

Empowering teenagers to self manage their asthma

PARTICIPANT INFORMATION SHEET (teenagers)

You are being invited to take part in a research study. Before you decide whether to take part it is important that you understand why the research is being done and what it will involve. Please take time to read this information carefully and discuss it with others if you wish.

- **Part 1** tells you the purpose of this study and what will happen to you if you take part.
- **Part 2** gives you more detailed information about how the study will run.

Please take time to read the following information and discuss it with your friends, family or GP if you wish. If anything is not clear and you require more information before you decide whether or not to take part in the study, please contact the a member of the study team (details at end of information sheet)

PART ONE

What is the purpose?

The purpose of this study is to find out what you think about the way your asthma is treated and how you feel your asthma could be treated better.

Asthma is one of the most common long-term health conditions affecting teenagers. Our previous research has shown that healthcare professionals (such as doctors and nurses) are not very good at communicating with people in your age group. This can lead to poorly controlled asthma. We would like to develop a better way of working with teenagers, based upon the real experiences of young people like you, to help us manage asthma more effectively in this age group. By using this approach, we hope to manage asthma more effectively in your age group and help teenagers to achieve better asthma control.

Why have I been invited?

You have been chosen because you have asthma and are aged between 12-17 years.

Do I have to take part?

No, it is entirely up to you and your parents as to whether you take part in this research. If you do decide to take part, you will be given a copy of this information sheet to keep and you and your parent will be asked to sign a consent form. You are free to withdraw from the study at any time and without having to give a reason.

What will happen if I take part?

You will be invited to take part in either two focus groups or two one-to-one interviews.

What will I have to do?

We will ask you and your parent to complete a short questionnaire to give us some background information about your asthma, any other illnesses and family.

Focus groups will be arranged with older participants (15-17 year olds). A focus group involves a group of people having a discussion about a particular topic. These groups will consist of up to 8 people and will be supervised by a researcher.

One-to-one interviews will be arranged for younger participants (12-14 years). Interviews will be conducted by a researcher who will talk to younger participants on their own.

Older participants will also have the option to have a one-to-one interview while younger ones can choose to join a focus group if they would prefer. The researcher will discuss with you and your parents the best option for you. Focus groups and interviews will be audio-taped and then typed up. We may use exact quotes (of something you have said during the interview or focus group) to present this information in reports. However this information will be completely anonymised (i.e. no-one will be able to tell that it was you who said this).

The information obtained will help us identify what works and what doesn't work when it comes to supporting you to manage your asthma. This will help us develop a better way of working with teenagers with asthma.

About three to six months later, you will be invited to a second focus group or interview. During this second visit, we will ask for your views on the new approach developed from the information obtained from the first focus groups and interviews. Your views will then be used to further improve the new approach.

What are the benefits of taking part?

You will have the opportunity to discuss views about how you would like your asthma to be managed. These views will guide the development of a teenage asthma approach designed to empower those in your age group to better self-manage their asthma.

Reasonable travel and parking expenses will be reimbursed to you and/or your parents where appropriate.

What are the possible disadvantages and risks of taking part?

It is important that all participants are able to be open and honest. In the unlikely event that you disclose information that suggests you may be at risk of harm, the researcher may need to discuss this with someone from your healthcare team (such as your asthma doctor or nurse). The researcher will try to ensure that participants in each focus group respect each other's confidentiality however the researcher cannot guarantee confidentiality between group members.

This completes Part 1 of the Information Sheet. Part 2 will give you more detailed information about the conduct of the study.

PART 2

Will my taking part in the study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. This means we will only tell those who have a need or right to know. Personal details (e.g. name) will be kept securely and separately from all other research data and accessed by the research team only. You will be allocated a code name/number on all other documentation so that at no time will any of your personal details be revealed. The procedure for handling, processing, storage and destruction of any data collected during the study are compliant with the Data Protection Act 1998 and in line with the University Hospital Southampton's NHS Foundation Trust Policy.

Any individual experiences or quotes used subsequently in reports of the study will not be attributed to the source.

Audiotapes, from which your voice could potentially be recognised, will be destroyed at the end of the study as per University of Southampton guidelines.

Who will have access to my health records?

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

Involvement of the General Practitioner

We would like your permission to notify your General Practitioner (GP) of your participation in this study.

What will happen to the results of the research study?

The results will be used to develop an approach for the management of teenagers with asthma.

The approach developed will be presented in a clinical study report, which may be used for publication and presentation at scientific meetings. You will not be identifiable in any publications arising from this project.

Who is organising and funding the research?

The study is being funded by Asthma UK and is sponsored by University Hospital Southampton NHS Foundation Trust.

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 questions (see contacts for further information below). If you still have questions or concerns, you can contact Research and Development, University Hospital Southampton NHS Foundation Trust (telephone number 02381 208215). 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 University Hospital Southampton NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints procedure will still be available to you.

Who has reviewed the study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. This study was given a favourable ethical opinion for conduct in the NHS by NRES Committee East of England- Cambridge Central.

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

Your decision to take part in this study is entirely your choice. You should take as much time as you need to decide whether to take part.

Contact for further information

Further information can be obtained from:

Research psychologist: Dr Simone Holley, Clinical & Experimental Sciences, University of Southampton, Faculty of Medicine, Southampton General Hospital. Telephone: 0238120 5227
s.l.holley@soton.ac.uk

Research nurse: Ruth Morris, Children's Asthma Research Nurse, NIHR Wellcome Trust Clinical Research Facility, 02381 204989, ruth.morris2@uhs.nhs.uk.

Chief Investigator: Prof Graham Roberts, Professor & Consultant, Paediatric Allergy and Respiratory Medicine, Clinical & Experimental Sciences & Human Development in Health, University of Southampton Faculty of Medicine & University Hospital Southampton NHS Foundation Trust. Telephone: 02381 206160.

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