

## **Technology Enhanced integrated AsthMa care (TEAM care): a randomised control trial of technology to improve outcomes among children with asthma**

**Chief Investigator: Professor Ingrid Wolfe, King's College London**

### **PARENT/LEGAL GUARDIAN INFORMATION SHEET**

**Please help us learn whether new technologies can improve asthma care for children**

#### **Why have I received this?**



We want to tell you about some exciting research about children's asthma care in London and the Southeast. We are a team of researchers, doctors and nurses at King's College London, Guy's and St Thomas' Hospital, Queen Mary's University London and The Royal London Hospital who are working with the specialist asthma teams in your area to try and make the asthma care children receive even better. We are giving families the opportunity to take part in a research study that will see whether using new technologies, alongside usual asthma care, can help reduce the need for unplanned or emergency asthma treatment.

Before you and your child decide whether you would like to help us, it is important to understand why the research is being done and what it will involve.

#### **What do I have to do?**

You may have already received an invitation for your child to attend an appointment for asthma care, and/or to discuss the research. If you and your child decide to take part in this research study, we will ask you to sign a consent form, giving us permission to enroll your child in the research study. This will allow us to collect some information about your child's asthma using the health records completed when your child receives healthcare for asthma, for example from a specialist asthma nurse, and also the records from GP appointments or hospital visits related to asthma care.

Once this consent form is signed, we will at random allocate your child in to one of the two study groups. It will not be possible to choose which of the groups your child is in, so you need to be happy with any of the possible options below before you agree that your child can participate in the research study.

Group 1	Group 2
<p>We will ask you and your parent or the person who looks after you some questions about your asthma and if you have seen a doctor or nurse recently</p> 	<p>We will ask you and your parent or the person who looks after you some questions about your asthma and if you have seen a doctor or nurse recently</p> <p>We will give you a special top to put on your preventer inhaler and a little recording machine.</p>  <p>The sensor will remind you to take your inhaler by sending a message to a phone. It will record how often you take your inhalers.</p> <p>The recording machine will help you and your parent/carer decide if you are wheezy.</p> <p>It is easy to do and if you get stuck we are here to help</p>

Once your child is enrolled in the study and has been assigned a group, you will be given information on how to use the smart sensor on their preventer inhaler and wheeze recording device if you are in the technology group. Parents in the technology group will be asked to register their child's details for the apps linked to the devices and start to use them at home. Our research nurses will be able to help you do that and the research team will be able to answer any questions you have once you are home and using the devices and apps. If your child is in the control group, they will continue to have their usual care for asthma.

For everyone taking part in the study, there will be a questionnaire to complete at enrolment, and after 6 months of taking part. We will also ask you to answer a couple of questions each month about whether you have needed any unplanned appointments with your child's GP or at an emergency department for their asthma care. Your child's participation in the research study will end after 6 months and they will continue to receive the necessary care for their asthma from their GP and/or specialist asthma team. All other aspects of your child's asthma care during the 6 months you'll be taking part in the study, will be the same as it would be if you were not taking part

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We will also be carrying out some recorded group interviews to ask about participant's experiences of using the technologies. Not all participants will take part in these recorded interviews, and you will have the opportunity to receive more information and consent to this part of the trial at a later date. The audio recordings from these interviews will be transcribed by a company called 1st Class Transcription who have expertise in handling confidential data. Audio files will be destroyed at the end of the project while transcripts will be archived and kept for 25 years along with other data from this study, as is recommended for paediatric studies.

### **Do I or my child have to take part?**

No, you and your child do not have to take part in this study if you do not wish to. However, taking part will help us to understand more about these new technologies and whether using them alongside the usual NHS service will improve patient care and asthma outcomes for children.

### **If I don't take part, would that affect the service my child is receiving?**

No, the care your child is receiving will not be affected by your decision not to take part in this study. Your child will continue to receive any current and future services that might be available through their GP or local health care providers.

### **Would my child's GP be told that we are part of this project?**

Yes, we will let your GP know the results of the Asthma Control Test questionnaire for your child so that your GP can provide care as required. Your child's GP will also be sent a letter explaining your child's involvement in the study. If you have concerns about this, please let us know.

