Virus Watch: Understanding how COVID-19 spreads in the community, how sick people become, the types of symptoms they experience and what activities put people at risk of catching it

Submission date	Recruitment status No longer recruiting	Prospectively registered		
18/02/2021		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/03/2021 Last Edited	Completed Condition category	Results		
		[X] Individual participant data		
26/08/2022	Infections and Infestations	Record updated in last year		

Plain English summary of protocol

Background and study aims

The coronavirus (COVID-19) pandemic has caused large numbers of deaths and severe societal disruption worldwide. To respond and support the NHS and public health decision-makers, researchers need to know how many people become infected, how many of them become ill, what their symptoms are and how many seek health care. They also want to learn how commonly infected people transmit the virus to their household contacts, what proportion need hospitalisation and what proportion die. They need to understand how the population responds to this virus in terms of handwashing, behaviours during and after coughing, sneezing or nosewiping, and whether people restrict their movements and social contacts. Since many of those infected will have relatively mild symptoms and not seek medical advice the only way to accurately obtain this information is to conduct large scale community studies. The researchers will follow up members of the public and contacts of cases using regular online surveys of symptoms and behaviours, secure tracking of participant movements, and testing for COVID-19 and other respiratory infections to build a detailed picture of how the virus spreads and the population responds. They will share this data with participants, health service and public health planners and the general public to help minimise the impact of the virus.

Who can participate?

People of all ages and families from all backgrounds to take part so the researchers can understand how the virus affects different communities. They are recruiting whole households (all members need to agree in order to take part).

What does the study involve?

The researchers will collect information in regular online surveys from over 50,000 people in England and Wales from June 2020 to August 2021. 10,000 of these people will receive tests for immunity and swab tests when they have symptoms to tell if they have caught COVID-19.

What are the possible benefits and risks of participating?

There are no major risks in taking part in this study. Some people may find completing the questionnaires inconvenient – the researchers have tried to make these as simple as possible. Nose and throat swabs involve virtually no discomfort although some people may gag a little. Taking a blood sample may involve minimal discomfort and cause a small bruise in some people. The researchers will use experienced health care professionals to take blood. They cannot promise that the study will benefit participants individually but the information that they get will be vital for planning how to deal with the current COVID-19 and any future pandemics. Those taking part in the swabbing study will receive their test results to know if they have been infected with COVID-19. Those participants providing a blood sample will receive the results of the COVID-19 antibody tests.

Where is the study run from?
University College London in conjunction with the NHS (UK)

When is the study starting and how long is it expected to run for? April 2020 to April 2025

Who is funding the study?

- 1. National Institute for Health Research (UK)
- 2. UK Research and Innovation (UK)

Who is the main contact? Prof. Andrew Hayward a.hayward@ucl.ac.uk

Contact information

Type(s)

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

281933

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 45822, IRAS 281933

Study information

Scientific Title

Virus Watch: Understanding community incidence, symptom profiles, and transmission of COVID-19 in relation to population movement and behaviour

Acronym

Virus Watch V1

Study objectives

The study does not have a main hypothesis, rather it is designed to describe the clinical features and risk factors for COVID-19 in England and Wales.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 21/05/2020, London - Hampstead Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8345, +44 (0)207 104 8328; hampstead.rec@hra.nhs.uk), REC ref: 20/HRA/2320

Study design

Observational; Design type: Cohort study

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

COVID-19 (SARS-CoV-2 infection)

Interventions

In addition to regular online surveys throughout the study, participants will be invited to follow different schedules of antibody testing and nasal/throat swabs for PCR testing. Virus Watch is an open cohort so the duration of observation and follow up will vary, but the study started in June 2020 and at present is set to end in August 2021 but it is likely that this will be extended.

Intervention Type

Other

Primary outcome(s)

Study 1: Online survey cohort:

- 1. Incidence of respiratory infection symptoms, including COVID-19 disease case definitions measured using self-reported weekly questionnaires (June 2020-August 2021)
- 2. Effectiveness and impact of recommended COVID-19 control measures including testing, isolation, social distancing, respiratory and hand hygiene measures on the risk of respiratory infection measured using self-reported baseline, weekly and monthly questionnaires, self-reported antigen data (June 2020-August 2021)
- 3. Frequency of adherence with public-health recommendations for these control measures measured using self-reported baseline, weekly and monthly questionnaires (June 2020-August 2021)
- 4. Proportion of community infections that result in hospital admissions and death measured using self-reported baseline, weekly and monthly questionnaire (June 2020-August 2021) and linked data quarterly and up to 5 years after the study ends
- 5. Vaccine effectiveness against asymptomatic and symptomatic infections measured using self-

reported baseline, weekly and monthly questionnaires self-reported antigen results (June 2020-August 2021), finger-prick antibody data (Feb-Aug 2021), linked data quarterly and up to 5 years after the study ends

Study 2: Laboratory testing sub-cohort:

- 1. Incidence of PCR-confirmed COVID-19 measured using Virus Watch laboratory antigen data (December 2020-May 2021) and self-reported antigen results (June 2020-Aug 2021), and linked data quarterly and up to 5 years after the study ends
- 2. Incidence of PCR-confirmed COVID-19 in those with non-respiratory presentations measured using Virus Watch laboratory antigen data (December 2020-May 2021) and self-reported antigen results (June 2020-Aug 2021)
- 3. Incidence of hospitalisation among PCR-confirmed COVID-19 cases measured using Virus Watch laboratory antigen data (December 2020-May 2021) and linked hospital data quarterly and up to 5 years after the study ends
- 4. Proportion of individuals with SARS-CoV-2 antibodies acquired through natural infection to pandemic coronavirus measured using Virus Watch collected whole blood and finger-prick antibody test data (October 2020-August 2021)
- 5. Proportion of individuals with cross-reacting antibodies to seasonal coronaviruses acquiring (or not) SARS-CoV-2 measured using Virus Watch laboratory self-reported weekly and monthly questionnaires (June 2020-Aug 2021) and Virus Watch laboratory antibody data (Oct 2020-August 2021).
- 6. Household secondary attack rates measured using self-reported weekly and monthly questionnaires and Virus Watch antigen and antibody results (December 2020-August 2021), linked data quarterly
- 7. Protective effect of antibodies on infection and re-infection as well as the severity and spectrum of presentation, measured using self-reported baseline, weekly and monthly questionnaires (June 2020– August 2021) and Virus Watch laboratory antigen and antibody data (October July 2021), finger prick antibody data (Feb-Aug 2021) and linked hospital data quarterly

Key secondary outcome(s))

There are no secondary outcome measures

Completion date

30/04/2025

Eligibility

Key inclusion criteria

- 1. Households self-select into the study
- 2. Participants need to join as a household (all must take part)
- 3. They need to have internet connection and email
- 4. At least one person in the household can read English

Participant type(s)

All

Healthy volunteers allowed

No

Age group

Sex

All

Key exclusion criteria

- 1. Number of householders exceeds 6
- 2. Those without an internet connection or an email address available to them as they will be unable to register
- 3. There is no adult in the household who can read English

Date of first enrolment

22/06/2020

Date of final enrolment

01/01/2022

Locations

Countries of recruitment

United Kingdom

Study participating centre

Virus Watch is working with NIHR Local Clinical Research Networks (and the equivalent in Wales) for the blood taking aspect of the laboratory cohort and for some participant recruitment (SMS, letters sent via GP clinics)

United Kingdom

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Sponsor information

Organisation

University College London

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

UK Research and Innovation

Alternative Name(s)

UKRI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Protocol article		23/06/2021	24/08 /2022	Yes	No
<u>Dataset</u>			24/08 /2022	No	No

HRA research summary			28/06 /2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11 /2025	No	Yes
Protocol (preprint)	non-peer-reviewed protocol in preprint	16/12/2020	08/03 /2021	No	No
Study website	Study website	11/11/2025	11/11 /2025	No	Yes