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COVID-19 infection survey of the UK general population

Submission date	Recruitment status	[_] Prospectively registered
13/09/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/09/2020	Ongoing	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/03/2023	Infections and Infestations	

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 had spread to many countries around the world and neither a vaccine against the virus nor specific treatment for COVID-19 had been developed. As of April 2020, it was advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus. Since then, multiple phases of vaccinations have been rolled out, restrictions have been lifted, and many people have returned to their usual daily activities with increased social contact.

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.

The COVID-19 pandemic has had, and continues to have, a profound impact across the UK. This study aims to find out how many people are still getting the infection and how many are likely to have had the infection, even if they haven't realised it at the time. This is particularly important as more people have now had multiple vaccinations against COVID-19. Although the vaccines work very well, they are not 100% protective, and it is necessary to monitor how well they work in the real-world.

One way to find out whether a person has an infection is to directly look for the microbe in their nose and throat. The main test used to diagnose COVID-19 uses a swab taken from someone's nose and throat. Once an individual has recovered from the infection, the virus cannot be found any longer. One way the body fights infections like COVID-19 is by producing small particles in the blood called "antibodies". It takes 2-3 weeks for the body to make enough of these antibodies to fight the infection. But once a person recovers, they still stay in the blood at low levels and give some protection against further infection. Getting vaccinated against COVID-19 is another way that people can get antibodies that can protect them against getting COVID-19.

Therefore scientists try to measure levels of both the virus and these antibodies to work out who has COVID-19 now (with or without symptoms) and who has had it in the past, or had developed antibodies against it after getting vaccinated.
The aim of this study is to find out how many people of different ages across the UK have COVID-19 over time, particularly as people have returned to work or school and as more and more people get multiple vaccinations, and how many have had COVID-19 in the past. The researchers will do this by testing for the virus in the nose and throat of people and by measuring levels of antibody in the blood. They also want to find out how many people have COVID-19 with symptoms or without knowing they have the infection because they don't have any symptoms. They want to do this in a group of people that reflects the population of the UK – so a range of ages and places where people live.

Who can participate?
Randomly selected households from all four countries of the UK have been invited to participate over the course of the study (see participant inclusion criteria section). We are not actively recruiting new participants at this time.

What does the study involve?
The researchers will ask everyone aged 2 years or older in each randomly selected household to have a nose and throat swab, and for those aged 12 years and older to answer a few short questions (parents/carers will answer for younger children). Until May 2022, this was done at a home visit undertaken by a trained individual. From July 2022, sample kits are posted to all participants, with questions being completed online or over the telephone. Those aged 12 years and older can take their own swabs using self-swabbing kits, and parents/carers will use the same kits to take swabs from their children aged 2-11 years. Adults and children aged 8 and over in a subset of these enrolled households are invited to also give a sample of blood, taken by a finger prick by the participants themselves. Posting sample kits to participants means swab and blood samples can be collected at every month, including in households where anyone has symptoms or is isolating/shielding.

The researchers will ask everyone joining the study to do the tests, and complete the questionnaire every week for the first month and then every month until the study ends. This is to find out how rates of infection and immunity change over time in individual people, and whether they can get the virus again with or without having symptoms. Participants are also followed up through their electronic health records for up to 15 years from their final study assessment. Consent for this electronic follow-up is required to join the study.

What are the possible benefits and risks of participating?
The possible benefits are that participants will get results from tests for SARS-CoV-2 that would not usually be done. This includes nose and throat swab test results for all participants and S-antibody blood test results for those invited to give a sample of blood. A small amount of compensation will be offered to each participant per assessment, to reflect their time and inconvenience. We will offer participants the option not to receive this compensation if they prefer.
The main disadvantage of taking part is the time and inconvenience of having to take samples and complete the questionnaire and either return them to a priority post box or organise a courier collection from home. When blood is taken from a finger prick, participants may need to prick several fingers to get enough blood and fingers may be sore. There is also a possibility of fainting.

Where is the study run from?
Office for National Statistics and the University of Oxford (UK), and delivered by IQVIA.

When is the study starting and how long is it expected to run for?
Assessments will be conducted from April 2020 to March 2023; follow-up through electronic health records will be through March 2038.

