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Daily contact testing schools and colleges trial

Submission date
28/04/2021

Recruitment status
No longer recruiting

Registration date
04/05/2021

Overall study status
Completed

Last Edited
26/08/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Daily contact testing (DCT) is the regular, daily testing of close contacts of individuals who have tested positive for COVID-19. People who have had close contact with a confirmed positive case are at a higher risk than normal of having the virus. The researchers are evaluating this through a clinical evaluation in a small number of schools, to find more COVID-19 cases and break the chains of transmission.
Daily Contact Testing uses Antigen Lateral Flow Device tests (LFDs) which can provide a rapid, large scale and cost-effective means of testing large groups or sub-populations in local areas. They can be particularly effective at identifying asymptomatic COVID-19 infections 'hidden' in the population and also in providing a level of reassurance that on the given day of an LFD that the individual is unlikely to be infectious.
Rather than undertaking a period of self-isolation, the contacted individual could undertake a daily LFD test in school/college for 7 consecutive days. If that daily test shows no presence of COVID-19 then the individual can undertake normal activities that day while self-isolating at home in the evenings and weekends. If a test result is positive the individual must self-isolate and remain in isolation pending the outcome of a confirmatory PCR test. After 7 days of clear tests, the individual would be considered infection-free and so able to resume normal activities. The aim of this study is to compare the impact of DCT to the usual practice of self-isolation for contacts, and measure how this affects days spent in face to face learning and COVID-19 transmission in schools and colleges.

Who can participate?
English secondary schools and colleges

What does the study involve?
Schools and colleges are randomly allocated into two groups. The first, the control group, will test individuals twice a week, followed by isolation of any positive cases and their contacts. The second, the intervention group, will follow the same twice-weekly testing for individuals, but any contacts of positive cases will be asked to test daily in school/college for 7 consecutive days as an alternative to self-isolation, and as long as they continue to test negative, they will be able to carry on going to school/college. The trial is voluntary. Participants who are part of active case finding can choose not to participate in DCT or drop out of DCT at any point.

What are the possible benefits and risks of participating?
Possible benefits of DCT include keeping students in face-to-face education for as much time as is possible, restricting self-isolation to a primary group of people (positive case), and reducing the impact of self-isolation to a secondary group of people (close contacts). Around one in three people who have COVID-19 have no symptoms and could be spreading it without realising it. By increasing the positive cases detected, Daily Contact Testing is potentially the best way to reduce the transmission of COVID-19 in the community. Participating schools/colleges will be able to access a small amount of funding to cover workforce costs relating to the trial. Independent schools will also receive funding.

Where is the study run from?
Department of Health and Social Care (DHSC) (UK)

When is the study starting and how long is it expect to fun for?
January 2021 to June 2021

Who is funding the study?
Department of Health and Social Care (DHSC) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
R&D 434

Study information

Scientific Title
A pragmatic cluster randomised trial in English secondary schools comparing the impact of a policy of weekly testing for COVID-19 followed by isolation of cases and their contacts, with a policy of weekly testing followed by isolation of cases and daily testing of contacts

Study objectives
1. The intervention arm (daily contact testing) will have increased school attendance compared to the control arm (self-isolation) (i.e. superiority)
2. The level of transmission of COVID-19 in the schools in the intervention arm (daily contact testing) is not inferior to (i.e. not higher than in) the control arm (self-isolation)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/03/2021, Public Health England Research Ethics and Governance Group (PHE Research Support and Governance Office, Wellington House, 133-155 Waterloo Road, London, SE1 8UG, UK; +44 (0)1980 612922; elizabeth.coates@phe.gov.uk), ref: R&D 434

Study design
Pragmatic cluster randomized controlled study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
See additional files

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

Interventions
Schools and colleges are stratified by size (<500 of ≥500 students on register), type (maintained, independent, residential, special provision), presence of a sixth form, and proportion of students eligible for free school meals (≤17% or ≥17%), then randomised within strata in blocks of 2.

Consenting first-order contacts of a COVID-positive index case will receive daily contact testing for 7 days from the point of being notified they are a close contact. This will consist of a daily lateral flow device (LFD) test*. Those that receive a negative LFD result can attend school for that day, but other than travelling to and from school will be instructed to continue to self-isolate outside the school setting. Those that receive a positive LFD result should not attend school and will be instructed to self-isolate for 10 days according to national guidelines. The contacts of all first-order contacts (i.e. 'second-order contacts') will be identified to allow the determination of the secondary attack rate.

The control group will test individuals twice a week, followed by isolation of any positive cases and their contacts. The intervention group will follow the same twice-weekly testing for individuals, but any contacts of positive cases will be asked to test daily in school/college for 7 consecutive days as an alternative to self-isolation, and as long as they continue to test negative, they will be able to carry on going to school/college. The trial is voluntary. Participants who are part of active case finding can choose not to participate in DCT or drop out of DCT at any point.

Intervention Type
Behavioural

Primary outcome measure
Co-Primary End-Points:
1. Number of school days missed among those eligible to be in school during the 9-week period of the study. Daily school attendances will be obtained from the school register and absences recorded with reconciliation with COVID-19 associated absences. This will be compared between study arms, to historic schools' data, and to national schools' benchmark data collected via a survey of non-participating schools.
2. Estimated number of in-school COVID-19 transmission events during the 9-week period of the study: the number of positive cases will be obtained from the following sources:
2.1. Weekly LFD active case finding (control and intervention arms) during the 9-week period of the study
2.2. Symptomatic individuals' NHS Test and Trace results obtained from Community Testing routine data (control and intervention arms) during the 9-week period of the study
2.3. In-school LFD DCT testing (intervention arm) during the 9-week period of the study

Positivity rates will be reported for each source separately to facilitate like-for-like comparison between arms

Epidemiological links between cases will be obtained from the NHS Test & Trace Contact Tracing and Advice Service database. Additional links will be obtained by membership of school-reported contact groups. Onward transmission from the index case will be determined by the following:
1. Genomic sequence of virus: the additional PCR swab collected from positive individuals will be used to determine the whole genomic sequence of isolates. A sample of apparent links will be assessed with comparisons of whole-genome sequencing. The diversity of genetic sequences both in the schools and the community (routinely determined by COG) will be used to help interpret the results. Preliminary work currently undertaken will determine the appropriate genetic distance to be used to exclude a direct transmission event between individuals. This is likely to be two SNPs.
2. Plausible epidemiological link (e.g. membership of same close contact group)
3. For positive individuals identified in DCT the DMIC will review all available data to determine if the individual's infection was likely to have resulted from onward transmission from the index case, or via co-infection from an unknown 'upstream' positive or out-of-school positive case.

Secondary outcome measures

1. Number of positive first-order contacts missed by daily LFD testing during the 9-week period of the study (intervention arm only). Routine qPCR of first-order contacts will be used to determine the performance of DCT testing with LFDs. Comparisons of PCR with the same day LFD will allow comparison between CT values and LFD results in a 'real world setting' These comparisons can also be used to compare the relative performance between assisted school-based testing and home/self-testing.
2. Number of COVID-19 cases transmitted to the first-order contacts of index cases during the 9-week period of the study ("primary attack rate"). The first-order close contacts of all index cases will be identified by the school based on their existing close contact management policy. LFD DCT testing and (for symptomatic individuals) routine NHS Test and Trace PCR testing will be used to calculate the primary attack rate. As above, genomic sequencing will be used, wherever possible, to exclude non-direct transmission events.
3. Number of COVID-19 cases transmitted to the second-order contacts of index cases during the 9-week period of the study ("secondary attack rate"). The second-order contacts of all index cases will be identified (regardless of the COVID-19 status of the DCT-contacts) as described in Section 3.7. The COVID-19 status of these second-order contacts will be measured in two ways:
3.1. Where the second-order contact is a consented participant in this study their COVID-19 status will be assessed by weekly LFD active case finding during the 9-week period of the study, and records kept by the school of any participants who become symptomatic and test positive via standard NHS Test and Trace community testing.
3.2. Where the second-order contact is not a consented participant in this study (e.g., household contact of the first-order contact), analysis of routine NHS Test and Trace data recorded during the 9-week period of the study will be used to determine if they subsequently become symptomatic and test positive in the community setting. As above, genomic sequencing will be used, wherever possible, to exclude non-direct transmission events.
4. Number and proportion of school attendees testing COVID-19 positive in weekly active case finding during the 9-week period of the study. LFD results and school attendance registers will be used to calculate the active case finding rate. This will be compared between study arms, and to national schools' benchmark data collected via a survey of non-participating schools.
5. Proportion of student and staff who accept an offer of weekly active case finding testing with LFD devices during the 9-week period of the study. Schools will maintain consenting records to allow participation rates to be calculated.

6. Proportion of student and staff first-order contacts who accept an offer of daily contact testing with LFD devices during the 9-week period of the study. Schools will maintain consenting records to allow participation rates to be calculated.
7. Behavioural outcomes for pupils, parents and staff: acceptability and feasibility of testing, self-reported perceptions and behaviour. Pupils and staff who have been asked to self-isolate to taking part in DCT will be invited to complete a questionnaire on day 7 of their self-isolation or testing period.

Overall study start date
01/01/2021

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Secondary school/further education college
2. Willing and able to follow the study protocol
3. Willing and able to undertake PCR testing of contacts in the event the school is allocated to the control group
4. Commits to maintaining contact management in line with national standards
5. Willing and able to provide regular data of test results to Test and Trace and to allow members of an index case's contact group to be flagged in a database.
6. Willing and able to support baseline data collection requirements (e.g., provision of school register, bubble allocation data, etc.)
7. Willing to communicate regularly to Participants via Participant Information Sheets and other communication materials
8. Willing and able to provide a dedicated DHSC-funded Research Assistant to support data collection

Inclusion criteria for DCT (in the intervention arm):
Staff (including temporary or contract staff) and students in secondary schools/further education colleges/year 7 and above in all-through schools' individuals, who are:
1. Contact of a positive case related to school
2. Asymptomatic
3. Onsite i.e. not self-isolating or shielding
4. Contact of an index case in the school's population i.e. a staff member or student who has tested positive

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
200 schools or colleges, average 1000 staff and students at each institution

Total final enrolment
200

Key exclusion criteria
1. The school's contact management policy does not conform to national standards
2. Inability to support in-school LFD testing (i.e. not part of the NHS Test and Trace Asymptomatic Testing Site network)

Exclusion criteria for DCT (in the intervention arm):
1. Contact of a non-school index case
2. Household contact of a diagnosed COVID-19 positive individual
3. Symptomatic individuals

Date of first enrolment
22/03/2021

Date of final enrolment
30/04/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Health and Social Care
39 Victoria Street
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Sponsor information

Organisation
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Sponsor type
Government

Website
https://www.gov.uk/government/organisations/department-of-health-and-social-care

ROR
https://ror.org/03sbpja79

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

Results and Publications

Publication and dissemination plan
Planned publication in an open access peer reviewed journal

Intention to publish date
01/07/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of consent to share.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v5		04/05/2021	No	Yes
Participant information sheet	version v5		04/05/2021	No	Yes
Results article		14/09/2021	21/09/2021	Yes	No
Protocol file	version 35	27/01/2020	22/08/2022	No	No