

Breathe4T (Breathe for teenagers)

Breathing exercises for teenagers with asthma using an online tool

Participant information sheet for teenagers [15-17years old]

You are invited to take part in our research study. Before you decide to take part, it is important that you understand what the study is about, why the research is being done, and what it will involve if you take part.

Please read this information carefully and talk to your parents, legal guardians, carers, family, or friends. If you would like more information, or something is not clear, you may contact us either by phone or email.

This information is in two parts:

- **Part 1** tells you what the study is about and what will happen to you if you take part.
- **Part 2** gives you more details that you need if you decide to take part.

Part 1

Why is this research being done?



Asthma is one of the most common long-term conditions for teenagers. We know from our work as doctors and scientists that many teenagers have asthma symptoms despite their asthma medicines. Teenagers tell us that it can be difficult to stay calm during an asthma attack. Our team have already developed a successful training programme to help adults use breathing exercises to stay calm and help their asthma. We now want to make this available for younger patients like you.

In this study, we want to find out:

Can a new website help teenagers to manage their asthma better and improve their overall lives?

We will compare a group of teenagers using the new website with a group of teenagers who are having the standard, usual care they normally have when they see their doctor and nurse.

Do I have to take part?



No, it is up to you whether you take part. If you do decide to take part, you will be asked to sign a consent form online. You can stop taking part in the study at any time and without having to give a reason – just email breathe4t@soton.ac.uk to let us know. This will not affect the usual care that you receive.

What will happen if I take part and what will I have to do?

The study will last 6 months. You'll also be able to use the website for another 6 months after that. If you decide to take part in this study:

- You will need to use a unique code to sign-up to the Breathe4T website and you will be asked if you would like to take part.
- You will be asked some questions about your asthma, general health and daily life.
- The website will then randomly put you into one of two groups.
 - **Group 1:** If you are put in this group you will be able to use the new website straight away. You will also carry on receiving your usual care from your doctors and nurses.
 - **Group 2:** If you are put in this group you will carry on receiving your usual care from your doctor or nurse. After 6 months, you will be able to use the new website.
- After 2 and 6 months, both groups will be asked to answer some more questions.
- During the study you may also be asked to tell us how you found this study via a telephone call or online chat. You do not have to do this if you do not want to.
- You will receive a £10 voucher as thanks for your time.

We don't know which group you will be put in as the website will decide at random. Both groups are equally important and both groups will get to learn the breathing exercises.

What are the benefits of taking part?

 One of the benefits of taking part is that you will have the opportunity to improve your understanding about your asthma and to learn breathing exercises. There is a chance that this could help you to control your asthma. However, you should continue to take your medications as prescribed. The breathing exercises work alongside these medicines. By taking part, you could also be helping towards transforming the care of teenagers with asthma across the UK.

Are there any risks to taking part?

 There are no disadvantages or risks of taking part in this study. You can spend as much or as little time as you'd like to spend on the website however, we will need you to answer some questions about your asthma. Both groups will be looked after by their asthma doctor or nurse as usual throughout the study.

This completes Part 1 of the Information Sheet. Part 2 will give you more detailed information that you need to know about the study if you are taking part.

Part 2

Who will know I'm taking part in the study? Will my information be kept private?

 We will need to let your GP know that you have decided to take part in this study. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. All information about you will be held in a separate, secure file on a University encrypted computer or locked in a filing cabinet. Data from the study will be stored for 10 years and then destroyed.

In the (perhaps unlikely) event of a loss of capacity to consent, you will be withdrawn from the study. The research team will retain tissue and personal data collected during this study and continue to use it confidentially for research purposes. This could include further research after the current project has ended.

What will happen to the results of the research study?

 The study results will be presented in a written, science report, which may be published and used at scientific meetings. We will write our reports in a way that no-one can work out that you took part in the study. After the study, we will send you and your parents/legal guardian a summary of the results.

Who is organising and funding the research?

The study is funded by National Institute of Health Research, Research for Patient Benefit and is sponsored by University Hospital Southampton NHS Foundation Trust.

Who has checked the study?

All research in the NHS must be checked by a Research Ethics Committee. This is a group of people who are not involved in the study and they check the research is fair. This study was given a look at by [insert research committee here] and the research team at the hospital.

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

 It is completely up to you to decide if you would like to take part, however there are only 116 places and you should decide by August 2021.

What if there is a problem?

 If you have a concern about any aspect of this study, you or your parents/legal guardian should speak to us (details below) and we will do our best to answer your questions. If you still have questions or concerns, you can contact Research and Development, University Hospital Southampton NHS Foundation Trust (telephone number 02381 205664).

Who can I speak to for more information?

If you have any questions or would like any more information you can contact:

 **Breathe4T Research Assistant** (Stephanie Easton): breathe4t@soton.ac.uk or 07767 833924
Research Nurse (Amber Cook): amber.cook@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.

What's next?

If you would like to take part, please see the **"Ready to Get Started?"** flyer which tells you how to find the Breathe4T website.

THANK YOU FOR YOUR TIME

Data Protection Privacy Notice

How will the research team use information about you?

We will need to use information from you and your GP for this research project.

This information will include:

- Your name
- Your age
- Your gender
- Your contact details

This information will be held securely by the research team. People will use this information 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 code number instead. We will keep all information about you safe and secure. Once we have finished the study, 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 study.

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

You can find out more about we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our GDPR leaflet from www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team.
- By sending an email to dataprotection@uhs.nhs.uk
- By ringing us on 023 8120 4743.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. 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.