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COVID-19 testing and infection control in schools

Submission date
02/10/2020

Recruitment status
No longer recruiting

Registration date
13/10/2020

Overall study status
Completed

Last Edited
02/09/2021

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 March 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 will meet the urgent need for surveillance and reduction of COVID-19 in schools in light of their re-opening in September 2020, which poses a major challenge due to the likelihood of cases showing no symptoms, the high number of contacts, the presence of vulnerable persons, and the potential for rapid onward transmission to family contacts of children and staff.

Who can participate?
Pupils and staff attending or employed at primary and secondary schools that are selected to participate in the study

What does the study involve?
Participants will be tested for COVID-19 infection and history of COVID-19 infection using saliva tests. Where an infection is identified, the researchers will invite the household to participate in a follow-up study in which they will test members of the household and close contacts weekly for 4 weeks. The researchers will undertake environmental surveillance by swabbing surfaces in schools. In partnership with the University of Middlesex they will undertake a study of COVID-19 viral RNA in wastewater sampled twice weekly from participating schools.

What are the possible benefits and risks of participating?
The benefits of participating in this study are that individuals, families and schools will have a clearer picture of the current and recent infection levels of COVID-19. Processes that help to prevent infection spreading will be developed and tested in the school setting, giving parents, teachers and pupils more confidence that schools are safeguarded, as far as is possible, against infection spread. The main risk for participants is the social and financial burden of household isolation, in line with current Public Health England infection control procedure, in the event of a positive test result for current COVID-19. The study team and Public Health England will provide affected individuals and households with information and guidance in line with current public health protection measures. The high degree of specificity and sensitivity of the saliva-based test for current COVID-19 infection means that the risk of false-positive results is very low.

Where is the study run from?
Bristol Medical School (UK)

When is the study starting and how long is it expected to run for?
September 2020 to March 2022

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Unfortunately, this study is not recruiting public volunteers at this time. This is because the researchers are directly identifying volunteers in participating schools. 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.

Study website
https://commins.org.uk/

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
290071

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 290071

Study information

Scientific Title
COVID-19 Mitigation and Mapping in Schools (CoMMinS)

Acronym
CoMMinS

Study objectives
CoMMinS is a broad programme of research, funded by a £2.8M grant from the MRC (ref: MR /V028545/1) and badged as Urgent Public Health Research by the Chief Medical Officer. It will meet the urgent need for mapping and mitigation of COVID-19 in schools in light of their re-opening in the autumn term 2020. Schools pose a major challenge for infection control, due to the likelihood of cases being asymptomatic, the high number of contacts, the presence of vulnerable persons, and the potential for rapid onward transmission to family contacts of children and staff. These challenges must be weighed against the benefits of resuming children's

education, peer interaction and social development. A deeper understanding of infection history and dynamics and enhanced mitigation measures will inform outbreak control and future pandemic resilience.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/10/2020, City and East Research Ethics Committee (Whitefriars, Level 3 Block B, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8171; cityandeast.rec@hra.nhs.uk), ref: 20 /HRA/4876

Study design
Observational epidemiological study

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
The researchers will undertake a large-scale mapping study of prior and current COVID-19 infection in pupils and staff, including prospective testing over 6 months, to dramatically enhance the understanding of infection patterns in this age group. Results will be mapped to home postcode location and linked to NHS system-wide data to highlight area-based and individual-level risk factors. Where an infection is identified, the researchers will invite the household to participate in a follow-up study in which they will test members of the household and close contacts weekly for 4 weeks. They will undertake environmental surveillance via swabbing of surfaces within schools. In partnership with the University of Middlesex they will undertake a study of COVID-19 viral RNA in wastewater effluent autosampled twice weekly from participating schools. To mitigate against infection transmission the researchers will adapt evidence-based digital tools and co-create whole-school interventions to support positive infection control practices by staff, parents and pupils. They will co-design and develop a system to collate multiple information sources to augment contact tracing and facilitate outbreak control. They will explore the impact of returning to school for staff and pupils' mental wellbeing, their attitudes towards actions taken to mitigate the spread of COVID-19, and potential interventions to address identified difficulties.

1. Saliva-based viral RNA PCR test. PCR for SARS-Cov-2 (multiplex E and N protein) will be carried out on saliva, to identify current COVID-19 infection. PCR samples will initially be pooled into groups to batch test and ensure rapid throughput. This assay has been robustly validated and the researchers are currently in the process of seeking NHS England and Public Health England accreditation. They do not intend to commercialise this test and therefore will not be seeking a CE Mark for it.
2. Saliva-based antibody test. Salivary IgA and IgG to SARS-Cov-2 spike and/or nucleocapsid will be tested on individual samples using an ELISA-based platform, to identify prior COVID-19 infection. This test is currently a research tool which will be evaluated during the course of the study.
3. Viral RNA genome sequencing will be undertaken on COVID-19 positive samples from the CoMMinS study. This will provide information on the phylogeny of the virus and generate valuable information on the degree of independence of the infection events as well as patterns of transmission in the study population.

Intervention Type
Other

Primary outcome measure
1. Prevalence of current COVID-19 infection in the sample population measured by saliva-based viral RNA PCR test at a single timepoint
2. Prevalence of prior COVID-19 infection as determined by saliva-based antibody test salivary IgA and IgG at a single timepoint

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/09/2020

Completion date
31/03/2022

Eligibility

Key inclusion criteria
1. Pupils and staff attending or employed at primary and secondary schools that are selected to participate in the study
2. Staff who complete a consent form and an online questionnaire
3. Pupils whose parents or guardians complete an online consent form and an online questionnaire

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
1,000 school staff and 5,000 children

Key exclusion criteria
1. Adults who lack capacity to consent
2. Children who attend a school for Special Educational Needs and Disabilities (SEND) and children attending Nursery Schools (additional ethical approval will be requested for these settings as a subsequent amendment to this application as a modified protocol will be required)

Date of first enrolment
23/11/2020

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Medical School
Canynge Hall
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United Kingdom
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Sponsor information

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University of Bristol

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Sponsor type
University/education

Website
http://www.bristol.ac.uk/red/

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in high impact peer-reviewed international journals. The protocol is available and can be provided on direct request to the study team.

Intention to publish date
01/09/2021

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?
HRA research summary			26/07/2023	No	No