

# Investigation of COVID-19 symptoms and potential immunity in the general population

<b>Submission date</b> 28/05/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/06/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/07/2020	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of April 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.

Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.

This study aims to track up to 90,000 individuals across England to provide scientists and national decision-makers with detailed information to help control and understand the COVID-19 pandemic. The study will investigate why some people have COVID-19 symptoms and others don't, and determine the risk factors for infection. It will help to determine the extent of infection in the general population and help to design new ways to prevent and treat such infections.

### Who can participate?

Individuals who participated in the INTERVAL, COMPARE or STRIDES BioResource studies

### What does the study involve?

Participants will be asked to provide monthly questionnaire information and a subset of willing participants will be asked to provide monthly fingerprick blood samples.

### What are the possible benefits and risks of participating?

There are no direct benefits to the study participants. The findings from this study will be

discussed with key government agencies responsible for helping with the COVID-19 pandemic (e.g., Public Health England). There is no risk associated with participation.

Where is the study run from?  
University of Cambridge (UK)

When is the study starting and how long is it expected to run for?  
March 2020 to June 2021

Who is funding the study?  
University of Cambridge (UK)

Who is the main contact?  
Unfortunately, this study is not recruiting public volunteers at this time. Please do not contact the research team as they will not be able to respond. For more information about COVID-19 research, visit the Be Part of Research homepage.

## Contact information

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Scientific

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Integrated Research Application System (IRAS)

283239

## Protocol serial number

2.0; IRAS 283239

# Study information

## Scientific Title

TRACK-COVID: a population-based epidemiological investigation of COVID-19 virus infection

## Acronym

TRACK-COVID

## Study objectives

To understand the frequency and evolution of symptoms compatible with COVID-19 and to define and monitor the evolution of population immunity by assay of biomarkers (e.g., IgG antibodies to SARS-CoV-2).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 04/05/2020, Nottingham Research Ethics Committee 2 (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8035, +44 (0)207 104 8103; nottingham2.rec@hra.nhs.uk), ref: 20/EM/0121

## Study design

Longitudinal observational study

## Primary study design

Observational

## Study type(s)

Screening

## Health condition(s) or problem(s) studied

COVID-19 (SARS-CoV-2 infection) symptoms and seroprevalence in the general population

## Interventions

Participants will be asked to provide monthly online questionnaire information for 12 months. The questionnaire will ask about COVID-19 related symptom experiences within last month, current medication as well as questions related to wellbeing. A subset of participants will be asked to provide a monthly blood sample (obtained at home via finger prick) for 12 months.

## **Intervention Type**

Other

## **Primary outcome(s)**

1. Symptoms compatible with COVID-19 measured using online questionnaire information monthly for 12 months
2. Population immunity measured using assay of biomarkers (e.g., IgG antibodies to SARS-CoV-2) on blood samples (obtained at home via finger prick) monthly for 12 months

## **Key secondary outcome(s)**

1. Asymptomatic or subclinical infections in the population measured using self-reported questionnaire data monthly for 12 months
2. Immunological evidence of previous SARS-CoV-2 infection measured using antibody tests monthly for 12 months
3. Risk factors for subsequent development of any, mild and severe COVID-19 like illnesses (correlates of protection) measured using self-reported monthly questionnaires with concurrent assessment of SARS-Cov-2 specific antibody levels monthly for 12 months
4. Duration of protection from COVID-19 like illness after confirmed infection, measured using SARS-Cov-2 specific antibody levels monthly for 12 months

## **Completion date**

06/06/2021

## **Eligibility**

### **Key inclusion criteria**

1. Have previously taken part in the INTERVAL, COMPARE or STRIDES studies
2. Have an email address for study participation
3. Reside in mainland England
4. Have a good understanding of the English language, both written and oral (study materials are not tailored to support non-English language speakers)

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

1. Have received three invitations from the INTERVAL/COMPARE/ STRIDES research study team to take part in other studies in the past year
2. Have withdrawn their consent to take part in the INTERVAL/COMPARE/STRIDES study

### **Date of first enrolment**

17/05/2021

**Date of final enrolment**

17/05/2021

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**The University of Cambridge**

Department of Public Health and Primary Care

Strangeways Research Lab

Worts Causeway

Cambridge

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## Sponsor information

**Organisation**

University of Cambridge

**ROR**

<https://ror.org/013meh722>

## Funder(s)

**Funder type**

Government

**Funder Name**

NIHR Blood and Transplant Research Unit in Donor Health and Genomics

**Funder Name**

Health Data Research UK (HDR UK)

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Sarah Fahle (donorhealth@medschl.cam.ac.uk). Data will be available to other researchers upon review of individual requests. All data will be anonymised.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes