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 Sponsor: Department of Health and Social Care

Principal Investigator: Prof. Tim Peto

Co-Investigators: Dr Tom Fowler, Prof Lucy Yardley, Tessa Griffiths, Sarah Maclean, Dr Nick Hicks

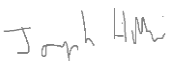
Chief Data Analyst: Joseph Hillier

Analyst: Fegor Ichofu

Affiliations

Prof Tim Peto	University of Oxford
Dr Tom Fowler	Queen Mary University of London (NHS Test & Trace Public Health Lead)
Prof Lucy Yardley	University of Bristol
Tessa Griffiths	Department for Education
Sarah Maclean	Department for Education
Dr Nick Hicks	Public Health England
Joseph Hillier	Department of Health and Social Care
Fegor Ichofu	Department of Health and Social Care

Document Approval

Role	Name	Signature	Date
Principle Investigator	Tim Peto		22/02/2021
Chief Data Analyst	Joseph Hillier		23/02/2021

A Note on Definitions

Throughout this protocol the following definitions are used. These are illustrated graphically in Figure 1 below

Index Case	*The first known positive COVID-19 case in chain of transmission.* This individual could be identified asymptomatically via LFD-based active case finding in the school or outside it, or via symptomatic NHS Test and Trace PCR testing
Bubble	*Grouping within school created by school to limit transmission of SARS-CoV-2 within the schools. Bubbles are meant to be distinct entities with no intermixing (i.e. a member of Bubble A should have no contact with members of Bubbles B, C, D, etc.)*
First-Order Contact	*Close contacts of the index case.* The subset of a bubble identified by the school as being a close contact of an index case, as defined by Government guidance: *https://www.gov.uk/government/publications/guidance-for-contacts-of-people-with-possible-or-confirmed-coronavirus-covid-19-infection-who-do-not-live-with-the-person/guidance-for-contacts-of-people-with-possible-or-confirmed-coronavirus-covid-19-infection-who-do-not-live-with-the-person* These individuals will be eligible for Daily Contact Testing or self-isolation according to national guidelines (depending on study arm and consent status)
Second-Order Contact	*Close contacts of a first-order contact.* These individuals will be identified and assessed for COVID-19 status in order to measure the secondary attack rate in each arm of the study
Primary Attack Rate	*The proportion of first-order contacts of the index case who themselves go on to be diagnosed with COVID-19*
Secondary Attack Rate	*The proportion of second-order contacts of the index case who themselves go on to be diagnosed with COVID-19*

