Participant Information Sheet for 16 -17 Year Olds

Prescription Alerts for Reliever Inhalers in Children (PARC) Project

Lead Researcher: Dr Anna Selby

Ethics/IRAS number: 332076

You are being invited to take part in the above research project. To help you decide whether you would like to take part, it is important that you understand why the project is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information. You may like to discuss it with others, but it is up to you to decide whether you take part or not. If you are happy to take part, you will be asked to sign a consent form.

What is the project about?

Asthma is very common in children and young people. It is a long-term lung condition which causes wheezing and breathlessness. Severe asthma/wheeze attacks may need hospital treatment and can be life-threatening. Two types of inhalers are typically used to treat asthma/wheeze: Relievers (usually blue) and preventers (usually taken in the morning and evening).

Children and young people who need to use a blue reliever inhaler more than 2-3 times per week are more likely to have severe asthma/wheeze attacks. It has been recommended that children and young people prescribed high numbers of blue reliever inhalers in the past 12 months should have a check-up.

We are aiming to find out whether an enhanced nurse-led check-up will reduce the number of asthma/wheeze attacks experience by young people using too many blue reliever inhalers.

In this project, general practices across Hampshire, the Isle of Wight and Thames Valley region will be randomly divided into two groups:

1. Practices offering enhanced asthma/wheeze check-ups to children and young people prescribed 7 or more blue reliever inhalers in the past year (intervention practices).
2. Practices providing usual care (control practices).

After one year, we will compare the number of severe asthma/wheeze attacks in children and young people from intervention and control practices. At the end of the project, children and young people from control practices (who have used 7 or more blue reliever inhalers in a year) will be offered an enhanced asthma/wheeze check-up. This will be exactly the same as the one offered to children and young people from intervention practices. If you take part in the project, you will not be told which group your practice is in.

Why have I been asked to take part?

You have been asked to take part because you have been prescribed 7 or more blue reliever inhalers in a year. This means that you may be at high risk of having an asthma/wheeze attack because you may have poorly controlled asthma. You may therefore benefit from a check-up.

What will happen to me if I take part?

If you decide you would like to take part in this project, you will be invited for an enhanced asthma check-up by a specially trained nurse. This will happen at a local clinic or virtually (if you cannot travel to an appointment elsewhere). The check-up will last about 30 minutes. At the check-up, you will be asked questions about your asthma including:

- What triggers your symptoms and how often they get them.
- Previous asthma attacks.
- Your asthma medications.

Your inhaler technique will also be checked, and your asthma action plan will be reviewed. We will also make sure that you are happy that you know what asthma is, how it affects the lungs, how it is treated and how different inhalers work. Changes may be made to your asthma treatment to improve your asthma control. Any changes made will follow existing asthma treatment guidelines and your GP will be made aware. Approximately 4 weeks after your check-up, you will be contacted to find out how you are getting on.

You may also be invited to take part an interview a few weeks later to ask how you found the check-up. This is entirely optional and you can still take part in the rest of the project if you choose not to have an interview.

How will I benefit?

Taking part in this project may improve your asthma control and reduce your chance of having asthma attacks in the future. It may also improve your quality of life as asthma can affect people's sleep and ability to take part in activities e.g. sport. Your participation will also help to improve our understanding of how to manage asthma in children and young people and therefore, may benefit others. If you attend a check-up, you will be given a £5 voucher to thank you for your participation.

Are there any risks involved ?

There are minimal risks associated with taking part in this project. The check-up is similar to a standard annual asthma check-up but will be longer and more detailed. No new medications are being tested and we are not doing any tests.

What data will be collected?

With your permission, we would like to collect information from your GP +/- hospital records. This will include information about your asthma treatment, any asthma attacks you have had, and any hospital care you have received for your asthma.

Personal data including your gender and ethnicity will also be collected. This information will help to ensure that we involve a wide range of people in the project. Project data (information collected during your asthma check-up and from your medical records) and personal data (e.g. your name and date of birth) will be stored on separate parts of a database and will be linked by a participant identification number. Only relevant people from the project team will have access to the databases.

Will my participation be confidential?

Your participation and the information we collect about you will be kept strictly confidential. Your GP will be informed of your participation and the outcome of your asthma check-up. This is important because your GP is responsible for your ongoing care.

We follow strict regulations about how health research is carried out. Sometimes, individuals from regulatory authorities may require access to the information we collect about you to check we are carrying out the project correctly. These people have a duty to keep information about you strictly confidential.

Do I have to take part and what happens if I change my mind?

It is entirely up to you whether you take part or not. If you would like to take part, you will need to sign a consent form to show you have agreed to this. You have the right to change your mind and withdraw from the project at any time without giving a reason. This will not affect your rights as a participant or your usual clinical care. If you would like to withdraw, please contact a member of the project team.

What will happen to the results of the research?

The results of the project will be written up as a report for the National Institute of Health Research (NIHR), who are funding the project. They may also be published in scientific journals and presented at research conferences. No information that could directly identify you will be included in reports.

Will I be asked to participate in further research?

We may invite you to take part in an interview with a researcher about your involvement in the project and your asthma check-up. If you are invited for an interview, we will provide you with another participant information sheet and consent form. Taking part in an interview is optional.

Who is organising and funding the project?

The project is funded by the NIHR Patient Benefit programme. University Hospitals Southampton NHS Foundation Trust (UHS) is the project sponsor.

Who has reviewed the project?

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

This project has been reviewed and given a favourable opinion by the West of Scotland Research Ethics Service. The reference number is 24/WS/0004 (IRAS 332076).

What happens if there is a problem?

If you have a concern about any aspect of this project, you should contact a member of the project team who will do their best to answer your questions (contact details below). If you remain unhappy or have a complaint about any aspect of this project, please contact the Patient Advice Liaison Service (PALS) at UHS.

UHS has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in the project. NHS indemnity operates in respect of the clinical treatment provided.

Contact Details

If you have any questions about this project or would like more information, please contact a member of the research team (led by Dr Anna Selby and Professor Graham Roberts).

Email: parc@soton.ac.uk

Phone: *TBC*

Thank you for reading this information sheet.

Data Protection Privacy Notice

How will the research team use information about me?

We will need to use information that you and your GP have given us about you for this research project. This information will include your name, age, gender, ethnicity and contact details.

This information will be held securely at the University Hospitals Southampton NHS Foundation Trust (UHS)/University of Southampton. It will be used 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 project ID number. We will keep all information about you safe and secure. Once we have finished the project, 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 project.

Where can I find out more about how my information will be used?

You can find out more about how we will use your information:

- At www.hra.nhs.uk/information-about-patients/ and www.hra.nhs.uk/patientdataandresearch
- By contacting the research team (details above)
- By contacting UHS's Data Protection Officer (dataprotection@uhs.nhs.uk)

What are my choices about how my information is used?

You can stop being part of the project at any time, without giving a reason. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

For the purposes of data protection law, the University Hospitals Southampton NHS Foundation Trust (UHS) is the 'Data Controller' for this project, which means that UHS is responsible for looking after your information and using it properly. UHS will keep identifiable information about you for up to 15 years after the project has finished. After this, any link between you and your information will be removed. To safeguard your rights, we will use the minimum personal data necessary to achieve our research project objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. UHS will not do anything with your personal data that you would not reasonably expect.