minutes. We will ask you how you would like us to contact you when we need you to fill in your questionnaires.

We will collect some information from your **medical notes** shortly after you enter the study and again after about a year. This will include information about your asthma, general health, medications, and times when you have had to seek advice about your asthma or problems caused by your asthma.

What will happen if take part and if my asthma review is done without the FeNO test?

If you are allocated to the group of people who will not have the FeNO test:

- Your health care professional will do your asthma review as they normally do. At the moment, GP surgeries do not normally do a FeNO test as part of a routine asthma review. Your GP surgery may do your asthma review face-to-face or remotely (e.g. telephone or video consultation).
- To help us understand how the FeNO test might influence the care patients receive for their asthma, we will still ask you to fill in our study questionnaires and provide peak flow readings. We will also still collect information from your medical notes for our study.

What will happen if my asthma review is done with the FeNO test?

If you are allocated to the group of people who will have the FeNO test:

- You will be sent a short booklet about the FeNO test and how it can help manage your asthma.
- You will have a FeNO test done. Your health care professional will use an online tool to help consider your FeNO result along with other information about your asthma.
- This will help them plan with you how to manage your asthma going forwards.
- Your health care professional may ask you to come back for more FeNO tests during the year that you are in the study.
- The FeNO test will only be done during **planned reviews** of your asthma. It will not be done if you have an asthma attack or if you consult your GP surgery for reasons other than your asthma.

Do I have to take part?

No, you are free to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time, without giving a reason. Withdrawing or not taking part will not affect your current or future standard of clinical care in any way.

What are the possible advantages and disadvantages of taking part?

The main advantage of taking part is an opportunity for you to contribute to research to improve how asthma is managed in GP surgeries. We do not yet

know whether the FeNO test and online tool will improve care for patients with asthma; that is why we are doing this research.
If you are allocated to the group of people who will be having the FeNO test:

- Your health care professional will be able to consider your FeNO result alongside the other information they normally consider during your asthma review.
- If you normally have your asthma review done over the telephone, you may have to go to the GP surgery or another clinic to have your FeNO test done.
- You may have concerns about Covid-19 infection as a result of having to been seen in person by a health care professional for your FeNO test. However, your GP surgery or clinic will put all necessary measures in place to keep you safe from Covid-19.

You may have concerns about researchers seeing your medical records. However, we would like to assure you that all data will be kept secure and confidential. We will ask you to spare a few extra minutes of your time to fill in our study questionnaires. However, your answers will be a valuable contribution towards our research, which may help improve care for asthma patients in the future.

Will my taking part in the study remain confidential?

Yes. It will not be possible to identify who you are from your study data. You will be referred to only by a unique study identification number. We will keep a separate record of people's real names and corresponding identification numbers. We will use as little personally-identifiable information as possible.

What will happen to my data?

We will be using information from you and your medical records in order to undertake this research. This research is being carried out with the aim of improving care for patients with asthma. Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

Your GP surgery and the research team will use your name, NHS number and contact details (address, telephone number, email) to contact you about the research study, to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

Where will my data be kept?

We will store research data linked to your unique study identification number and any research documents with personal information (such as consent forms) securely at the University of Oxford for up to ten years after the end of the study. This will ensure that we have enough time to analyse it all, and to write papers and reports. After the end of the study, we will fully anonymise all our research data. This will mean that we can still do further analyses if needed but there will be no way of linking your data to any personal information about you.

Who will be able to see my data?

Responsible members of the Universities of Oxford, Southampton, Nottingham, Bristol and Bath, and the Clinical Commissioning Group may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

The only people who will have access to information that identifies you are people who need to contact you for the research study, collect information from your medical records or audit the data collection process.

The people who analyse the information we collect during the study will not be able to identify you and will not be able to find out your name or contact details.

What are my data rights?

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate.

To safeguard your rights, we will keep the amount of information we use which could potentially identify you to a minimum.

Where can I find out more about how my data are used?

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/

You can find out more about how we use your information by contacting the research team using contact details at the end of this leaflet.

What will happen if I do not want to carry on with the study?

If you decide you no longer wish to take part in our study, please let us or your health care professional know. You can find our contact details at the end of this leaflet.

You can withdraw from the study at any time without giving a reason. If you wish to withdraw, we will still keep and use any information we have already collected about you. We will, however, ask your permission to extract information from your medical records. If you decide not to give your permission, that is OK. If you decide to withdraw, this will not affect the standard of care you receive. The research team will respect your decision and will be happy to answer any questions you may have.

What will happen to the results of this study?

The results will be published in scientific journals and on our website (www.define-study.com) for you to read. You will not be identifiable in any reports or publications arising from this research study.

Will I be reimbursed for taking part?

If you fill in all our study questionnaires and provide us with a peak flow reading after a year, we will be able to offer you £10 in e-vouchers for online shopping or a suitable alternative.

Will I be asked to take part in further research?

We may also invite you to take part in an interview with a researcher about your care. If we invite you, we will provide you with another participant information sheet and consent form. If you agree to an interview, we will be able to offer you an additional £20 in e-vouchers or a suitable alternative. However, taking part in an interview is optional. Even if you decide not to take part in an interview you may still take part in the rest of the study.

Who is organising and funding the study?

The study is funded by National Institute for Health Research (NIHR). It is part of the **D**evelopment and **E**valuation of an online **F**eNO-guided asthma management **IN**terv**E**ntion in primary care (DEFINE) research programme. The University of Oxford is the research sponsor. This means that it is legally responsible for organising the study and overseeing the work of the researchers. The study team is led by Dr Kay Wang (University of Oxford). The Primary Care Clinical Trials Unit at the University of Oxford has set up and is running the study.

How have patients been involved in this study?

Patients with asthma were involved in helping prepare this leaflet and design this study.

What if there is a problem?

The University of Oxford has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment that is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during this study, you should contact the research team whose details are given below. Alternatively, you may contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) office on 01865 616480, or the head of RGEA (ctrg@admin.ox.ac.uk).

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee (REC). The REC is there to protect your safety, rights, wellbeing and dignity.

This study has been reviewed and given favourable opinion by London – Fulham East Research Ethics Committee. The reference number is 22/LO/0139 (IRAS no: 307116).

Contact details

Please contact the research team if you would like further information:

Email address: define@phc.ox.ac.uk
Phone number (office hours only): 0186 5289350

Thank you for considering taking part in this study.

Please ask if you have any questions.