

We invite you to take part in the Immune Defence study

Please read the information below carefully and contact us if anything is unclear or you would like to ask any questions.

What is this study about?

We are inviting you to take part in our research study about colds, flu, and similar infections (like ear, chest, throat, and sinus infections). We would like to see if nasal (nose) sprays and websites that help you be more active and reduce stress can help people get fewer infections and less severe infections. This also includes COVID-19. Although it can cause more serious problems, we catch COVID-19 in a very similar way to coughs, colds and other infections.

- **You may be eligible for the study if you have had one or more infections in the last year.**
- If you decide to take part, you will be put in to one of four groups by chance:
 - Group 1:** Use of a gel-based nasal spray.
 - Group 2:** Use of a liquid-based nasal spray.
 - Group 3:** Use of websites that help you to be more active and reduce stress.
 - Group 4:** Usual care for infections: This is perhaps the most important group. Without this we will not be able to know if the other treatments make any difference. After 12 months you will be given access to the websites used in Group 3 for a short time.
- **You will not be able to choose which group you are put in or change groups after you have been allocated, so it is important that you are happy to be in any of the groups before deciding whether to take part.**
- The study will last for 12 months. Each month we will ask you to complete some questions about colds, flu and similar infections, and your general health.
- Everyone in the study will continue to receive their usual NHS care.
- This study is being run by researchers at University of Southampton, Oxford and Bristol and is funded by the National Institute for Health Research, the main funder of research in the NHS.

Why have I been invited?

We are inviting people to take part who might be interested in trying to avoid colds, flu, and similar infections. You have been invited because either i) you have a medical problem that makes your risk higher of getting infections (such as heart disease, lung disease, diabetes, liver disease, neurological problems or obesity), or ii) you are aged 65 or over or eligible for the flu vaccination or iii) you have talked to your GP about colds, flu or similar infections (like ear, chest, throat or sinus infections) in the last year. Please be assured that you can have your annual flu vaccination and COVID vaccinations while taking part in the study.

Is the study right for me?

If you normally get at least one infection per year and are interested in trying out ways to get fewer infections, you may be eligible to take part in the Immune Defence study.

Do I have to take part?

No, it is entirely up to you to decide whether to take part. If you decide you want to take part, you will need to complete a consent form online.

What would I do in the study?

1. If you agree to take part in the Immune Defence study, you will need to sign up to the Immune Defence website (please see the enclosed 'How to Take Part' sheet).
2. You will then be asked to complete a consent form online to show that you agree to take part.
3. You will then be asked about any colds, flu, or similar infections you have had in the last year to see if the study is right for you. You will be able to take part if you normally have at least one infection per year.
4. We will also ask you some general questions about your health to check that the study is right for you. The study is not right for everyone. Unfortunately, you will not be able to take part if you have a known allergy to nasal sprays, or regularly use nasal sprays when you have a cough, cold or similar illness (you can still take part if you use nasal sprays for hayfever or nasal decongestants). Also, if you are currently pregnant or planning pregnancy in the next 12 months, or breastfeeding, you will not be able to take part in the study.
5. If the study is right for you, you will be asked to fill in some further questions about yourself and your general health. You will then be put into one of 4 groups completely by chance. Putting people into groups by chance will make sure that the groups are the same to start with and allow a fair comparison between the groups. You will not be able to choose which group you are put in or change groups after you have been allocated, so it is important that you are happy to be in any of the groups before deciding whether to take part. In all groups you will carry on receiving usual care from your doctor or nurse.

Group 1: Use of a gel-based nasal spray

If you are put in this group will be asked to use the gel-based nasal spray when you feel at risk of getting an infection. We will give you access to a website that will give you detailed advice on how to use the nasal spray. We will give you the gel-based nasal sprays for you to use during the study.

Group 2: Use of a liquid-based nasal spray

If you are put in this group will be asked to use the liquid-based nasal spray when you feel at risk of getting an infection. We will give you access to a website that will give you detailed advice on how to use the nasal spray. We will give you the liquid-based nasal spray for you to use during the study.

Group 3: Use of websites that help you to be more active and reduce stress

If you are put in this group will be given access to two study websites: one to help you to be more active and another to help reduce stress. These websites have relevant advice and support whatever your age, health status, physical ability or fitness

Group 4: Usual Care for infections

If you are put in this group you will continue to manage your colds, flu, or similar infections in the way you normally do. For this group we ask that you do not to use any other nasal sprays (other than sprays your doctor currently advises you to use e.g. beconase for hay fever). This is very important, otherwise we will not be able to see if the other groups work. After 12 months, you will be given access to the websites used in Group 3 for a short time.

