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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 12 to 15 years

**Would you like to join a research project to find out whether we
can improve care for people with asthma using a breath test
called FeNO?**

Before you decide if you want to join, it's important to understand why the research is being done and what it will involve for you. So please think about this leaflet carefully. Talk to your family, friends, or your doctor or nurse if you want to.

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. This tells us how swollen (inflamed) your airways are. People whose airways are swollen breathe out more nitric oxide than people whose airways are healthy. Many asthma medications aim to reduce swelling in the airways to help prevent asthma attacks.



The FeNO test is safe and does not hurt. 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>

*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 doctor or nurse will take steps to protect you from Covid-19 infection if needed.

Why have I been invited to take part?

We are looking for people with asthma aged 12 years and over who have their asthma checks done by their GP surgery. You have been invited to take part in this study because you are due for your asthma check.

Do I have to take part?

No, you don't have to take part, but you may want to talk to your mum, dad or carer before making up your mind.

Will the study help me?

No, but the information we collect might help people with asthma in the future.

What will happen if I decide to take part?



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



If you are happy to take part, we will ask your mum, dad or carer to fill in a consent form. We will also ask you to fill in an **assent form** to say that you are happy to take part. You may complete these forms in person, online or over the telephone.



You will then have your asthma checks either **with or 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 doctor or nurse nor the research team will have any control over whether your asthma checks will be done with or without 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. You can ask your mum, dad or carer to help you with these if you like. We will ask you how you would like us to let you or your mum, dad or carer know 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, your general health, medications, and times when you have had to seek advice about your asthma or problems caused by your asthma.

If I take part, will my information be kept confidential?

Yes. It will not be possible for anyone to find out who you are from looking at your information. We will use a unique study number to link your information to you but keep a separate record of people's real names and study numbers. Once the study is complete we will keep your information for up to 10 years. This will help us make sure that we have enough time to look at your information and tell people what our study has found.

What will happen if I want to stop doing the study?

If you want to stop doing the study at any time, please tell the researcher or get your mum, dad or carer to tell them. You are free to stop taking part at any time without giving a reason. If you wish to stop, we will keep and use any information we have already collected about you. If you decide to stop, this will not affect the quality of care you receive. The research team will respect your decision and be happy to answer any questions you may have.

What will happen to the results of the study?

When the study has finished we will tell people about what we have learned from it in medical magazines and websites that doctors and nurses read. We will also put the results on our website (www.define-study.com) for you to read. It will not be possible for anyone to work out who you are from learning about the results of the study.

Will I receive something 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 something else worth the same amount of money.

Will I be asked to take part in further research?

We may also ask you if you would like to take part in an interview with a researcher about your care. If we ask you, we will give you another information sheet and assent form to fill in to say that you are happy to take part. If you agree to an interview, we will be able to offer you an additional £20 in e-vouchers or something else worth the same amount of money. However, you do not have to take part in an interview if you don't want to. Even if you decide not to take part in an interview you may still take part in the rest of the study.

What if there is a problem or something goes wrong?

If you are unhappy about anything about the study, please tell us or ask your mum, dad or carer to tell us. You and your mum, dad or carer can get in touch with us using the details at the end of this leaflet.

Who is organising and funding the research?

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 **I**NtervEntion 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.

Who has checked the study?

Before any research goes ahead, it is checked by a Research Ethics Committee. This is a group of people who make sure the research is ok to do. This study has been checked by the 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:

Trial manager: Samuel Paul

Email address: define@phc.ox.ac.uk

Phone number (office hours only): 01865 289350

***Thank you for reading this.
Please ask if you have any questions.***