Participant Information Sheet

You are invited to take part in the Therapies for Long COVID (TLC) study.

You have been invited because either:

a) You have experienced COVID-19, or
b) You have *not* had COVID-19.

Before you make your decision, it is important for you to understand why the research is being done and what it will involve. Please take time to read the information in this leaflet. You may want to talk to others about the study before deciding to take part.

Summary

We want to understand people's experiences of COVID-19 and compare those to people who have not had COVID-19. We are particularly interested in understanding more about 'Long COVID' (when symptoms last more than 12 weeks).

If you decide to take part in the study, you will be asked to complete a series of questionnaires monthly, for 12 months. There is also an optional study, which involves giving a blood sample and wearing a Garmin device that records heart rate and other measures.

Why are you doing this project?

Approximately 1 in 10 people with COVID-19 continue to experience symptoms and impaired quality of life beyond 12 weeks, which is known as **'Long COVID'**. People living with Long COVID suffer with a range of symptoms. However, they often feel 'abandoned' and 'dismissed' by healthcare providers and receive limited or conflicting advice.

The reason people get Long COVID is not well understood, and we do not know what the best treatment options are. There are research studies focusing on Long COVID in hospitalised patients. However, we need to understand more about the needs of people living with Long COVID who did not go to hospital.

Our research aims to understand people's experiences with COVID-19 and how this affects their life, compared to people who have not had COVID-19. We aim to recruit 4000 individuals who have previously had COVID-19 and 1000 similar individuals to compare against who have not had the infection. Our ultimate goal is to develop a remotely delivered intervention to support people with Long COVID symptoms.

Why have I been chosen?

Your GP identified you as being eligible to take part. You were randomly selected either because:

a) You have previously tested positive for COVID-19 and have not been hospitalised because of this (you don't need to have had Long COVID), or
b) You have *not* tested positive for COVID-19.

Do I have to take part?

No. It is up to you to decide if you wish to take part. Your participation is completely voluntary, and you can withdraw at any point if you change your mind during the study.

There is an option to express an interest to take part in a sub-study, which involves giving a blood sample and wearing a Garmin watch. You can choose on the consent form if you want to find out more about potentially taking part in this optional sub-study. However, not everyone who expresses an interest in the sub-study will be selected to take part.

What would taking part involve?

The study will last for **12 months**. You will be asked to complete a series of questionnaires **once a month** through either a website or an app called Atom5™ (developed by Aparito Ltd)**.**

The study will be done remotely and no face-to-face appointments are needed for the main study. **You can still take part even if you don't have a smart phone or access to the internet - more information is provided in the next section.**

If you take part, you will be asked to do the following:

<insert QR code>

1. **Either: A) Use the QR code to download the Atom5™ app** onto your smart phone or tablet, *or*
   B) Visit the website: https://tlc.atom5.co.uk/
2. **Log in:** Use the **Login details** from your **invitation letter**. For the app you will only need to enter your password, for the website you will need to enter your username and password.
3. **Give consent to take part in the study**: Follow instructions to consent to take part in the study. This involves agreeing to a series of statements on the consent form. Some parts of the study are optional. It is clear on the consent form which parts you would have to agree to, and which parts are optional.
4. **Complete a short demographic questionnaire:** This will include information such as your age, gender, ethnic group, and whether you have had the COVID vaccine. We will also ask for your name and contact details so that a research nurse can contact you if needed – providing this is optional.
5. **Complete questionnaires once a month, for 12 months:** The questionnaires take about 15 to 20 minutes to complete. They contain questions about symptoms, quality of life and impact on work/education. You will be sent reminder notifications for when you need to fill in your next questionnaire. You can access telephone and online support to help complete your questionnaires. Where possible, we will provide alternative language versions of each questionnaire.
6. ***Optional:* Give a blood and saliva sample and wear a Garmin device:** If you express an interest and are selected to take part in the sub-study, you will be sent another information sheet with more details at which point you can decide whether to take part. The blood and saliva sample would be a one off. You would be asked to wear the Garmin device for 4-weeks at the start of the study, for 4-weeks after 6 months and for 4-weeks after 12 months.

In addition, we will collect the following information from your GP practice medical records and linked hospital data: primary care consultations, prescriptions, A&E attendances and hospital admissions. This information will be collected for up to 12 months after you agree to take part in the study.

Questions you might want to ask

What happens if I want to take part but do not have access to an electronic device?

If you do not have access to an electronic device or are unable to use the app due to preference, language, or other requirements, please contact a member of the research team on the number provided at the bottom of this information sheet.

A nurse will then contact you by phone or video call with translators if required. The nurse will audio record your consent to participate (using an encrypted digital recorder), and a copy of the consent form will be posted to you. The questionnaires will then be completed over the phone or by video call and the nurse will record your answers on the Atom5™ database.

How do I download the Atom5™ app?

Download the app for free via Google Play or the App store. You can find it by searching for "Atom5". If you need support to download the app, please contact the Therapies for Long COVID (TLC) research nurses.

Telephone: 07766 070 945 (Covid Research Team)

E-mail: TLCstudy@contacts.bham.ac.uk

Will I be offered any support during the course of the study?

You will have access to telephone and online support to help complete your questionnaires.

If you report severe symptoms during the study, a research nurse may contact you to review your symptoms. This nurse-led support team can signpost to medical assistance but will not be able to provide direct medical care or aid. If you report severe symptoms and cannot be reached after three attempts over the course of 24 hours, we will contact your GP (if you have provided your GP details). You will be able to view a summary of your symptoms in Atom5™ app or website.

Please note that the data will not be seen by your GP or usual care team.

If you become concerned about your symptoms or experience a sudden deterioration in symptoms, we encourage you to discuss this with your GP or call 111. Support is also available from the Samaritans by ringing 116 123. **In an emergency, please dial 999.**

You may wish to refer to the NHS Your COVID Recovery website (https://www.yourcovidrecovery.nhs.uk) for more information on recovering from Long COVID.

What are the possible disadvantages or risks to taking part?

We anticipate minimal risks for participating in this study. However, some of the questionnaires contain sensitive questions which you may find upsetting, difficult or may lead you to recall challenging moments in your life. For example, questions about anxiety.

Taking part in the study and any answers you give in questionnaires will not negatively affect the quality of your treatment, care or legal rights. In addition to the support above, if any parts of the study become emotionally challenging or difficult to be involved in, you are free at any point to stop taking part with no explanation required.

Should you wish to disclose any challenging personal circumstances which are affecting your wellbeing, the research team will signpost you to receive support through 111 or in an emergency through 999. If your concerns are related to your personal safety, the research team may be duty bound to share your details with the relevant authority (e.g., Police) if necessary.

What are the possible benefits to taking part?

This study will help us understand people's experiences with COVID-19 and help develop an intervention to support people with Long COVID symptoms. You may find it rewarding to take part in research that may help us improve healthcare for people who have Long COVID.

Will I be paid to take part?

You will receive up to £20 in voucher codes to take part via the Atom5™ platform. You will get:

- £10 voucher code after you complete the first questionnaire
- £10 voucher code when you complete the final questionnaire (at 12 months).

If you are selected to take part in the sub-study, you can keep the Garmin device if you complete the sub-study.

What is Aparito?

Aparito Ltd is a global healthcare medical technology company, based in the United Kingdom (UK), who are providing the digital platform to collect data for our study.

How will we use information about you?

We will need to use anonymised information from you and from your medical records for this research project.

People will use this information to do the research or to check your records to make sure that the research is being done properly. You have the option of providing your

name and contact details to receive research nurse support and be invited for future related studies. 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 keep all information about you 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 you took part in the study.

Will my data be kept confidential?

