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Study of children and young people who may be experiencing long COVID

Submission date	Recruitment status	[_] Prospectively registered
05/04/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/04/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/09/2025	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.
It seems that some children and young people remain ill for a long time after infection with the COVID virus. They are said to have 'long COVID'. Doctors don't know how to diagnose long COVID, how common it is or how long it goes on for. There is no simple test for long COVID. Doctors need to know more about it if they want to treat it. In this study the researchers are approaching children and young people who had a COVID test to see whether they have health problems at 3, 6,12 and 24 months after the infection. They will compare any problems of those who had a positive COVID test with those who didn't test positive. They can then agree on what is a medical diagnosis of long COVID and how they might treat it.

Who can participate?
Children and young people aged 11-17 who have had a recorded positive SARS-CoV-2 test and matched 11-17-year-olds who have had a recorded negative SARS-CoV-2 test

What does the study involve?
Parents and children are asked to go onto the study website and fill out some information and sign a consent form. The child is then asked to complete questionnaires online two or three times over the next 24 months. Each time would take about 20 minutes. The questions do not need to be completed all in one go. The researchers will contact when the child is due to complete the next set of questionnaires. The questionnaires ask about physical and mental health. After completing the final questionnaire, the child will receive a £25 voucher.

What are the possible benefits and risks of participating?
The researchers want to better understand COVID so that they can help people who are having symptoms get the help they need early. They will provide information about where to get help for health problems if needed. Answering questions about health can be difficult for some

children and young people but there are no specific risks from taking part in the study. Children and young people will not be deprived of any treatment that they should receive as a result of taking part in this study.

Where is the study run from?
Public Health England (UK)

When is the study starting and how long is it expected to run for?
February 2019 to May 2023

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Michael Lattimore
Clock@phe.gov.uk

Unfortunately, this study is not recruiting public volunteers at this time. This is because the research isn't ready for volunteers yet or the researchers are directly identifying volunteers in certain areas or hospitals. 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

Type(s)
Public

Contact name
Mr Michael Lattimore

Contact details
Public Health England
61 Colindale Avenue
London
United Kingdom
NW9 5EQ
-
Clock@phe.gov.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
293495

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 293495, CPMS 48927

Study information

Scientific Title
Children and young people with long COVID (CLoCk) study

Acronym
CLoCk

Study objectives
Tracking the impact of COVID-19 on the mental health of children, young people and families.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/03/2021, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8079; southyorks.rec@hra.nhs.uk), REC ref: 21/YH/0060

Study design
Longitudinal cohort study

Primary study design
Observational

Study type(s)
Quality of life

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

Interventions
Setting/population:
Public Health England (PHE) has been conducting national surveillance of SARS-CoV-2 since the start of the pandemic in England. PHE receive daily electronic notifications of all SARS-CoV-2 RT-PCR tests performed in healthcare settings (Pillar 1 tests) and in the community (Pillar 2 tests) and the results of their test through the Second Generation Surveillance System (SGSS). Information within the SGSS reports includes NHS number, name, age, sex, postcode, date of sample, reporting laboratory and test result. PHE also has access to the electronic Patient Demographic Service (PDS), which contains the names, addresses and status (alive/dead) of all patients registered with the NHS.
For this study 15,000 children and young people (CYP) 11-17 years old when tested positive for SARS-CoV-2 during 3 individual months separated by 3-month intervals (Sept 2020, Dec 2020, Mar 2021) and the same number matched for age, sex and region identified through SGSS will be linked to PDS using available identifiers and their postal addresses received. These will then be

used to write a letter that will be posted to them, informing them about the study and inviting them to take part using an online link. This link will provide them with information about the study, an option to consent online and complete a short recruitment questionnaire

Design:
A longitudinal cohort of SARS-CoV-2 positives aged 11-17 years compared with age, sex and region matched SARS-CoV-2 test negative controls ('cohort-analytic' study), identified by PHE.

Sample:
Eligible participants will be those that have had a COVID-19 test between 01/09/2020 and 28/02/2021. Participants will be recruited in a ratio of 1:1:2 with twice as many participants being recruited in months January and February compared to September-October, and November-December in order to reduce recall bias.

Using the PHE COVID tests conducted between the months of September 2020 and March 2021, the researchers plan to construct two groups of 10,000 CYP (5,000 positive tests and 5,000 negative). This sample, potentially captured within specified monthly time frames of 5,000 "exposed" and 5,000 "unexposed", will be contacted, anticipating recruiting 20% in each group, as estimated by CYP recruitment rates in other PHE studies on COVID-19 (sKIDs; Ladhani, 2020). The researchers do not anticipate that CYP (except perhaps small numbers at high risk) will have received mass COVID vaccination by Mar 2021 although of course test positive rates may fall as a result of social distancing and the initial vaccination of healthcare workers and older and high-risk adults.

Families of CYP within these cohorts will be contacted 6, 12 and 24 months after the CYP's SARS-CoV-2 test (depending on recruitment month) and invited to take part in the study. With online informed consent, the CYP will self-complete an online questionnaire about their mental and physical health. CYP towards the lower end of the 11-18 age band and CYP with SEN or disability may require the help of a carer.

Intervention Type
Other

Primary outcome(s)
1. Physical symptoms assessed using a checklist based on items from the ISARIC Paediatric COVID-19 questions at any or all of 3, 6, 12 and 24 months post-COVID test depending on the time of test
2. Emotional and mental health measured using the Strengths and Difficulties Questionnaire at any or all of 3, 6, 12 and 24 months post-COVID test depending on the time of test
3. Quality of life/functioning measured using the EQ-5D-Y at any or all of 3, 6, 12 and 24 months post-COVID test depending on the time of test
4. Fatigue measured using the Chalder Fatigue Questionnaire at any or all of 3, 6, 12 and 24 months post-COVID test depending on the time of test
5. Wellbeing assessed using the short version of the Warwick Edinburgh Mental Wellbeing Scale (WEMWBS) at any or all of 3, 6, 12 and 24 months post-COVID test depending on the time of test
6. Loneliness assessed using the adapted UCLA 4 items at any or all of 3, 6, 12 and 24 months post-COVID test depending on the time of test

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
09/05/2023

Eligibility

Key inclusion criteria
1. Participants must be aged 11-17 years and have had a recorded positive SARS-CoV-2 test
2. These will be matched by age, sex and region to include 11-17-year-olds who have had a recorded negative SARS-CoV-2 test (negative controls)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Child

Lower age limit
11 years

Upper age limit
17 years

Sex
All

Total final enrolment
6804

Key exclusion criteria
Age range outside of study design

Date of first enrolment
12/04/2021

Date of final enrolment
30/04/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Public Health England
61 Colindale Avenue
London
United Kingdom
NW9 5EQ

Sponsor information

Organisation
NIHR Academy

ROR
https://ror.org/02nv4he32

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

Results and Publications

Individual participant data (IPD) sharing plan
Data is being collected on an online secure survey hosted by PHE. The survey requests consent for participation.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/02/2022	11/02/2022	Yes	No
Results article		04/01/2023	06/01/2023	Yes	No
Results article		29/09/2025	30/09/2025	Yes	No
Protocol article		26/08/2021	31/08/2021	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Child 11-15		19/04/2021	No	Yes
Participant information sheet	Child 16-18		19/04/2021	No	Yes
Participant information sheet	Parent/Carer		19/04/2021	No	Yes
Preprint results		10/08/2021	30/09/2021	No	No