Who is funding the study?
Funding for the survey in England, Wales, Northern Ireland and Scotland is provided by the UK Health Security Agency and the Department of Health and Social Care, as agreed with the Treasury. In-kind support is provided by the Welsh Government, the Department of Health on behalf of the Northern Ireland Government, the Scottish Government, the Office for National Statistics, the Northern Ireland Statistics and Research Agency, the University of Oxford (in particular through the Oxford National Institutes of Health Research (NIHR) Biomedical Research Centre and the NIHR Health Protection Research Unit in Antimicrobial Resistance and Healthcare-Associated Infections in collaboration with the UK Health Security Agency [NIHR200915]).

Who is the main contact?
This study is not recruiting at this time. Please do not contact the research team as they will not be able to respond.

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
283248

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
CPMS 46962, IRAS 283248

Study information

Scientific Title
Incidence of COVID-19 (SARS-CoV-2) infection and prevalence of immunity to COVID-19 (SARS-CoV-2) in the UK general population as assessed through repeated cross-sectional household surveys with additional serial sampling and longitudinal follow-up - an Office for National Statistics Survey

Acronym
CIS

Study objectives
The main aims of this observational study are
1. To estimate the prevalence of symptomatic and asymptomatic SARS-CoV-2 infection in the general population and how this varies over time
2. To estimate the incidence of new symptomatic and asymptomatic SARS-CoV-2 infection in the general population, and how this varies over time
3. To estimate immunity to SARS-CoV-2 in the general adult population and how this varies over time, as reflected by immunoglobins

Added 28/02/2023:
4. To estimate the association between the prevalence of symptomatic and asymptomatic infection in individual members of households
5. To estimate the association between immunity to SARS-CoV-2 across individual members of households

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/04/2020, Berkshire B Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 1048310; berkshireb.rec@hra.nhs.uk), REC ref: 20/SC/0195

Study design
Surveillance study based on repeated cross-sectional surveys of representative households across the UK, with nested longitudinal serial sampling of participants providing additional optional consent for this

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
Current interventions as of 28/02/2023:
Consenting adults, adolescents and children aged 2 years or older in randomly selected households will self-swab their throat and nose and answer some short questions either at a home visit by a trained individual (through July 2022) or, from July 2022, online or over the telephone with sample test kits posted and returned by post or courier. A random percentage of households will also be approached for additional consent for blood draws in those aged 16 years or over. Each participant will complete questionnaires and return samples weekly for one month from enrolment and then monthly until the end of the study. All participants will provide follow-up through available routine electronic health records for up to 15 years from their final study assessment to evaluate use of healthcare, results from tests for COVID-19 infection done within the NHS and equivalent bodies in Devolved Administrations, and mortality.

Previous interventions:
Consenting adults, adolescents and children aged 2 years or older in randomly selected households will self-swab their throat and nose and be asked some short questions by a survey team member. A random percentage of households will also be approached for additional consent for blood draws in those aged 16 years or over. Depending on the consent/assent provided by each individual participant, their involvement may be (i) for one home visit only (cross-sectional survey) (ii) for five home visits (cross-sectional survey then optional to repeat visits every week for the next month) or (iii) for 16 home visits (cross-sectional survey then optional to repeat visits every week for the next month and then monthly for a total of 12 months from the first visit). All participants will provide follow-up through available routine electronic health records for one year from their final study visit to assess use of healthcare, results from other tests for COVID-19 infection and mortality.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 28/02/2023:
Presence vs absence of SARS-CoV-2 virus assayed from a nose and throat swab using a polymerase chain reaction (PCR) test, every calendar day from the start of the study until study end (note: the outcome measure is at the population level, not the individual level as this is a surveillance study), with analysis based on continuous time and the latest test available in the prior 2 weeks.

Previous primary outcome measure:
Presence vs absence of SARS-CoV-2 virus assayed from a nose and throat swab using a polymerase chain reaction (PCR) test, every calendar week from the start of the study for 1 year (note: the outcome measure is at the population level, not the individual level as this is a surveillance study)

