SPIROmetry to Manage Asthma in Children

Invitation to take part

We would like to invite your child to take part in a study called SPIROMAC. The SPIROMAC study will see if a breathing test called spirometry every three months can help prevent asthma attacks. Take your time to decide whether or not you would like your child to take part.

Before you decide, it is important for you and your child to understand why the research is being done and what it will involve. The first part of the Participant Information Leaflet tells you the purpose of the study and what will happen to you if your child takes part. Then, in the second part we will give you more detailed information about how the study is run.

Please take time to read this information leaflet and to talk with family and friends if you want. Ask us if there is anything that is not clear or if you would like to know more.

Thank you for reading this.

Asthma in children

Asthma affects 1.1 million children in the UK. An asthma attack happens when asthma symptoms get much worse. Every 20 seconds a child is admitted to hospital in the UK due to an asthma attack. These attacks are frightening for the child and their family.

The regular asthma *preventer treatment* received by children with asthma reduces the chances of them having an asthma attack. Asthma preventer treatments include inhalers and tablets. Children with asthma usually also have a blue *reliever inhaler* which they use when they need to quickly relieve asthma symptoms.

What is the purpose of the SPIROMAC research study?

Usually at an asthma check-up the doctor or nurse asks how your child's asthma has been, about any coughing or wheezing, and how often they need their blue reliever inhaler. The doctor or nurse uses this information to help decide whether the asthma preventer treatment that your child takes should stay the same or be changed. We are doing the SPIROMAC study to see whether asthma teams should also use a breathing test called spirometry to help guide children's asthma preventer treatment.

Your child might already have done spirometry at an asthma check-up. The test is done by blowing hard into a machine. At the moment doctors and nurses don't know how best to use the results from spirometry when deciding whether asthma preventer treatment should stay the same or be changed.

In SPIROMAC the children who take part will be placed into one of two groups.

- One group will have their asthma preventer treatment decisions based on how their asthma is (their asthma cough, wheeze and breathlessness, and how often they use their asthma preventer and reliever inhalers); this is how asthma is usually managed in the UK.

- One group will have their asthma preventer treatment guided by both spirometry and how their asthma is (their asthma cough, wheeze and breathlessness, and how often they use their asthma preventer and reliever inhalers).

We will collect information about any asthma attacks from all the children who take part. We will then compare whether one group has fewer asthma attacks than the other group.

To do this study properly we need 550 children aged 6-15 years with asthma from up and down the UK.

What would taking part involve?

If your child takes part in the study, we would like you and your child to come to an appointment every three months for a year.

These appointments will be at your local hospital. These visits will replace the usual asthma clinic appointments your child has with your hospital asthma doctor or nurse. Your hospital asthma team will still be available to speak to you if you want.

The first visit will last up to 60 minutes. During this time, the research team will talk to you about the study and answer any questions that you or your child have. If you do decide to take part, we will ask you to sign a consent form. Your child can give their permission to take part either by signing a form or telling the research team during the visit that they are happy to take part.

We will ask questions about your child's asthma, including recent cough, wheeze and need for blue inhaler. We will also measure their height and weight. We will ask your child to do spirometry. We will also ask you and your child to complete a questionnaire about how asthma affects your child's quality of life.

We would also like to measure the amount of a gas called nitric oxide, or FeNO, that your child breaths out. Everyone breathes out nitric oxide, but people with asthma have more nitric oxide in their breath than people without asthma. We will measure your child's nitric oxide levels by asking them to breathe out slowly into a small machine for six to ten seconds. You can also see a video of these tests on the SPIROMAC website www.spiromac.co.uk.

At the end of your first visit, your child will be randomly placed in a group. Either they will be in

- the group where asthma preventer treatment is guided only by asthma symptoms
  OR
- the group where asthma preventer treatment is guided by both asthma symptoms and spirometry.

We put the children taking part in SPIROMAC into a group so that when the study is finished, we can compare how many children have had asthma attacks in each group.

While your child is taking part in the study, you won't know which group they are in, but we will tell you when the study is finished.

Regardless of which group your child is in, their asthma treatment may stay the same or be changed slightly. The treatment will be guided by what we call a treatment algorithm. This is a computer program: the asthma team will enter information about your child's asthma into the computer program and this makes a recommendation about what asthma treatment they should take. The asthma team can decide to follow this recommendation, or they can make their own recommendation as to what asthma treatment your child should take. Regardless, there will be no big changes to your child's asthma treatment. These types of treatment algorithms are used widely across the NHS for all different kinds of treatment.

If the asthma treatment is going to be changed this will be done in the same way as normally done in the asthma clinic. For example the research team will either give you a prescription to go to the hospital pharmacy to collect the new treatment, or we will write to your child's GP to ask them to write a prescription for the new treatment so that you can collect this from your local pharmacy.

After the first visit, we will write to your child's GP to let them know that your child is taking part in the study. We will also

inform them about the visit, including any changes to treatment.

We will give you a diary to make a note of any asthma attacks your child has between visits. We will check your child's inhaler technique and review their asthma action plan (or give them one if they do not have one already).

We will also put a "logging device" (or smart inhaler) on your child's preventer inhaler which records when their asthma inhaler is taken. We can download the information from the device which allows us to see whether any asthma symptoms might be due to forgetting to take the inhaler. Here are some photos of inhalers with their logging devices in place. They will not have a logging device on their "reliever" inhaler.

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SmartDiskTM ©Adherium (NZ) Ltd 2013

The second, third and fourth visits will last for 30-60 minutes and will take place about three, six and nine months after the first visit. We will ask you to fill in a questionnaire about your child's recent asthma symptoms, and ask you about any attacks since the last visit. We will ask your child to do

spirometry and measure their height. We will download the information on your child's inhaler logging device. We will also measure exhaled nitric oxide (like at the first visit).

At the end of the visit, your child's asthma treatment may stay the same or may change. If the asthma treatment is going to be changed, the research team will either give you a prescription to go to the hospital pharmacy to collect the new treatment, or we will write to your child's GP to ask them to write a prescription for the new treatment so that you can collect this from your local pharmacy.

After each visit, we will write to your child's GP with details of the visit, including any changes to treatment.

The last visit will last for up to 60 minutes and will take place about twelve months after the first visit. This will be like the second, third and fourth visits. We will ask you to fill in a questionnaire about your child's recent cough, wheeze and need for their blue inhaler, and ask you about any attacks since the last visit. We will ask your child to do spirometry and measure their height. We will download the information on your child's inhaler logging device. We will also measure exhaled nitric oxide (like at the first visit). We will also ask you and your child to complete a questionnaire about how asthma affects your child's quality of life.

At the end of the visit, your child's asthma treatment may stay the same or may change. If the asthma treatment is going to be changed, the research team will either give you a prescription to go to the hospital pharmacy to collect the new treatment, or we will write to your child's GP to ask them to

write a prescription for the new treatment so that you can collect this from your local pharmacy.

After the last visit, we will write to your child's GP with details of the visit, including any changes to treatment.

Your child's hospital asthma doctor will see your child in clinic three to six months after the last study visit.

If your child is not able to attend a follow-up visit, we will send you a copy of the questionnaire to fill in at home. If your child is not able to attend the last visit we will ask their GP if they have had any asthma attacks since the last visit.

There are no blood tests at all.

The table below summarises what would happen at each appointment.

	First visit	Second, third and fourth visits	Last visit
Spirometry	✓	✓	✓
Nitric oxide	✓	✓	✓
Questionnaire about your child's asthma symptoms	✓	✓	✓
Questionnaire about how your child's asthma affects them	✓		✓
Height	✓	✓	✓
Weight	✓		
Inhaler logging device		✓	✓

Collection of spit samples

There is another part to the SPIROMAC study that your child can take part in if they want. But they don't have to if they don't want to. In this part of the study we would collect some spit from your child's mouth. We will ask them to rinse their mouth with water and spit this into a small container. The container will be labelled with a number that will identify your child within the study, but the label will not include their name, date of birth or other personal information. The samples will be moved to Aberdeen and stored securely by the study team. Only the study team will have access to the samples. We plan to look for extra funding to test the spit for genes that are related to asthma and allergies. If we do not manage to get the extra funding to test the spit samples, we will destroy them two years after the end of the SPIROMAC study.

Your child can take part in the main SPIROMAC study without providing a spit sample

What are the possible benefits of taking part in SPIROMAC?

Your child may not benefit personally from taking part. The research team can help update your child's asthma action plan. If your child does not have an asthma action plan, the research team can help develop one.

The results of this study may help children with asthma in the future and will help health services to provide effective care for children with asthma. If you are having problems or are unhappy with your management during the study, you will be

able to contact the local research nurse to discuss alternative treatment.

At the end of the study, we will write and tell you and your child the results of the study.

What are possible disadvantages, risks and side effects when taking part?

We do not think that there are any disadvantages to your child. However, sometimes doing the breathing tests can make children cough.

Travel expenses

We can help with travel expenses to attend the study appointments. Please ask your research nurse for information about how to claim any travel expenses.

Does my child have to take part?

No. It is up to you and your child whether or not your child can take part. Please take as much time as you need to make this decision. You can read this information leaflet as many times as you wish and ask your doctor and/or research nurse as many questions as you like.

If you decide to take part, you or your child can decide to withdraw from the study at any time and without giving a reason. This decision will not affect the standard of care you or your child receives now or in the future. If you make this decision, your child should continue attending appointments with the asthma team and/or GP as part of their routine care.

If you decide to withdraw from this research study, we will keep and use all the data (information) we have previously collected about your child. We will not collect any further information about your child. This information will remain confidential and will not be used for any other purpose. To protect your child's identity, we will use the minimum personally identifiable information possible.

What happens when the research study stops?

If the study is stopped earlier than expected for any reason, we will tell you and arrange continuing care for your child.

What if relevant new information becomes available?

Sometimes during the course of a research project, new information becomes available. If new relevant information about spirometry in children becomes available, we will contact you to let you know about the choices available to your child. However, we are not aware that any new, relevant information is likely to become available before the end of this study.

