**Participant Information Sheet (MAIN)**

**Version: 2.0 Date: 24th Nov 2016**

**Study Title: Improving asthma treatment using inhaler technology**

**Principal Investigator: Dr Dominick Shaw**

**1. Invitation**

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with friends or family if you wish.

Ask 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.

2. **What is the purpose of the study?**

Although we aim to keep asthma symptoms controlled, lung function at its best and to reduce adverse effects from medicines, these aims are not always achievable. One way to better understand why this happens is by using inhalers that can record information about your asthma.

Our aim is to involve 50 patients, all of whom have had at least one asthma attack in the past year. Each patient will be involved for 6 months and will be asked questions about their asthma. There are only 2 planned visits to the Nottingham Respiratory Research Unit; one at the start and one at the end of the study. During the rest of the 6 months, the study team will keep in touch with you by phone, email or text message. The study is taking place at Nottingham University Hospitals NHS Trust.

3. **Why have I been chosen?**

You have been chosen because you have been diagnosed with asthma, are prescribed a preventer (steroid) inhaler for your asthma, and have had at least one asthma attack in the past year where you have needed tablet steroids (or more than your usual dose if you already take tablet steroids every day). You will also already be using a mobile phone that can connect to the Internet (for example, to check your email or to use Facebook).

4. **Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time and without giving a reason. However if you do withdraw, the information collected so far cannot be erased and the information may be used in the final project analysis as it is valuable for the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive

5. **What will happen to me if I take part?**

If after reading this information sheet and talking to a member of the research team, you would like to take part in this study, you will be seen at Nottingham City Hospital in the Nottingham Research Respiratory Unit and asked to sign a consent form to give us permission to involve you in the study.

This first visit takes about 1 hour and the following will take place:

1. **Information about your asthma:** we will ask you about your asthma history and also look at your medical records from the hospital and your GP (where possible) to get as much information about your asthma as possible
2. **Questionnaires**: you will fill out questionnaires on your current asthma symptoms (every 4 weeks) and your medications
3. **Spirometry**: we will measure the amount of air that you can breathe out. You will be asked to blow as hard as you can into a tube which is connected to a recording device and repeat this several times. We will then give you 4 puffs of salbutamol, wait 15 minutes and ask you to repeat the test. You may have to withhold some of your usual inhalers a few hours before this test, but we will let you know in advance (you may have done this test before at your GP practice).
4. **New inhalers casings provided**: To allow us to collect information about your asthma, you will be provided with new inhaler casings that clip around your current preventer and reliever inhalers. The casings help tell us how well controlled your asthma is. The casings link up to your mobile phone and send this information back to us via the internet. We will show you how to swap over the casings onto your new inhalers that you use during the study.
5. **Inhaler technique** **and asthma action plan:** we will provide you with a written asthma action plan and check your inhaler technique.

Your participation in the study lasts for 6 months. After this first visit, you will complete a questionnaire about your asthma, and the new casings once every month and we will contact you (by text, email or phone) to remind you if needed. Otherwise, you can go about your daily life as usual. We will make an appointment to see you at Nottingham City Hospital at the end of the study. This final visit will take about 1 hour. We will measure your spirometry (as above), find out how your asthma has been over the past 6 months and collect your inhaler casings. We will also discuss how you felt about using the new casings.

You may also be asked at the end of the study if you would like to take part in an interview with one of our research team, where you will be asked about your experience in the trial. This conversation will be audio recorded so the research team can concentrate on what you are saying without having to take notes. Interviews will then be transcribed anonymously. Anonymised quotes from these transcriptions may be used publications generated from this study.

We will give you contact details for our research team in case you have any questions over the 6 months.

6. **What do I have to do?**

You should carry on as normal; this study should not affect your lifestyle and you should continue to take your normal medication as per usual.

The day-to-day care of your asthma with remain in the hands of your General Practitioner (GP). If during the study you have an asthma attack, you should go to see your GP, or go to an out-of-hours clinic/call 111 or the hospital emergency department (ED) and seek medical care - you will receive the same care and treatment as you would do if you were not involved in the study. Your asthma action plan will also provide you with guidance as to when to seek help or start a course of tablet steroids for your asthma

7. **What is the drug / treatment that is being tested?**

We are not testing any drugs in this study – you will continue to use your usual current inhaled preventer and reliever asthma treatments.

8. **What are the alternatives for diagnosis or treatment?**

If you choose not to take part in the study, your care will not be affected and you will continue to be treated as per usual.

9. **What are other possible disadvantages and risks of taking part?**

Performing spirometry can make you feel light-headed and short of breath, but the test is generally very safe.

If you do decide to take part in the study, you must report any problems you have to your study nurse or doctor. There is also a contact number given at the end of this information sheet for you to phone if you become worried at any time. In the unlikely event of an emergency occurring during the conduct of the study, we may contact your nominated next of kin.