Key secondary outcome(s))
Current secondary outcome measures as of 28/02/2023:
1. Incidence of new presence of SARS-CoV-2 virus measured from a nose and throat swab using a PCR test, separately in previously negative and previously virus-positive individuals (to estimate re-infection after clearing the virus), every calendar day from the start of the study until study

end
2. Immunity to SARS-CoV-2 measured from blood using an enzyme-linked immunosorbent assay for IgG antibodies, every calendar day from the start of the study until the study end, with analysis based on continuous time and the latest test available in the last month.
3. Presence or absence of SARS-CoV-2 virus assayed from nose and throat swabs taken from different members of the same household, for each household visit
4. Concentrations and thresholds of IgG to SARS-CoV-2 assayed from the blood of different members of the same household, for each household visit
5 Inpatient admissions measured from centrally stored hospital records (Hospital Episode Statistics) up to 15 years from the final study visit
6. Outpatient attendances measured from centrally stored hospital records (Hospital Episode Statistics) up to 15 years from the final study visit
7. A&E attendances measured from centrally stored hospital records (Hospital Episode Statistics) up to15 years from the final study visit
8. Consultations with a General Practitioner measured from centrally stored hospital records (Hospital Episode Statistics) up to 15 years from the final study visit
9. Overall mortality and cause of death as measured from centrally stored records (Office for National Statistics) up to 15 years from the final study visit

Previous secondary outcome measures:
1. Incidence of new presence of SARS-CoV-2 virus measured from a nose and throat swab using a PCR test, separately in previously negative and previously virus-positive individuals (to estimate re-infection after clearing the virus), over calendar time from the start of the study for 1 year
2. Immunity to SARS-CoV-2 measured from blood using an enzyme-linked immunosorbent assay for IgG antibodies, over calendar time from the start of the study for 1 year
3 Inpatient admissions measured from centrally stored hospital records (Hospital Episode Statistics) over 1 year from the final study visit
4. Outpatient attendances measured from centrally stored hospital records (Hospital Episode Statistics) over 1 year from the final study visit
5. A&E attendances measured from centrally stored hospital records (Hospital Episode Statistics) over 1 year from the final study visit
6. Consultations with a General Practitioner measured from centrally stored hospital records (Hospital Episode Statistics) over 1 year from the final study visit
7. Overall mortality and cause of death as measured from centrally stored records (Office for National Statistics) over 1 year from the final study visit

Completion date
31/03/2038

Eligibility

Key inclusion criteria
1. Adult, adolescent or child aged 2 years or older, male or female
2. Currently resident in a household where a household member has participated in an ONS or NISRA Survey and has consented to be approached for future research or where the household has been randomly selected from databases of addresses. ‘Currently resident’ is defined according to 2011 Census definitions, specifically, a ‘resident’ is defined as a person who typically stays overnight in the address at least 4 nights out of 7 and a ‘household’ is defined as one person living alone; or a group of people (not necessarily related) living at the same address who share cooking facilities and share a living room or sitting room or dining area
3. If 16 years or older: Participant is willing and able to give informed consent for participation in

the study.
4. If 2-15 years at last birthday: A parent/carer is able to give informed consent for participation in the study; those aged 10 years and older should also provide assent.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
535751

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
26/04/2020

Date of final enrolment
31/01/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Office for National Statistics
1 Drummond Gate
Pimlico
London
United Kingdom
SW1V 2QQ

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Department of Health and Social Care

Alternative Name(s)
Department of Health & Social Care, DH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
UK Health Security Agency

Results and Publications

Individual participant data (IPD) sharing plan
De-identified study data are available for access by accredited researchers in the ONS Secure Research Service (SRS) for accredited research purposes under part 5, chapter 5 of the Digital Economy Act 2017. Individuals can apply to be an accredited researcher using the short form at https://researchaccreditationservice.ons.gov.uk/ons/ONS_registration.ofml. Accreditation requires the completion of a short free course on accessing the SRS. To request access to data in the SRS, researchers must submit a research project application for accreditation in the Research Accreditation Service (RAS). Research project applications are considered by the project team and the Research Accreditation Panel (RAP) established by the UK Statistics Authority at regular meetings. Project application example guidance and an exemplar of a research project application are available. A complete record of accredited researchers and their projects is published on the UK Statistics Authority website to ensure transparency of access to research

data. For further information about accreditation, contact Research.Support@ons.gov.uk or visit the SRS website.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Interim results article	interim results for April to November	01/01/2021	16/12/2020	Yes	No
Participant information sheet			13/03/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results	non-peer-reviewed results on prevalence of new variant in preprint	15/01/2021	19/03/2021	No	No
Preprint results	non-peer-reviewed results	09/06/2021	11/06/2021	No	No
Preprint results	non-peer-reviewed results	16/09/2021	21/09/2021	No	No
Preprint results	non-peer-reviewed results of the behavioural effects of COVID-19 vaccination in the UK	16/11/2021	19/11/2021	No	No
Protocol (other)			13/03/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes