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Classroom air cleaning technology study

Submission date
03/03/2022

Recruitment status
No longer recruiting

Registration date
11/03/2022

Overall study status
Completed

Last Edited
07/03/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English Summary

Background and study aims
The COVID-19 pandemic has wreaked havoc upon the education of a whole generation of school children. It is estimated that school children have lost at least a half of an academic year due to the pandemic. Education analysts have assessed the numbers of children achieving or exceeding the expected level for their age in reading, writing and maths compared with pre-pandemic scores.
Whilst rates of transmission of COVID-19 have dropped during the summer months there is a high risk that if no action is taken to mitigate airborne transmission, the risk of infection is likely to increase again in the autumn and winter seasons. The result being further school closures.
The aim of this study is to conduct an early phase trial of two air cleaning technologies with a focus on feasibility and practical implementation. The air cleaning technologies have the potential to mitigate the aerosol transmission of viral particles - including the SARS-CoV-2 virus - within schools. This study seeks to explore the practicalities and possible benefits of fitting schools with these technologies.

Who can participate?
The study will be conducted within 30 primary schools in Bradford, UK.

What does the study involve?
The study will have three arms: a control arm and two intervention arms; one with installation of portable high efficiency particulate air (HEPA) filter units, and the other with installation of germicidal ultraviolet (GUV) devices.

What are the possible benefits and risks of participating?
There is a potential benefit for children and staff within the schools with air cleaning technology (i.e. reduced infection from air bourne illness) but this remains to be determined. There are little to no risks associated with the research (the worse case scenario is a data breach that would reveal data – schools absences – that are already collected within the Local Authority).

Where is the study run from?
The study is run from the Centre for Applied Education Research which is based at the Bradford Teaching Hospitals NHS Foundation Trust, UK.

When is the study starting and how long is it expected to run for?
January 2021 to September 2022

Who is funding the study?
The study is funded by the Department for Health and Social Care (UK)

Who is the main contact?
Prof. Mark Mon-Williams, M.Mon-Williams@leeds.ac.uk

Study website
https://caer.org.uk/air-cleaning-technologies/

Contact information

Type(s)
Principal Investigator

Contact name
Prof Mark Mon-Williams

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
BTHFT 2662

Study information

Scientific Title

Phase 1 trial of COVID-19 airborne transmission prevention technologies

Acronym
Class-ACT

Study hypothesis
Air Cleaning Technologies reduce the transmission of COVID-19 in school pupils and staff

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/12/2021, School of Psychology Research Ethics Committee (School of Psychology, University of Leeds, LS2 9JT, UK; +44 113 343 5724; G.S.Finlayson@leeds.ac.uk), ref: PSYC-414

Study design
Multi centre randomized controlled trial of environmental interventions

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to reuest a particpant information sheet

Condition
Prevention of COVID-19 transmission in school pupils and staff

Interventions
This study will be an early phase trial of two air cleaning technologies with a focus on feasibility and practical implementation. This study seeks to explore the practicalities and possible benefits of fitting schools with these technologies in order to mitigate the aerosol transmission of viral particles -including the SARS-CoV-2 virus. The study will be conducted within 30 primary schools in Bradford, UK.

The study will have three arms: a control arm and two intervention arms; one with the installation of portable high-efficiency particulate air (HEPA) filter units, and the other with the installation of germicidal ultraviolet (GUV) devices. Participating schools will be randomly allocated to each arm.

Randomisation process: Schools names were drawn from a bag

Intervention & follow up length: 1st August 2021 – 1st August 2022

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
portable high-efficiency particulate air (HEPA) filter units, germicidal ultraviolet (GUV) devices

Primary outcome measure
School absences for COVID-19 measured using anonymised data contained in schools information management systems and relayed to Local Authority at weekly intervals

Secondary outcome measures
1. CO2, humidity, PM2.5 & PM10 levels in classrooms measured through air monitoring devices at 60 second intervals and relayed via API.
2. Power usage levels for HEPA devices measured through power consumption monitoring devices at 60 second intervals and relayed via API.
3. Primary and secondary Care level data will be collect via Connected Yorkshire data set at weekly intervals. The Connected Yorkshire programme links disparate routine electronic data in an anonymised database across primary care, secondary care, community care and social care for over 700,000 individuals at Bradford Teaching Hospitals NHS Foundation Trust.

Overall study start date
05/01/2021

Overall study end date
30/09/2022

Eligibility

Participant inclusion criteria
1. Primary school
2. 5 - 11 year-old students
3. Naturally ventilated buildings

Participant type(s)
Other

Age group
Mixed

Sex
Both

Target number of participants
30 schools

Total final enrolment

Participant exclusion criteria
1. Mechanically ventilated schools
2. Secondary schools
3. Further education establishments

Recruitment start date
01/06/2021

Recruitment end date
31/08/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Applied Education Research
Temple Bank House
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

Sponsor details
Duckworth Ln
Bradford
England
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+44 1274 36 6878
Jane.Dennison@bthft.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.bradfordhospitals.nhs.uk/

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
UK Health Security Agency

Results and Publications

Publication and dissemination plan
Key findings will be reported back to participating schools, in the form of individual site reports. Findings will be reported to the Department for Health and Social Care in the form of reports. Presentations at scientific meetings and conferences as well as peer-reviewed open access publications will be used to disseminate the wider findings of the study

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in the non-publically available repository within the Bradford Institute of Health Research. The datasets generated during and/or analysed during the current study are/will be available upon request. (M.Mon-Williams@leeds.ac.uk)

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			07/03/2022	No	Yes
Protocol file			07/03/2022	No	No