What if there is a problem?

If you have a question or concern about the study, you can ask to speak with the research team who will do their best to answer your questions. Contact details for your local study nurse and the Study Office can be found on the last page of this information sheet. If you wish to complain formally or have any concerns about any aspects of the way you have been approached or treated during this study, you can do this through the normal NHS Complaints Procedure. Details can be obtained from your hospital.

We do not expect any harm to come to your child by taking part in this study. In the event that something does go wrong, and you believe that your child is harmed by taking part in this study, you have the right to pursue a complaint and seek compensation through the research sponsors of this study, the University of Aberdeen and NHS Grampian, researchgovernance@abdn.ac.uk.

If your child is harmed due to someone's negligence, then as a patient of the NHS, they may have grounds for legal action. You may have to pay for your legal costs yourself.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information which is collected about your child for the purpose of this research study will be handled in strict confidence and securely stored by the University of Aberdeen.

Who will have access to my child's information if they take part in the study?

The local research team at the hospital or GP practice where your child was recruited to the study will have access to their information. The research team will use your name and contact details and your child's name to contact you about the study. The research team will use your child's name to make sure that relevant information about the study is recorded for their care, and to oversee the quality of the study.

The study team, who are based in the Centre for Healthcare Randomised Trials (CHaRT) at the University of Aberdeen, will have access to your name and address and your child's information. This will allow us to contact you about the study,

for example to send you the questionnaires, and for quality control purposes, such as auditing the data collection process. All electronic data collected for the purpose of the research study will be confidentially and securely stored on computer servers maintained by the University of Aberdeen. The local research team will pass information collected from you and your child and your child's medical records to the study team.

The statistical analyses of the study are being conducted at the University of Aberdeen. To maintain confidentiality, the statistics team will only analyse results which do not include name or addresses. The people doing the analysis will not be able to identify your child.

Your child's GP - we will tell your child's GP that your child is taking part in the SPIROMAC study. Occasionally, we might ask your child's GP for information about any asthma attacks that they have had while they are taking part in the study. The reason for this is to make sure that we have the correct information about all the children taking part in this study and ensure that the results are as accurate as possible.

Other individuals from the University of Aberdeen, NHS Grampian, and the Research and Development Department of your local NHS Organisation may look at your child's medical records and the data collected for the study. They would do this is to check that the study is being carried out correctly and to check the accuracy of the research study. All will have a duty of confidentiality to your child as a research participant. This means that they have been trained in the importance of confidentiality and will not share any of the information they see.

Other researchers may wish to access anonymous data from this study for future ethically approved research. If this is the case, they would be expected to follow legal, data protection and ethical guidelines. It will not be possible to identify your child from this data. The information will only be used for the purpose of health and care research and cannot be used to contact you or your child or affect your child's care.

How long will my information be kept?

All information which is collected about you and your child during the research, including identifiable data, will be held securely for 10 years after the trial has finished in accordance with Sponsor requirements and data legislation.

Who is responsible for my child's information?

The University of Aberdeen is the data controller for this study and is responsible for looking after your child's information, using it properly and complying with their rights. You can find more about this at www.abdn.ac.uk/privacy or by contacting us at the address below.

Your child's rights to access, change or move your child's information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

What will happen to the results of the study?

We will share the results of the study with doctors across the UK who look after children with asthma. The results will be published in scientific journals and presented at scientific

meetings. The results will help inform how we can better treat children with asthma in the future.

Your child will not be identified in any publication of results of the study. We will let you know the results of the study when it is finished unless you tell us that you do not wish to know.

Who is organising and funding the study?

This study is sponsored by the University of Aberdeen and NHS Grampian who have overall responsibility for the management of the study.

The research is being funded by the Efficacy and Mechanism Evaluation (EME) Programme, a Medical Research Council and NHS National Institute for Health Research (NIHR) partnership. The NIHR is the research arm of the NHS.

The research is being carried out by experienced asthma doctors and researchers from the Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered Clinical Trials Unit at the University of Aberdeen in collaboration with the Universities of Liverpool and Leicester and Asthma UK,

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your child's interests. This study has been reviewed and given favourable opinion byWest Midlands - Black Country Research Ethics Committee.

Thank you for taking the time to read this information leaflet. We hope that it has been helpful in enabling you to decide if your child would like to participate in the SPIROMAC study.

Please ask us if you have questions or would like more information about the study.

Further information and contact details

If you have any questions or would like any more information, or would like to take part please contact:

Local contact details
SPIROMAC Study Office Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit University of Aberdeen Health Sciences Building Foresterhill Aberdeen AB25 2ZD Tel: 01224 438089 Email: spiromac@abdn.ac.uk Web: www.spiromac.co.uk
We are working in association with Asthma UK. You can also find more information about asthma here. **Web: https://www.asthma.org.uk/**

Your local Patient Advice and Liaison Service (PALS) can give advice about taking part in research. They can also help if you need to make a complaint. Their contact details are below (insert details)

Thank you very much for taking the time to read and to consider taking part in this study.