Adult Participant Information Sheet

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4S Sore Throat Study - **S**cores and **S**wabs to **S**elf-assess **S**ore Throat Feasibility Study **(Stage II)**

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You are being invited to consider taking part in a research study that is undertaken at home. Before you decide if you would like to participate, please take time to read the following information carefully and discuss the information with others if you wish. It will take approximately 10 minutes for you to read this information sheet. If you have any queries before you sign the consent form, or at any stage in the study, please contact the research team on: 07342 700682 or 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 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. But 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. This home assessment will involve taking a swab of the patient's throat, but we are not sure if this is possible or practical.

In this study we want to find out if it's possible (feasible) to run a research study to see how well patients can assess features of sore throat and take throat swab and saliva tests (to assess for bacteria, common viruses, COVID-19 and inflammation) with support from written and/or video information. We want to determine if this is achievable in adults aged 16-65 years and if parents or guardians can assess and test children aged 3-15 years.

Why have I been invited?

We want to recruit adults aged over 16 and parents/carers of children (aged 3-15) who have developed a sore throat (that started within 2 weeks). Participants must have internet

access and be able to communicate efficiently via telephone or video in English. We do not want to pose any risks to participants and therefore would not recruit those who have had recent surgery to the throat, have other conditions which could prevent taking swabs or other conditions which may make completing the study difficult. We will find all this information out at before you start the study.

You have been invited because you have consulted a clinician with a sore throat or have responded to our social media advertisements.

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 participate, you are free to withdraw from the study 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 will have either been given the link for the study website from your GP or obtained this from the social media advert. You will be sent a sample kit by our research team. You will then access the information on the website, to guide you in assessing the features of a sore throat (including fever, cough or runny nose, pus on tonsils, tender glands) and in taking throat swabs and saliva samples. A member of the research team will then contact you to arrange a convenient time for a video call with the study Research Fellow.

During the video call, if you are happy to, your consent to participate, or for your child to participate in the study, will be taken electronically. The consent is simply to take part in the study, it does not involve any treatment.

We will observe you assessing the sore throat and taking samples. We will also ask you about the processes and training material from the website, in order to refine and improve the material/s.

The samples need to be returned using pre-paid envelopes (or we may arrange a courier for some samples) along with a completed sample form, which we will provide along with the sample kit. 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.

We will also gather some information about you and/or your child, including age, gender, ethnicity and duration and severity of symptoms. 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 £20 Love 2 Shop voucher as compensation for your time. By taking part, you will help us determine if people can adequately 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 potentially

reduce unnecessary antibiotic use, which is of great importance. The laboratory results that we will get from this work will not be used to guide treatment. It is important you understand, you will not receive any results for the samples you take, they are for research purposes only. Participants in the trial are expected to access healthcare as usual during the trial.

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 participants. Some people find that they gag during a throat swab, and it is possible that taking a swab could make your throat sorer, although this is uncommon. You may find it a little embarrassing to be observed taking the swab and assessing your sore throat but we are not there to judge how well you do it, just to find out if it is possible.

What happens after the research study finishes?

You will not need to do anything else after the research 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. Your name will not appear on any of the reports or articles we publish.

What if there is a problem?

We do not anticipate there being any problems with this simple study however any complaint about the way you and/or your child have been dealt with during the study or any possible harm you and/or you child might suffer will be addressed. If you have a concern about any aspect of this study, you should ask to speak to the research team who will do their best to answer your questions (07342 700682). If you have a complaint and remain unhappy, you can do this by telephone to Head of Research Integrity and Governance, University of Southampton (023 80595058) or the Patient Advisory Liaison Service (023 8079 8498). 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 University of Southampton. However, you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Will my taking part in the study be kept confidential?

Yes. We will collect some personal information from you, such as your name and phone number. However, this personal information will be stored securely and will not be stored with any information about your and/or your child’s sore throat, or the things that you tell us. Your and/or your child’s swab results will also be gathered pseudonymously and not stored with your and/or your child’s personal information. Your and/or your child’s swab

sample will be disposed of at the end of the study. We will follow ethical and legal practice and all information about you and/or your child will be handled in confidence. Only the study team will have access to any information that you provide. Electronic information will not be directly identifiable and will be password protected with only essential access. Any paper-based information will be kept in locked storage. 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. All will have a duty of confidentiality to you as a research participant and we will endeavour to meet this duty.

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 if relevant new information becomes available?

If new information becomes available or the study is stopped for any reason, we will tell you.

What will happen if I don't 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 medical care in any way. If you are willing to, we would ask for your feedback at an exit interview. If you 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.

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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 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, if you or the child you care for has developed a sore throat.

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/ls/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.