6. Each month for 12 months we will email you to ask you to complete some brief questions about any infections that you have had. These questions will take around 5 minutes to complete. You will receive a reminder email if the study team don't hear from you.
7. After 3, 6 and 12 months we will ask you to complete some more questions about any infections you have had and your general health. These will take around 10-20 minutes to complete and you will receive a reminder email if the study team don't hear from you. These questions are really important, so the study team may also send you the questionnaires in the post or call you to ask you to complete the main questions over the telephone.
8. We may also ask you to complete a daily symptom diary when you have a cold, flu, or similar infection to record any symptoms you have if you get an infection, and about your overall health. A paper diary will be sent to you when you sign up for the study and we will ask you to return it to the study team in a freepost envelope if you complete it. However, completing the diary is optional and it is up to you whether you want to complete it or not.
9. At the end of the study, staff at your GP surgery or authorised members of the research team will look at relevant sections of your medical records to find out whether you have had an appointment with your doctor/nurse about respiratory infections during the study, about any prescriptions you have been given, and whether you have been referred for any further treatment or investigation.
10. We may also ask you to take part in an interview about your experiences of taking part in the Immune Defence study, including using the Immune Defence website and completing the research questionnaires. This would usually be over the telephone and will take about 1 hour. It is up to you whether you take part in a research interview. If you agree by completing a consent form, a researcher from University of Southampton will contact you when the interview is due, giving you some more information about what would be involved and asking for your consent.

What are the possible pros and cons of taking part?

Using nasal sprays or being more active and reducing stress may help you get fewer infections. Your participation will help us know if any of the treatments make a difference during the time of the COVID-19 pandemic. It will also help us plan more studies in the future to find out which treatment is best to reduce the number of cold and flu infections that people get during 'normal' winters.

The main disadvantage is that it will take up some of your time to fill out the questions. Rarely the gel-based nasal spray can cause dryness in the nose resulting in a nosebleed. If you get a nosebleed, you can pause using the spray and try again in a few days. If you get a heavy nosebleed then you should stop using your spray and talk to your doctor if you are concerned. You will not be withdrawn from the study if you suffer a nosebleed unless you decide you no longer wish to take part.

Can this study help me avoid COVID-19?

This research will help us find out if common nasal (nose) sprays, and websites to help you be more active and reduce stress can help people get fewer infections, such as colds, flu and similar infections (like ear, chest, throat and sinus infections). COVID-19 is one of these infections. Although it can cause more serious problems, we catch COVID-19 in a very similar way to coughs, colds and other infections. So, things we do to try to reduce the number of infections we get, could possibly help with COVID-19, but equally it might not. This research will help us to find out one way or the other.

Can I change my mind?

It is up to you if you want to take part in the study. You can change your mind at any time. You do not have to tell us why. Any information that you have provided up to this point may still be used. If you wish to withdraw from the study, please contact Samantha Williams, Trial Manager, at IDStudy@soton.ac.uk.

What happens to the data collected?

- Electronic questionnaires will be collected using a secure online data collection service which meets the highest industry standards for privacy and security of data. Data will then be downloaded to the University of Southampton server and stored securely behind the University of Southampton firewall, until the end of the study.
- Questionnaires completed on paper will be entered onto a password-protected database. Paper questionnaires will be stored in a secure filing cabinet at Aldermoor Health Centre, University of Southampton where the research team is based, and destroyed at the end of the study.
- At the end of the study anonymous questionnaire data will be deposited in a secure data archive which will be made available to researchers at University of Southampton for secondary data analysis. Making data available for further analysis means the data can be checked by others, allows the data to be used for other scientific purposes, saves public money by research not being repeated, and helps with teaching new researchers about data collection methods and analysis. We will securely store your name, email address and any other demographic data in a separate list, so we know who has taken part.

What will happen to the results of the study?

We will use information from the study to write reports, but this won't include any information that makes it possible for you to be identified. We will send you a summary of the results if you would like to see them.

Who is conducting the study?

This study is organised by researchers at the Universities of Southampton, Bristol, and Oxford, with input from a panel of patient contributors, who provide advice, monitoring and support to the research team. The Chief Investigator is Professor Paul Little. The study is funded by the National Institute for Health Research, which is part of the Department of Health and has been approved by the Health Research Authority and the National Research Ethics Committee [20/SS/0102]. The research is being sponsored by University of Southampton.

What if there is a problem?

If you have any concerns about any aspects of the study, please contact the Immune Defence Study team on tel: 023 8059 1768 or email IDstudy@soton.ac.uk. If you remain unhappy or have a complaint about any aspect of this study, please contact the Research Integrity and Governance Manager at the University of Southampton (rgoinfo@soton.ac.uk or 023 8059 5058).

What next?

If you are interested, please see the 'How to Take Part' sheet which tells you how to find the Immune Defence Study website. Your GP will be notified of your involvement in the study.

Where can I get more information?

If you would like to know more about the study or discuss anything in this information sheet please contact the Immune Defence Study team on tel: 023 8059 1768 or email IDstudy@soton.ac.uk.

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. 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>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you. 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>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it. Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

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. To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

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).

