PARTICIPANT INFORMATION

David Hide Asthma & Allergy Research Centre
ISLE OF WIGHT

Study Title: The effect of Dyson Air Purifier on Asthma Control; A Randomised, Controlled Trial

Short Title: Dyson air purifier in asthma

You are being invited to participate in the **Dyson Air Purifier in Asthma Study**. Before you decide whether to participate it is important for you to understand why the research is being done and what it will involve.

- Section one tells you the purpose of this study and what will happen to you if you take part.
- Section two gives you more detailed information about the conduct of the study.

Please read the following information carefully and discuss it with others if you wish. Please do not hesitate to contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Contact Details for Further Information

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SECTION ONE

What is the purpose of the study?

Asthma is one of the commonest chronic diseases. It is characterised by inflammation and narrowing of the airways in the lungs alongside a "twitchiness" of those airways that leads to symptoms like wheezing and breathlessness. While many new medications have been introduced to treat asthma in recent years, there remains a shortage of non-drug or environmental interventions that can improve asthma with minimal risk of adverse effects. In addition, in recent decades, there has been an increase in the number of people with asthma and other allergic diseases. The precise cause for this increase in asthma is not known but it has coincided with changes to the quality of indoor air with increase in the levels of allergens and pollutants.

The energy efficient houses of today with high indoor temperatures and humidity may, by a number of mechanisms, increase exposure to likely allergens. In addition to allergens, the indoor environment contains other biological materials and pollutants, which can adversely affect asthma control and symptoms. Maintaining high air quality with lower levels of allergens and pollutants could improve the health of individuals with asthma. Therefore, a feasible

and practical intervention that can reduce allergen and pollutant levels in the indoor air might reduce asthma symptoms and improve control.

The purpose of this study is to determine the effect of using a Dyson Air Purifier to reduce or remove indoor allergens and pollutants from the home on asthma control and the twitchiness of the airways (bronchial hyper responsiveness) in people with symptomatic asthma.

Why am I being invited?
You are being invited to take part because we believe you may meet the inclusion criteria:

- Patients aged between 18 and 75 with a confirmed diagnosis of asthma.
- Asthma that is not fully controlled.

You will not be able to take part if you meet any of the following exclusion criteria:

- Patients with other significant chronic respiratory disease such as COPD or bronchiectasis.
- Patients with any other severe disease (such as cardiovascular disease, dementia etc.), where adherence to the study protocol may cause an unjustified stress.
- Those who are being treated with allergen specific immunotherapy.
- Patients with a history of significant alcohol or drug abuse.
- Patients who are taking an investigational drug for asthma.
- Patients who are unwilling, unlikely or unable to comply with the study protocol.
- Patients who are likely to be started on biological asthma therapy during the study period.
- Pregnancy.
- Patients already using air purifiers in their dwellings.
- Patients without a WIFI connection in their dwelling.
- Patients planning to move house within the study period.

What will happen to me if I take part?
We will ask you to attend a clinic at The Allergy Centre 4 times over twelve months where you will answer a few short questionnaires, have an allergy skin test to common allergens (House Dust Mite, Grass Pollen, Tree Pollen, Cat, Dog, Hamster, Poultry Feathers and moulds), a blood sample and perform lung function tests.

Part of the lung function testing involves breathing in a substance called Methacholine, which can cause asthma type changes to your lung function so that the twitchiness of your airways can be measured. However this change only lasts for a very short while and will be reversed by the administration of the blue asthma inhaler (salbutamol). The breathing test is safe and will be carried out by a registered trained nurse with the additional presence of a doctor in the building. Female participants will be asked to provide a sample of urine to exclude pregnancy prior to performing the Methacholine challenge, please see Section Three of this information sheet (not applicable if post-menopausal).

You will also be asked to breathe into a small machine and a reading will appear on the screen to measure a substance called nitric oxide in the air you breathe out. This will tell us how inflamed the airways in your lungs are and therefore how well controlled your asthma is.

In addition to visiting The Allergy Centre, we would like to visit you at home to install 2 Dyson Air Purifiers (one in your bedroom and one in the lounge) and also to change the filters during the trial. At home visits, we would like to collect four small samples of dust from your home, two samples from each room with a Dyson Purifier.

We will contact you periodically to complete additional short questionnaires. For a two weeks period, before each visit to The Allergy Centre and before each telephone questionnaire completion, we would like you to keep a symptom and peak flow diary. This will all be explained to you by the nurse at the first visit.

What are the possible disadvantages and risks of taking part?

- Skin prick testing may cause temporary discomfort, however in most cases, this is considered to be minimal.
- Rarely, you may experience temporary light-headedness or dizziness after being given salbutamol. In most cases, when this is experienced, it passes quickly.
- With the Methacholine test, you may develop some tightness in your chest, cough or become wheezy: this will resolve very rapidly with salbutamol. Rarely a Methacholine test can cause headaches, throat irritation, or light headedness. We will observe you and give the right treatment until the symptoms are completely resolved.
- Blood sampling may cause some pain. If you request, a small amount of local anaesthetic cream will be applied to your skin to minimise any discomfort. Your body will replace the small amount of blood (20 ml) in a very short time.