If you notice any problems with the inhaler casings or if any become lost, we will give you contact details for our team so that we can repair/replace them.

**10. What are the possible benefits of taking part?**

We cannot promise the study will help you, but it is hoped that we will be able to learn about asthma attacks and medication use. This will allow us to better understand and plan future care for people with asthma.

**11. What happens when the research study stops?**

We will review your progress in the 6 months of the study with you at your final study visit. We intend to publish the results in a scientific respiratory journal. A summary of the results will be available to you should you wish. The device is for research purposes only at present and will therefore not be available to you after the study has finished.

**12.** **What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital or you can contact PALS (Patient Advice and Liaison Service) telephone 0800 183 0204.

In the 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 a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

**13. Will travel expenses and phone data charges be reimbursed?**

Yes, mileage/travel allowance will be available. You will also receive an allowance for phone data charges (maximum £20 allowance overall for 6 months).

**14. What if new information becomes available?**

Sometimes during the course of a clinical trial, new information becomes available. If this

happens, we will tell you about it and discuss with you whether you want to or should continue in the study. If you decide to withdraw, we will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

On receiving new information, we might consider it to be in your best interests to withdraw you from the study. If so, we will explain the reasons and arrange for your care to continue.

**If the study is stopped for any other reason, you will be told why and your continuing care will be arranged.**

**15.** **What will happen if I don’t want to carry on with the study?**

You can withdraw from the study at any time but we will use the data collected up to your withdrawal. We will also need to collect the inhaler casings that we have provided you.

**16. Will my part in this study be kept confidential?**

If you consent to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely on paper and electronically at your treating hospital and at Nottingham University Hospitals NHS Trust under the provisions of the 1998 Data Protection Act. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be allocated a trial number, which will be used as a code to identify you on all trial forms.

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by the Research Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly. A copy of your consent form may be sent to the Research Sponsor during the course of the study. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

***The information collected about you may also be shown to authorised people from the UK Regulatory Authority and Independent Ethics Committee; this is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant.***

If you withdraw consent from further study treatment, your data will remain on file and will be included in the final study analysis.

In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 15 years. Arrangements for confidential destruction will then be made.

With your permission on the Consent form, your GP (and other doctors who may be treating you) will be notified that you are taking part in this study.

Data collected during the study may be transferred for the purpose of processing, analysis, to associated researchers within or outside the European Economic Area. Some countries outside Europe may not have laws which protect your privacy to the same extent as the Data Protection Act in the UK or European Law. The Sponsor of the trial will take all reasonable steps to protect your privacy.

Your asthma control data will be stored on a password-protected website. The website will not contain any identifiable information about you and will use a code that is only known to researchers.

If you are willing to participate in the final interview, anonymous quotes taken from this interview may be published. Neither the transcriptions of this interview nor any of these quotes will contain any identifiable information about you.

**17. Informing your General Practitioner (GP)**

With your permission on the Consent Form, your GP (and other doctors who may be treating you) will be notified that you are taking part in this study. Your GP (and other doctors who may be treating you) will also be provided information on your progress at the end of the study.

If you take a course of steroids for your asthma, either in tablet or liquid form or into your veins in hospital, then we would like you to make a note of the date this treatment started together with how many days you were treated for; you will be asked about this at each study vists This is so that we can keep a record of when your asthma has been troublesome. We will ask for your permission on the Consent Form to obtain further information about your health from the hospital or GP records. To make sure that we have all the information we need about the attack, we will need to contact the health service provider involved to check the medical details.

**18. What will happen to any samples I give?**

We are not taking any samples.

**19. Will any Genetic testing be done?**

No.

**20.** **What will happen to the results of this clinical trial?**

The results of the study will be available after it finishes and will usually be published in a medical journal or be presented at a scientific conference. The data will be anonymous and none of the patients involved in the trial will be identified in any report or publication.

Should you wish to see the results, or the publication, please ask your study doctor.

**21.** **Who is organising and funding this clinical trial?**

The Nottingham University Hospitals NHS Trust will act a sponsor the research. GlaxoSmithKline has provided funding for the study.

**22.** **Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the NHS by London Central Research Ethics Committee.

The study has also been reviewed and approved by the Research & Innovation department of Nottingham University Hospitals NHS Trust.

**23. Contact for further information**

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the intervention involved. If you wish to read the research on which this study is based, please ask your study nurse or doctor. If you require any further information or have any concerns while taking part in the study please contact one of the following people: at the end of this information sheet.

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

**24**. **Contact Details**

**Doctor**

Name Dr Ireti Adejumo

Tel. Number: 0115 82 31935

**Research/Specialist Nurse**

Name Mrs Norma Thompson

Tel. Number: 0115 82 31315

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