

Sano Genetics Patient Information Sheet

Title of the study:

How do our Genetics impact Long Covid Symptoms and Recovery?

Description of the study:

This study is for people who experience covid-like symptoms for multiple weeks at a time, named Long Covid. A positive covid test or a hospital stay are not requirements.

Understanding more about the genetics of Long Covid sufferers will enable us to determine the biological cause of symptoms, develop a diagnostic criteria, develop treatments and guide rehabilitation services.

We currently have 3000 spaces in our Long Covid study for UK and US based participants. We are planning to achieve gender parity and ethnic diversity (equal or above the UK population average) for study participants. So, if you're Black, Asian, Hispanic, Native American, or from a minority ethnic group, please sign up.

We are working hard to get extra funding from further grants and collaborations to make the number of people we can include in our study at least 20,000, and to spread to more countries, so please do still sign up if you're interested.

We ask you to fill in a survey about your COVID-19 symptoms. If you're selected to join the study, we'll ask you to give us a saliva sample from home for DNA analysis. Your data belongs to you, so we'll ask your permission to share it with each Long Covid researcher we are working with. If you already have DNA data you are able to share it with researchers by uploading it to our site.

In return you'll have access to 15+ free reports (such as how related you are to Neanderthals, eye colour, freckles), regular study updates, as well as the chance to join further research studies via our platform.

Sano Genetics is a member of the COVID-19 Host Genetics Initiative and is partnered with other academic researchers interested in Long Covid, such as [Dr David Strain](#), Senior Clinical Lecturer at the University of Exeter. David was the lead on the COVID ward for older adults at the Royal Devon & Exeter NHS Foundation Trust. David is investigating the links between Long Covid and Chronic Fatigue Syndrome, and how alterations in patient microvasculature in the brain, heart, and rest of the body may play a part in both conditions.

It's likely our study will be used as a comparison to other studies involving severe or hospitalised cases (PHOSP-COVID, Genomics England, Coronagenes). And we want to work with clinicians to encourage development of a healthcare pathway for Long Covid cases.

What is the purpose of the study?

Long Covid is becoming more widely reported. And has a huge impact on society with those affected often unable to do daily activities.

There is currently a limited understanding of Long Covid. Additionally, those that weren't initially hospitalised with COVID-19, or do not have a positive COVID-19 test, may find themselves without care or not being included in research studies.

Understanding more about the genetics of Long Covid sufferers will enable us to determine the biological cause of symptoms, develop a diagnostic criteria, develop treatments and guide rehabilitation services.

Who is eligible?

We are looking for participants who have Long Covid, either formally diagnosed or presumed. Long Covid is an illness that is suspected to arise in some patients after COVID-19 infection. Typically covid-like symptoms last over 3 weeks, and some patients still have symptoms over 12 weeks. For our study a positive test or a hospital stay are not requirements.

We are planning to achieve gender parity and ethnic diversity (equal or above the UK population average) for study participants.

You need to be 16 years old or over to take part.

What's the time frame for the study?

We expect recruitment of 3000 participants to take 3 months. Collection of the DNA samples and DNA analysis will take a further 3 months. The sooner we can recruit participants, the sooner the results will be released.

How many others will be in the study?

We currently have 3000 spaces in our Long Covid study for UK and US based participants. We are planning to achieve gender parity and ethnic diversity (equal or above the UK population average) for study participants.

We are working hard to get extra funding from further grants and collaborations to make the number of people we can include in our study at least 20,000, and to spread to more countries, so please do still sign up if you're interested.

Do I have to take part?

No, participation in the study is voluntary. It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. If you decide to take part you are free to withdraw from the study at any time and without giving a reason. If you do not take part, or if you withdraw from the study, this will not affect the standard of care you receive.

What will happen to me if I decide to take part?

We ask you to fill in a survey about your COVID-19 symptoms.

If you're selected to join the study, we'll ask you to give us a saliva sample from home for DNA analysis. Your data belongs to you, so we'll ask your permission to share it with each Long Covid researcher we are working with. If you already have DNA data you are able to share it with researchers by uploading it to our site.

Due to the nature of the analysis we may look at genes related to Long Covid as well as unrelated genes.

We may ask further survey questions via the Sano platform for long-term monitoring or follow up purposes.

This study is observational. There are no therapeutic interventions.

Will my General Practitioner/family doctor (GP) be informed of my participation?

No. They will only be informed if you decide to tell them.

Will my taking part in the study be kept confidential?

Yes. Unless you decide to tell anyone.

Can I take part if I am already taking part in another research study?

If you are already enrolled in another research study, this will not affect your ability to take part in this study. Similarly, if you wish to take part in another research study

you can remain in this one. We will ask your permission to link your information from other studies to the information collected for this study.

What happens to my information?

This is a complex study and involves many research and delivery partners, such as universities, laboratories, data processing and logistic operators. To deliver the study we will need to share your personal information with some of these partners. We will only share the minimum information with these partners to undertake the task they are performing. They are bound by the same rules as us to keep your information confidential and safe.

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 access other research and public data, we will use your information along with that data to answer some of our research questions.

Some of your information may be sent to our partners outside of the European Economic Area (EEA), where data rules are different, however they must follow our rules about keeping your information confidential and safe.

We will write our study reports and publications in a way that no-one can work out that you took part in the study.