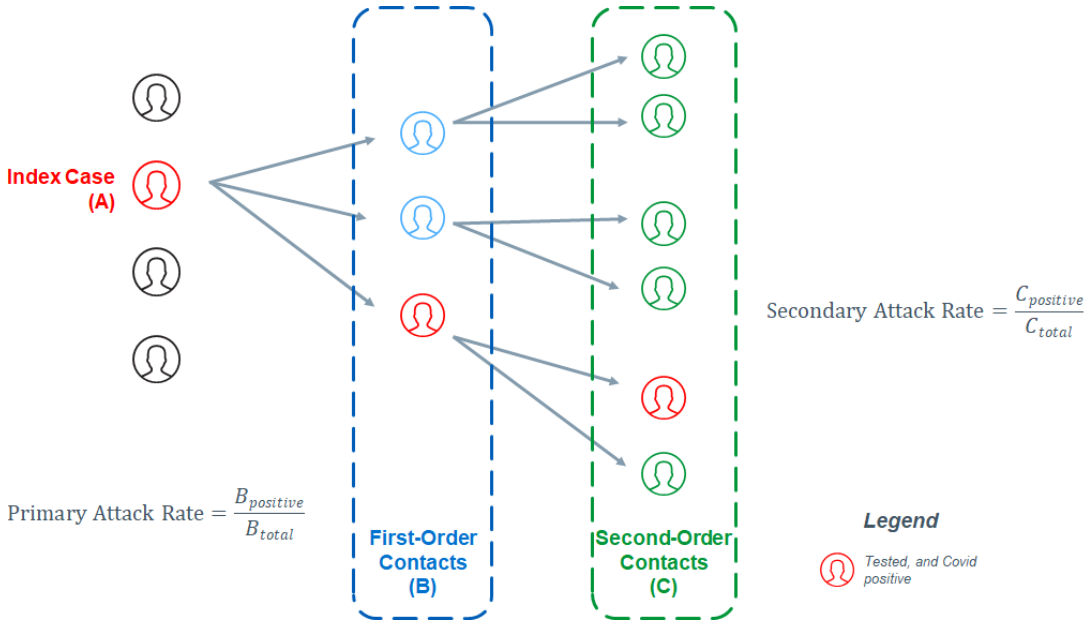


Figure 1: Definitions used for the chain of transmission

1. Rationale

When a person in a school / FE college[1] is diagnosed with COVID-19, first-order close contacts are required to self-isolate for 10 days. In schools, some groups of these close contacts (often managed as 'bubbles') may be quite large (e.g. a whole year group of over 250 pupils) and self-isolation has negative impacts on the education, psychological health and wellbeing of those affected[2]. There is some evidence that suggests that compliance with self-isolation outside the school setting may be as low as 11% in asymptomatic contacts[3] (although this may have improved since self-isolation has become a legal requirement). Modelling data shows daily testing of first-order contacts, using rapid lateral flow tests, could avert a similar level of onward virus transmission as self-isolation. In addition, recent work, has found that contacts identified by Test and Trace in the same household are more likely to become infected than first-order contacts at work, school or elsewhere. Primary age children are less likely to infect someone else and contact in schools with an infected child and are at a lower risk of transmission[4].

It is proposed that when a positive case is detected, first-order close contacts will be offered the choice of being tested daily using rapid Lateral Flow Device antigen testing as an alternative to the requirement to self-isolate. A first-order contact with a negative test at the start of the school day can remain in school. However, they will be advised to self-isolate outside school. A person who tests positive with LFD will follow national protocols and self-isolate for ten days. This process is referred to here as Daily Contact Testing (DCT). DCT will enable the pupil's education to continue and reduced the health and wellbeing impacts of self-isolation.

The success of DCT relies on having a rapid test result. Antigen lateral flow devices (LFD) currently give the quickest result turnaround of all the COVID-19 tests with results available in 30 minutes. Currently NHS Test and Trace has deployed an in-school 'Asymptomatic Testing Site (ATS)' model for LFD testing within schools, where students are tested by a trained workforce (also known as 'assisted testing'). Initial roll-out of LFD-enabled DCT within secondary schools and FE colleges will only be offered at an in-school ATS. Subsequently, at-home self-testing or testing by their parent or guardian ('self testing') may be introduced during the course of the study, conditional on the finalisation of an operational delivery model by NHS Test and Trace, and in agreement with regulators.

As part of the evaluation (rather than as an intervention) a parallel qRT-PCR test will be taken from contacts (by nose and throat, or if this is not tolerated, by anterior nares) to assess how many positive cases are missed by DCT.

[1] Please note that any reference to "school" in this protocol should be taken to include further education colleges also

[2] Academic Year 2019/20: Schools, pupils and their characteristics. National Statistics.

[3] Smith et al. Adherence to the test, trace and isolate system: results from a time series of 21 nationally representative surveys in the UK. September 2020.

[4] Lee at al. An observational study of SARS-CoV-2 infectivity by viral load and 2 demographic factors and the utility lateral flow devices to prevent 3 transmission. 2021.

2. Evaluation Overview and Objectives

2.1 Study Hypotheses and Objectives

The study hypotheses are as follows:

1. That the intervention arm (daily contact testing) will have increased school attendance compared to the control arm (self-isolation**)** (i.e. superiority)

2. That 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)

The primary objective of the study is to assess the effectiveness, in terms of in-school COVID-19 transmission and student / staff in-school days lost to self-isolation, of two different COVID-19 control strategies implemented at a school level using regular active case finding with lateral flow antigen tests.

Both arms of the study will include weekly active case finding of students and biweekly active case finding of staff. The arms will differ in the management of contacts of positive cases:

(i) Arm 1: routine self-isolation of all first-order contacts of positive tests
(ii) Arm 2: daily LFD testing of asymptomatic first-order contacts of positive tests at the beginning of the school day with self-isolation restricted to individuals with positive results.