What are the possible benefits of taking part?

Your participation in this study will allow us to assess whether asthma control and therefore quality of life are affected by using an air purifier. If the study shows an improvement it could be a cost effective non-medical intervention for some people with asthma.

What makes this study "Randomised"?

You will be randomly assigned to one of two groups of participants; Group A will receive two purifiers with "active" filters installed, Group B will receive two purifiers with "placebo" (or inactive) filters installed. After the first six months the filters in all of the purifiers will be changed for "active" filters. You and the study team will not know which group you have been assigned to.

How big are the purifiers and how much will they cost to run?

The purifiers are 1054mm high, 206mm wide and 117mm deep. The official power consumption figure for each purifier is 40W, this is calculated on a purifier running at full power. We would like participants to use the purifiers in "auto" mode which means they will turn on and off according to the allergen/pollutant level in the air. The manufacturer has monitored UK based purifiers and found that the average monthly consumption for purifiers running in "auto" mode is 5.04kWh. It is therefore estimated that the average running cost is less than £9 per year for each purifier.

How does the manufacturer monitor the purifiers?

The purifiers will be connected to your home internet through WIFI, the purifier will securely send information to the manufacturer about how long it has been running, what mode is running and how the sensors and filters are performing. It will not be possible to identify you from this information.

Do I have to take part?

You do not have to take part. It is entirely up to you to decide. If you do decide to participate, you will be given this information sheet to keep and asked to sign a consent form. You will receive a copy of the signed consent form. You are free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your medical care.

What will happen to the data I provide?

The Isle of Wight NHS Trust is the sponsor for this study based in England. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Isle of Wight NHS Trust will keep identifiable information about you for 15 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at https://www.hra.nhs.uk/information-about-patients/ or http://www.iow.nhs.uk/about-us/Freedom-of-information/data-protection.htm.

The David Hide Asthma and Allergy Centre will collect information from you and/or your medical records for this research study in accordance with our instructions.

The David Hide Asthma and Allergy Research Centre will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the Isle of Wight NHS Trust and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The David Hide Asthma and Allergy Research Centre will pass these details to the Isle of Wight NHS Trust along with the information collected from you and/or your medical records. The only people in the Isle of Wight NHS Trust who will have access to information that identifies you will be people who need to contact you to monitor or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

The David Hide Asthma and Allergy Research Centre will keep identifiable information about you from this study for 15 years after the study has finished.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

What will happen to the samples I provide?

The samples that we collect will be stored in our Ultra-Low Temperature Scientific Freezers at the David Hide Asthma and Allergy Research Centre; the freezers are in a locked room accessible only by approved staff. We will remove personal details from the samples and label them with a coded study number before they are stored.

We plan to perform the following analyses on the samples that you provide:

Dust: We will look at allergens and pollutant particles to study whether the installation of air purifier reduces the amount of these substances in the settled dust.

Blood Samples. We will analyse these samples at a later date to see if reduction in allergens and pollutants in your environment and thus breathing a cleaner air has an effect on how your immune system responds to these allergens and chemicals.

Who will analyse the data and samples?

To analyse the samples and data we will work in collaboration with researchers at the University of Southampton. Our collaborators will only receive anonymous samples and extracts of data that do not contain sufficient information to identify you. Only the staff at the Allergy Centre will have access to the information needed to link data or samples to you. We keep this to ensure that the study is run in a safe and consistent manner and it is never shared with anybody outside of the Isle of Wight NHS Trust.

Will there be a change to my ongoing asthma care or management during or after the study?

No, your normal asthma care/management will continue during and after the study, you should continue to visit your GP, Asthma Nurse or the Allergy Centre as normal. At the end of the study we will contact you to organise what you should do with the purifiers.

Further Information and Contact Details

If you have any questions or concerns about this research study, please speak to a member of the study who will be able to help you, their contact details (during office hours) are:

Maria Larsson:	Telephone: 01983 552147
	Email: maria.larsson@iow.nhs.uk
Prof Hasan Arshad:	Telephone: 023 8120 5232
	Email: sha@soton.ac.uk

You can also contact the Study Team at The David Hide Asthma and Allergy Research Centre, during office hours on 01983 534113 or iowstudy@iow.nhs.uk.

If you would like some independent advice about whether you should take part, or you would like to discuss this study with somebody outside of the research team, or you would just like some more information about medical research, please contact the Isle of Wight NHS Trust Research and Development Team on 01983 532354 or the Patient Advice and Liaison Service at St Mary's Hospital on 01983 534850 or email PALS@iow.nhs.uk.