### **Who will have access to my child's information?**

Your child's information will be stored on a research database provided by our partners Health Touch Ltd. The research database will be password protected and only accessible to members of the research team at King's College London. We will keep your information confidential, safe and secure on our NHS and King's College London computers that are password protected and at Health Touch Ltd on an encrypted database. Any information used for scientific reports will not have your child's name or any personal information on it. Researchers at King's College London will see the data without any identifiable information. If you are in the technology group, the companies administering the devices and associated Apps will have access to any information you provide via the App or website, including personal, identifiable information. This data will only be used with reference to the trial and not for any commercial purposes. Both the technology companies using tracking cookies to verify users. A link to each of their Privacy Statements is included on the following page.

Your child's information will not be shared with anyone else without your prior permission. Anonymous information collected for the research might be accessed by other members of Guy's and St Thomas's NHS Foundation Trust or King's College London for data auditing, regulatory inspection and or database maintaining. Data collected as part of this research will be safely archived for 25 years (this is the recommended length for children's studies) at King's College London after the end of the study.

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After the study has finished, you will be emailed or posted the overall trial results or told how to access these online.

### **What if I would like to ask more questions about the study?**

If you have any more questions about the study, please talk to us by calling our research team on 020 7188 5351 (ext 85351) or via email, [gstt.teamcarestudy@nhs.net](mailto:gstt.teamcarestudy@nhs.net)

### **What do I need to do to get involved?**

If you and your child would like to get involved in our study, please read the consent forms attached to this information sheet. You will be asked to sign a copy of the consent form, usually when you attend your child's appointment. There is also a child-friendly version of the information sheet to read with your child, they will also have to 'sign' an assent form to say they understand the study and are happy to take part. If you have any questions about anything in the information sheet or consent form or about taking part in the study, you can contact the study team on 020 7188 5351 (ext 85351) or via email, [gstt.teamcarestudy@nhs.net](mailto:gstt.teamcarestudy@nhs.net).

### **Where can I find out more about how my information is used?**

The GSTT, KCL, Smart Respiratory (inhaler smart sensors) and Wheezo privacy notices can be found below:

[www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx](http://www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx).

<https://www.kcl.ac.uk/research/support/rgei/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research>

<https://smartrespiratory.com/privacy-policy/>

<https://respiri.co.uk/privacy-policy/>

For more information on how your data will be used you can also contact the GSTT Data Protection Officer: Nick Murphy-O'Kane, Contact: [DPO@gstt.nhs.uk](mailto:DPO@gstt.nhs.uk)

### **What happens if I change my mind?**

If you or your child want to stop taking part at any point please contact us on 020 7188 5351 (ext 85351) or via email, [gstt.teamcarestudy@nhs.net](mailto:gstt.teamcarestudy@nhs.net); data collected before you stop taking part will still be used as part of the project but we will not contact you about the project again in the future.

### **What are the benefits/disadvantages of taking part?**

The information you provide will help us understand if usual asthma care services can be improved by using technologies not currently part of the NHS service. If you and your child decide to take part in this study, we would like to thank you and your family with a £15 voucher.

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We do not anticipate any disadvantages to taking part in this project. Any information we learn regarding your child's health will be reported back to your child's GP.

### Who is sponsoring and funding this project?

This project is sponsored by King's College London and Guy's & St Thomas' NHS Foundation Trust and is funded by the National Institute of Health Research (NIHR).

### Who has reviewed this project?

This project has been developed by researchers at Kings College London University, Guy's and St Thomas' Hospital, Queen Mary's University London and The Royal London Hospital and reviewed by an NHS research ethics committee.

### Concerns about this project?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Please write to Ingrid Wolfe, by email at [Ingrid.wolfe@kcl.ac.uk](mailto:Ingrid.wolfe@kcl.ac.uk). If you remain unhappy and wish to complain formally, you can do this through the Guy's and St Thomas' Patients Advice and Liaison Service (PALS) on 020 7188 8801, [pals@gstt.nhs.uk](mailto:pals@gstt.nhs.uk). The PALS team are based in the main entrance on the ground floor at St Thomas' Hospital and on the ground floor at Guy's Hospital in the Tower Wing.

In the event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against Guy's and St Thomas' NHS Foundation Trust and/or King's College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).



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