

Adult Participant Information Sheet

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4S Sore Throat Study - Scores and Swabs to Self-assess Sore Throat Feasibility Study (Stage I)

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You are being invited to take part in a research study. Before you decide if you would like to take part, please take time to read the following information carefully and discuss the information with others if you wish. If you have any questions about the study, you can contact the research team by phoning 07342 700682 or emailing fours@soton.ac.uk.

Research Summary:

What is the purpose of the study?

Most sore throats are caused by viruses. Taking antibiotics does not help with viruses and can result in side effects and antibiotic resistance (which means that antibiotics become less effective for when they are required). General practitioners often assess people with sore throats to decide if it is likely to be caused by bacteria using a scoring system based on symptoms. Antibiotics are more likely to help if the sore throat is caused by bacteria. Since the start of the COVID-19 pandemic, people with problems like sore throats are often assessed through telephone or video consultations. It may be possible for patients to help by assessing their own, or their child's, sore throat. This may help the doctor decide what the best treatment is. The study will involve looking in your throat and attempting to take a swab from your throat. This will not hurt you, but we want to find out how easy or difficult people find this.

In this study, we want to find out if people can assess features of sore throat and take throat swabs and saliva tests (to assess for bacteria, common viruses, COVID-19 and inflammation), with support from written and/or video information.

Why have I been invited?

We are looking for adults aged over 16 and parents/guardians of children (aged 3-15). Participants must have a computer or smart phone with access to the internet and be able to speak and understand English clearly when using a telephone or video call. People who

have had recent surgery to the throat or other conditions which could prevent taking swabs, or other conditions which may make completing the study difficult, are not able to take part. We will discuss this with you before you start the study.

Please note: You do not have to have a sore throat at the time of taking part in the study.

Do I have to take part?

Taking part in the study is voluntary. It is up to you to decide whether to take part. If you decide to take part, you are free to withdraw at any time, without giving any reason and without affecting your future treatment in any way.

What would happen to me if I, or the child I care for take part?

You have obtained the link for the study information website from the social media advert. The website gives you more information about the study and you can provide consent to take part. It will also ask you for some information about you and/or your child, including age, sex, and ethnic group.

If you choose to take part, a member of the research team will contact you to arrange a convenient time for a video call. You will be sent a sample kit from our research team and a link to the study website. You will then be able to access information on the website to guide you in assessing the features of a sore throat (such as whether you or your child have a fever, cough or runny nose, or pus on the tonsils) and in taking throat swabs and saliva samples.

During the video call a researcher will watch you assessing the throat and taking samples. They will also ask you about the processes and training material from the website, in order to see what you did and did not find helpful so that they can improve the material/s.

The samples need to be returned using pre-paid envelopes along with a completed sample form, which we will provide along with the sample kit. The researcher can help you sort out how to package the samples. It doesn't matter if you have difficulty with taking one or more of the samples. Understanding any difficulties and trying to find ways to make it easier is exactly why we are doing this study.

Taking part in this study should last around 45-50 minutes in total.

What are the possible benefits of taking part?

We do not expect there to be any direct benefits to you from taking part. However, we will provide you with £25 Love 2 Shop voucher as compensation for your time. By taking part,

you will also help us to find out how well people can assess sore throats at home. This is important for us to know as more healthcare is being delivered remotely, particularly during the COVID-19 pandemic. This study could lead to further work, which could possibly reduce unnecessary antibiotic use, which is of great importance. Any results of laboratory tests from this study will only be used for research purposes. We will not tell you or your doctor the results of any tests that we do, and they will not be used to guide treatment. If you need healthcare during the study you will need to contact your GP surgery or other healthcare provider(s) as normal.

What are the possible risks and disadvantages of taking part?

The assessments and swab tests that the study will use are widely used by doctors, nurses and pharmacists and there should be minimal risks to taking part. Some people find that they gag during a throat swab, and it is possible that taking a swab could make your throat feel a bit more sore, although this is uncommon. You may find it a little embarrassing to be observed taking the swabs and assessing your and/or your child's sore throat, but we are not there to judge how well you do it, just to find out how best to help people assess sore throats.

What happens after the research study finishes?

You will not need to do anything else after the study finishes. We plan to publish the results in medical journals and present them at international medical meetings. We will send you a brief summary of the results at the end of the study, and you may contact us via the study website or email if you have further questions. None of your personal details, such as your name, date of birth, address, will appear on any reports or articles we publish.

What if there is a problem?

We do not anticipate there being any problems with this study, however if you have any complaints or comments about the way you and/or your child have been dealt with during the study, or if you feel that you or your child has been harmed in any way, please tell the research team (phone: 07342 700682 or email: fours@soton.ac.uk). If you still have a complaint or remain unhappy, you can contact the Head of Research Integrity and Governance, University of Southampton by telephone (023 80595058). In the unlikely event that something does go wrong and you and/or your child are harmed during the research and this is due to someone's negligence, then you may have grounds for legal action for compensation against the University of Southampton. However, you may have to pay your legal costs.

Will my taking part in the study be kept confidential?

Your personal information will be stored securely and will not with other information about you or your child. Any swab results will also be stored pseudonymously and not stored with personal information. The swab samples will be disposed of at the end of the study.

Only the research team will have access to any information that you provide. Some parts of the data collected for the study may be looked at by authorised persons from the University of Southampton, or regulatory bodies to check that the study is being carried out correctly.

What happens to any videos collected?

Video-recordings:

- Any videos will have identifiable information removed and faces distorted, and be stored on a secure, password-protected folder on the University of Southampton's computer system, which will only be accessible by the members of the research team and University of Southampton IT services).
- The videos may be transcribed (the speech typed up) by a trusted, University approved third party, or a member of the study team. All transcribers will sign a confidentiality agreement to keep the data confidential.

What will happen if I do not want to carry on with the study?

You and/or your child have the right to withdraw from the study at any time and do not have to give a reason for doing so. This will not affect your and/or your child's medical care in any way. If you are willing to, we would ask for your feedback at an exit interview. If you and/or your child withdraw from the study, any data that has already been gathered at the point of withdrawal will be retained. This is in order to protect the validity of the research and is permissible as an exemption to data subject rights under GDPR.

Who is organising and funding the research?

Our research team includes GPs, academic researchers and patient representatives from the Universities of Southampton, Oxford, Bristol and Cardiff. The research is funded by National Institute of Health Research School for Primary Care Research (NIHR SPCR). The research is being conducted by and sponsored by University of Southampton. The local research team includes Prof Nick Francis, Dr Mark Lown, Dr Kirsten Smith and Kirsty Rogers.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Cornwall and Plymouth Research Ethics Committee – Ethics No. 20/SW/0175.

Where can I get further information about the study?

If you have any unanswered questions about the study, then please feel free to contact the research team via the study website, email: fours@soton.ac.uk or study mobile:07342 700682.

What's the next step?

If you and/or your child wish to sign up as a participant on the study, please contact us via the study website or email address fours@soton.ac.uk .

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. The University's data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/Is/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

Thank you for taking the time to read this Participant Information Sheet and for considering taking part in our research.