The University of Birmingham is the sponsor for this study, based in the UK. We will be using information from you in order to undertake this study and we will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Birmingham will keep identifiable information about you for 10 years after the study has finished, even if you choose not to take part in future research, unless you withdraw from the study and request removal of your personal data.

Data collected from questionnaires, the Garmin wearable device and blood sample analysis will be stored on the Atom5™ platform. The data will be stored on an Azure Microsoft Cloud in the UK. Data will be transferred securely to the University of Birmingham under the provision of a data sharing agreement.

Once the study has ended and the data has been exported to the University of Birmingham, all Participant Identifiable Data (PID) stored on the Atom5™ platform will be deleted at the time of decommissioning and all data transferred to the University of Birmingham (study sponsor).

Everyone involved in this study will keep your data safe and secure. We will follow all privacy rules. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

In this study we will use information from your questionnaires and medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. People who do not need to know who you are will not be able to see your name or contact details.

Your personal information will only be used to contact you about the research study and only designated members of the research study team will have access to these personal details. The exception to this is that sometimes designated individuals from the University of Birmingham and regulatory organisations may look at your research records to check the accuracy of the research study.

Your test data will not have your name on it but will be linked to your personal details by your unique study number. Your information will be kept securely by both

organisations for 10 years. At the end of the study, we will save some of the data in case we need to check it and for future research. We will ensure that no one can work out who you are from the reports we write.

If you consent (optional) we may also share your data with other research groups with whom we collaborate in the UK, Europe, and the rest of the world (including the USA) including biotechnology companies, in line with the Data Protection Act 2018. All data will be associated with a unique code in place of personal details and so you will not be identifiable to them.

We need to manage your 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 you.

If you have any queries about how your data is being handled, you can contact the Sponsor's Data Protection Officer for handling policy queries: dataprotection@contacts.bham.ac.uk.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- at www.birmingham.ac.uk/privacy/index.aspx, or
- by asking one of the research team.

What happens if I change my mind and no longer want to take part in the study?

You can stop being part of the study at any time, without giving a reason. We will keep data collected about you up to the point that you withdraw from the study.

If you no longer wish to take part, please delete the app. Alternatively, contact the study team using the details at the end of this information sheet.

What happens if I lose my phone or accidentally delete the Atom5™ app and still wish to continue participating in the study?

You may telephone the research team and request a new password. However, you will need to provide your username for the new password to be issued so please keep a note of your username for future reference.

Who is organising and funding the research?

The study is sponsored, insured and co-ordinated by the University of Birmingham. The study is funded by the National Institute for Health Research (NIHR) and UK Research and Innovation (UKRI).

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 is approved by the Solihull Research Ethics Committee.

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

A group consisting of people who have experienced Long COVID are actively involved in supporting this study.

This group was involved in reviewing the documents for this study, including this Information Sheet. They have given feedback on the design of the study, in particular how to support people who do not have access to a smart device or the internet. The group continues to be involved in the study and provide valuable insight.

What if I have a complaint or have any further questions about how my information is used?

If you have any questions about any aspects of the study, please contact a member of the research team in the first instance. If the study team cannot resolve your query, it will be escalated to the Chief Investigator of the study.

If you wish to discuss the study with someone other than the study team, if you wish to raise any concerns about the study, or wish to make a complaint, contact **Dr Birgit Whitman** who is Head of Research Governance & Integrity at the University of Birmingham and is independent to this study:

Email researchgovernance@contacts.bham.ac.uk

Phone: +44 (0)121 415 8011

Will I receive any results from this study?

An overall summary of the study results will be made available to all participants when the study has completed.

THANK YOU for taking the time to read this information sheet

If you would like further information or would like to speak to someone about the study, please contact the Therapies for Long COVID (TLC) research nurses: **Email:** TLCstudy@contacts.bham.ac.uk

Phone: +44 (0)7766 070 945 (Covid Research Team)