

Breathe4T (Breathe for teenagers)

Breathing exercises for teenagers with asthma using an online tool

Participant information sheet for parents/legal guardians

We are inviting your teenager to take part in our research study. Before you decide whether your teenager should take part, it is important that you understand what the study is about, why the research is being done, and what it will involve. Please read this information carefully and discuss it with others if you wish.

Your teenager has been provided with age-appropriate information about the study. If anything is not clear, or you would like more information before you decide whether you are happy for them to take part, please contact a member of the study team (details at the end of this information sheet).

This information is in two parts:

- **Part 1** tells you what the study is about and what will happen if your teenager takes part.
- **Part 2** gives you more details about the conduct of the study.

Part 1

What is the purpose of this research?

Asthma is one of the most common long-term conditions for teenagers. Our previous research shows that many teenagers have asthma symptoms despite using appropriate medication.

We would like to develop a way of helping teenagers with asthma to use breathing exercises to control their asthma symptoms. Our team have already developed a successful training programme to help adults use breathing exercises to stay calm and help their asthma. We would like to see whether this also works in younger patients.

In this study, we want to find out:

- If a new website can help teenagers to self-manage their asthma and achieve better asthma control.
- If a new website can improve the quality of life for teenagers with asthma.

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. The group that your teenager is put in will be decided at random by the website.

Why has my teenager been invited?

Your teenager has been invited to the study because they are aged between 12-17 years old, with diagnosed asthma.

Do they have to take part?

No, it is up to you and your teenager whether they take part. This information sheet can help you decide. If you and your teenager decide they will take part, you will be asked to sign a consent form online. Your teenager 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 they receive.

What will happen to my teenager if they take part and what do they have to do?

The study will last 6 months. After that, participants will also be able to access the website for a further 6 months. If your teenager decides to take part:

- You will need to register your teenager to the Breathe4T website. You will need to answer 3 short questions to check they are suitable for the study and you will be asked to confirm you are happy for them to take part.
- You will also be asked to provide your teenager's email address – this is so that we can send them their own unique code to sign-up to the study.
- Once your teenager signs up, they will be asked some questions about their asthma, general health and daily life.
- The website will then put your teenager into one of two groups.
 - **Group 1** will be able to use the new website straight away. They will carry on receiving the usual care they receive from their doctor or nurse.
 - **Group 2** will be able to use the new website in 6 months. They will also carry on receiving the usual care they receive from their doctor or nurse.
- Both groups will be asked to answer some more questions after 2 months and at the end of the study.

- During the study, your teenager may also be asked to take part in an interview to tell us how they found using the website. They do not have to do this if they do not want to.
- Your teenager will receive a £10 voucher in appreciation for their time.

We don't know which group your teenager 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 techniques.

What are the benefits of taking part?

One of the benefits of taking part is that your teenager will have the opportunity to improve their understanding about their asthma and to learn breathing exercises. There is a chance that this could help your teenager to control or improve their asthma. However, they should continue to take their medications as prescribed. The breathing exercises work alongside these medicines. By taking part, your teenager 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. Your teenager can spend as much or as little time as they'd like to spend on the website, however we will need them to answer some questions about their 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 your teenager is taking part.

Part 2

Will my teenager's taking part be kept confidential?

We will inform your teenager's GP that they are taking part in this study. The procedure for handling, processing, storage and destruction of any data collected during the study are compliant with the General Data Protection Regulations 2018 and in line with the University Hospital Southampton's NHS Foundation Trust Policy. All information about your teenager 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, before being destroyed.

What will happen to the results of the research study?

The study results will be presented in a clinical study report, which may be published and presented at scientific meetings. Your teenager will not be identifiable in any publications arising from this project. After the study, you and your teenager will be provided with a summary of the study 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.

What if there is a problem?

If you or your teenager have any concerns about this study, you should ask to speak to one of the researchers and we will do our best to answer your questions (contact details at the end of this sheet). If you still have questions or concerns, you can contact Research and Development, University Hospital Southampton NHS Foundation Trust (telephone number 02381 205664).

Who has reviewed 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 check the research is fair. This study was given a look at by Leeds West Ethics Committee and also the research team at the hospital.

How long do we have to decide whether my teenager takes part?

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

Contact for further information:

If you have any questions or would like any further information, please contact:

Research psychologist: Stephanie Easton (breathe4t@soton.ac.uk, 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.

What's next?

If you and your teenager decide that they would like to take part:

- Go to www.breathe4t.co.uk to register your teenager
- Enter the unique code found on your invitation letter
- Complete the online consent form
- Enter your teenager's contact details

Your teenager will receive an email within 24 hours with instructions to sign-up to the study.

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, your teenager and their GP for this research project.

This information will include:

- Your name
- Your email address
- Your teenager's name
- Your teenager's age
- Your teenager's gender
- Your teenager's 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 teenager's records to make sure that the research is being done properly. People who do not need to know who your teenager is will not be able to see their name or contact details. Their data will have a code number instead. We will keep all information about your teenager 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 your teenager 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?

Your teenager can stop being part of the study at any time, without giving a reason, but we will keep information about them that we already have. We need to manage their 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 your teenager.