A copy of your consent form will be kept with any samples that are retained, this is to demonstrate you gave us your consent to keep them. As with all of the study documents, these will be stored securely and the minimum number of people will have access.

Where will the study take place?

The study is a “spit-and-post” design. Study participants will receive an at-home saliva collection kit. The sample will be sent back to our partner labs in the US or the EU, depending on the location of the participant. Data will then be securely sent to research partners involved in the study. This allows those who are severely affected with Long Covid to join the study.

What will happen to the samples I give?

As part of this study we will use the samples to look at how the body is affected by COVID-19. We will use samples to analyse your DNA (genetic variation).

We take sample security and patients' privacy very seriously. All samples will be kept secure according to the UK's and international highest standards, overseen by

ethical review. All institutions partnered on this study have adopted these standards and use them routinely, and comply with the Human Tissue Act 2004 and all other relevant regulations and legislation, including the General Data Protection Regulation (GDPR).

Samples stored after this study ends will be stored in line with all relevant legislation, this may be in a secure central repository. If you wish to find out further information on how we are using samples please speak with a member of the study team.

What will happen to my data?

We take data security and patients' privacy very seriously. All data will be kept secure according to the UK's and international highest standards, overseen by ethical review. All institutions partnered on this study have adopted these standards and use them routinely, and comply with all other relevant regulations and legislation, including the General Data Protection Regulation (GDPR).

Your data will be held securely on the Sano platform. Your data belongs to you, so we'll ask your permission to share it with each Long Covid researcher we are working with. Your data will only be used by researchers who have relevant scientific and ethical approval for research. They will manage the data safely and securely in line with the practices outlined above.

If you already have DNA data you are able to share it with researchers by uploading it to our site.

What if I want to delete my data?

You are able to delete your data via the Sano platform.

What are the possible benefits of taking part?

There is no direct benefit to you personally. The information we learn may help in caring for other patients in the future.

You'll be participating in important research to understand more about people with Long Covid. However, we do not know what the exact outcome is, and this is why we are conducting research. We hope that participants will be empowered to learn more about their condition and the outcome of the study will benefit others with a similar condition in the future.

You will have access to 15+ free reports (such as how related you are to Neanderthals, eye colour, freckles), regular study updates, as well as the chance to join further research studies via our platform.

Are there any possible disadvantages or risks from taking part?

If you take part in the study and we collect data from your records there is minimum risk, all information will be used anonymously (no one will know that this information relates to you).

This study includes genetic testing to identify host genetic variants associated with disease progression or severity. There is a very small chance that these tests may result in the incidental discovery of information that is relevant to the participant's health. Since the samples will be analysed anonymously in batches, and often in non-clinical laboratories with investigational techniques, we will not attempt to identify and inform participants of any results from genetic tests. If we were to do so, there would be a considerable risk of accidental harm in the form of unnecessary anxiety and distress.

Will I receive results of tests on my DNA?

The DNA measured using your samples will be looked at to try and work out what contributes to the risk of getting COVID-19, how severe the infection is and how people recover from it. These will be looked at in batches and will not have any details on them about who they belong to, therefore, we will not attempt to identify you or inform you of any results from your sample testing.

You and your GP will not receive individual results from these tests as they are not being used for diagnostic purposes, they are solely for research and safety purposes.

What will happen to the results of this study?

Any study results will be shared at a collective level with the study participants via Sano's platform.

Study results will also be published in research journals.

We hope that the researchers we work with will be able to use the results of this study to inform future COVID-19 studies that allow understanding of the illness and treatment options.

Individual participants will not be identifiable from any report or publication in the public domain.

What if something goes wrong?

It is unlikely that you will be harmed by taking part in this study. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Sano Genetics via contact@sanogenetics.com.

There is no compensation available in the event that you are harmed as a consequence of taking part in this study.

What happens at the end of the study?

Participants will be thanked for their contribution, and will be able to remain on the Sano platform so they can have access to further research studies.

What will happen if I don't want to carry on with the study?

Taking part in the study is entirely voluntary, and you can change your mind at any time without this affecting your care. There are no penalties to withdrawing from the study.

Will I be re-contacted?

With your permission, we may contact you about future research studies that you may be interested in and eligible for. This is entirely optional and agreeing to be contacted also does not oblige you to take part in any future research.

If you agree your contact details would be stored electronically on a secure server and only authorised individuals at your participating site will have access to it. You can ask us to have your contact details removed from our database at any time by contacting Sano Genetics, or at the time you receive an invitation for future research.

Will I be reimbursed for taking part?

No.

Who is organising and funding the study?

The study has been funded by Innovate UK, the UK's Innovation agency and Sano Genetics.

The study is organised by Sano Genetics.

Who has reviewed the study?

All research is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study is in the process of review. We will not collect any genetic information or use your information in any way before the approval of the study. Approval does not guarantee that you will not come to any harm if you take part. However, approval means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision.

How have patients and the public been involved in this study?

Patient and public involvement (PPI) has been central to the development of the study. We have interviewed Long Covid patients to gather their feedback and ideas, which have been incorporated into the study design. Some examples:

1. We've engaged with Long Covid online support groups.
2. We've consulted Long Covid sufferers to understand desired criteria for inclusion in the study.
3. We've listened to the press coverage of Long Covid patients.
4. We've created blog and podcast content on COVID-19.
5. We plan to create a Public and Patient Involvement Steering Group that involves patients, expert clinicians, representatives from Long Covid support groups.