You may also find the following internet resource useful:

- http://www.invo.org.uk/ - INVOLVE is a *National advisory group that supports greater public involvement in NHS, public health and social care research*

If you are unhappy about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (see contacts for further information above). If you still have questions or concerns, you can contact the Research and Development Department, St Mary's Hospital, Newport, Isle of Wight, PO30 5TG.

This completes section 1; section 2 will give you more detailed information about the conduct of the study.

SECTION TWO

What if something goes wrong?

In the very unlikely event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for legal action for compensation against the Isle of Wight NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?

The personal information collected in this study will be kept confidential. The data we collect from you will not be labelled with your personal details and will be stored securely. Data collected during the study may be shared with our research collaborators; however they will not know who the information belongs to as your name and address will only be kept at The David Hide Asthma and Allergy Research Centre. Only the study personnel will have access to your personal details. The sponsor of the study (Isle of Wight NHS Trust) may also wish to access the records as part of their monitoring of ongoing research. You will not be individually identified in any reports or publications resulting from the study. We will keep your data on file for use in future studies approved by the Research Ethics Committee.

Who will have access to my health records?

Senior Investigators and the research team on this project will need to look at your health records to ensure safe conduct of the study procedures.

Involvement of your General Practitioner

We would like your permission to notify your General Practitioner (GP) of your participation in this study. With your permission we will send your GP the results of your allergy and lung function tests as they may be useful for your future medical care.

What will happen to the results of the research study?

We aim to publish the results of the study in medical journals so that other doctors and researchers can make use of them. This is likely to be accompanied by an article in the press. It will not be possible to identify any individuals involved in this study from these published results. You will be informed of the results of this study.

Who is organising and funding the research?

The researchers at The David Hide Asthma and Allergy Research Centre, Isle of Wight are organising and carrying out this research. The study is being funded by Dyson Technologies Limited.

Will my travel expenses be paid?

We will reimburse you for travel and parking expenses incurred by participating in this study. Please discuss this with a member of the study team.

Who has reviewed the study?

This study has been reviewed and given a favourable opinion by HRA West Midlands – Solihull Research Ethics Committee, reference number 18/WM/0277.

How long do I have to decide whether I should take part?

Your decision to participate in this study is entirely voluntary. You should take as much time as you need.

At the end of this study

The study team will be analysing all of the collected data, and will share and publish their findings as mentioned above. This study will contribute to the better management of asthma and further improve our understanding of Asthma and Allergy. With your consent, we may contact you in the future using the NHS Summary Care Records System in order to let you know of any similar research studies that we think you might be interested in participating in. If you would like more information on this, please speak to the study nurse or doctor.

SECTION THREE (female participants)

Conducting a bronchial challenge test on women who are pregnant

Although there are no known adverse effects of a bronchial challenge test using methacholine on pregnancy, as an additional safety measure, this test will not be performed in pregnant women. Therefore, it is a standard requirement for all female study participants to first undergo a pregnancy test. This will involve a quick test on a small sample of your urine. We understand that at this time you may not be sexually active or that you may be using a reliable birth control measure. If you do not wish to undertake a pregnancy test we can schedule the bronchial challenge to be performed during your period.

Should the pregnancy test be positive you will not be able to enter or continue with the study.

What are the implications of undergoing a pregnancy test?

Before you consent to having a pregnancy test, we would like you to take time to consider the implications of taking the test and the result you may receive. A urine pregnancy test is a screening test only and you may require further testing to confirm your pregnancy.

What support is available in the event of a positive pregnancy test?

Trained staff will be available at the Allergy Centre to discuss, in confidence, the implications of your pregnancy test and direct you to the appropriate sources of further confidential guidance and professional support available through the Sexual Health Service, St Mary's Hospital (Tel: 01983 534202) or your GP. Alternatively The British Pregnancy Advisory Service (BPAS) website www.bpas.org.uk offers valuable information.

This completes Section Three (female participants) of the Information Sheet.

Thank you for taking time to read this information sheet.

Dyson Air Purifier in Asthma – Study Journey

Screening Visit

- Questionnaires
- Asthma Diary
- Skin Prick Test
- Lung Function Tests
- Blood Test
- Physical Examination

2 – 4 Weeks

Home Visit

- Asthma Diary
- Install Purifiers
- Dust Samples

6 Weeks

Telephone Contact

- Questionnaires
- Asthma Diary

6 Weeks

Allergy Centre Visit

- Questionnaires
- Asthma Diary
- Lung Function Tests
- Physical Examination

6 Weeks

Telephone Contact

- Questionnaires
- Asthma Diary

6 Weeks

Allergy Centre & Home Visit

- Questionnaires
- Asthma Diary
- Skin Prick Test
- Lung Function Tests
- Blood Test
- Physical Examination
- Dust Samples
- Change Filters

6 Weeks

Telephone Contact

- Questionnaires
- Asthma Diary

6 Weeks

Allergy Centre & Home Visit

- Questionnaires
- Asthma Diary
- Skin Prick Test
- Lung Function Tests
- Blood Test
- Physical Examination
- Dust Samples
- Return Purifiers