Co-Primary End-Points

(i) Number of school days lost from COVID-19 or contact with COVID-19 cases
(ii) Estimated number and rate of within-school COVID-19 transmission events

Secondary End-Points

(iii) Number and rate of positive contacts missed by daily LFD testing
(iv) Number and rate of COVID-19 cases transmitted to the school-based and household first-order contacts of the index case ("primary attack rate")
(v) Number and rate of COVID-19 cases transmitted to the school-based and household second-order contacts of the index case ("secondary attack rate")
(vi) Number and proportion of school attendees testing COVID-19 positive in weekly active case finding
(vii) Proportion of student and staff first-order contacts who accept an offer of daily contact testing with LFD devices

Secondary objectives:

1. To gain knowledge on the operational aspects of this process; specifically, to understand uptake and barriers for schools and individuals as well as operational challenges.
2. To improve understanding of a range of behavioural factors, including reasons for participating, response to negative and positive test results, and compliance with self-isolation

2.2 This Study in the Context of Overall Evaluation of DCT

An ongoing evaluation of DCT in several settings is ongoing across several dimensions of investigation. This protocol focusses predominantly on the Public Health Effectiveness and Behavioural Factors dimensions, but also touches on the Operational Feasibility and Broader Societal Benefit dimensions. The Scientific Knowledge dimension is not addressed in this study.

The dimensions of the NHS Test and Trace Daily Contact Testing Evaluation Framework can be found in Appendix 1

Within the broader DCT Programme of Evaluation, this study provides the following incremental value:

1. It is the first DCT evaluation to include a control arm
2. It is the first study to combine dual LFD-PCR swabbing with measurement of participant and institution-level behavioural factors
3. It represents a significant expansion of the sample size of previous pilots of DCT in the school / FE college context, allowing for appropriately powered analyses of study endpoints

3.2 Methods

3.1 Overview of Design

This is a pragmatic cluster randomised controlled study. Eligible participating schools will be stratified according to institution type, size, Free School Meal prevalence and local COVID-19 prevalence and randomly allocated into the two study arms. A schematic summarising the study design and participant sub-groups can be found in Figure 2 below.

Regular Active Case Finding. In schools participating in either arm of the study, consent will be obtained from adults/parents/guardians for voluntary weekly testing of all students and biweekly testing of all staff[5]. Tests will be performed with lateral flow devices (LFD)*, and results will be reported in the NHS Test and Trace database. LFD Tests will initially be performed as an assisted test in a school setting. Once a reliable protocol for home testing and recording of LFD is available, schools will be offered the option for at-home self-testing for weekly case finding.

Individuals who test positive will self-isolate and identify first-order contacts according to national guidelines. In addition, symptomatic cases who test positive via NHS Test and Trace, and asymptomatic cases who test positive outside the in-school testing regimen will self-isolate and report their results to the school. All individuals with a positive test will be asked to provide a PCR swab test for genomic sequencing.

1. **Intervention (Daily Contact Testing) Arm**
    a. *Public Health Intervention:* 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[6]. This will consist of a daily LFD*. 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 secondary attack rate.

    *****Daily Contact Testing LFD tests will initially be performed as an assisted test in the school setting. Results will be recorded electronically and reported to NHS Test and Trace. On non-school days participants will not receive LFD testing. Where day 7 of DCT falls on a Saturday or Sunday, a negative LFD test will be needed to exit DCT testing. Once a reliable protocol for home testing and recording of LFD is available, and relevant regulatory approvals are in place, participants may be offered the option for at-home self-test DCT.

    Additionally research component: Consenting first-order contacts will be tested via self-administered qRT-PCR at days 2 and 7 from the point of being notified they are a

[5] Biweekly LFD active case finding among staff is already underway outside the context of this evaluation

[6] For clarity, the day on which they are notified they are a contact is Day 0

close contact[6]. These qRT-PCR samples will be collected for research purposes and run in batches every two weeks, after which results will be available for participants.

2. **Control Arm**
    a. *Public Health Intervention:* First order contacts of a COVID-positive index case will be instructed to self-isolate according to national guidelines (i.e. there will be no change to the public health intervention compared to non-participation in the evaluation). The contacts of all first-order contacts (i.e. 'second-order contacts') will be identified to allow the determination of secondary attack rate.

    b. *Additionally research component:* Consenting contacts will be provided with two home qRT-PCR test kit and asked to self-test at days 2 and 7 from the point of being notified they are a close contact[6]. These qRT-PCR samples will be collected for research purposes and run in batches every two weeks, after which results will be available for participants.

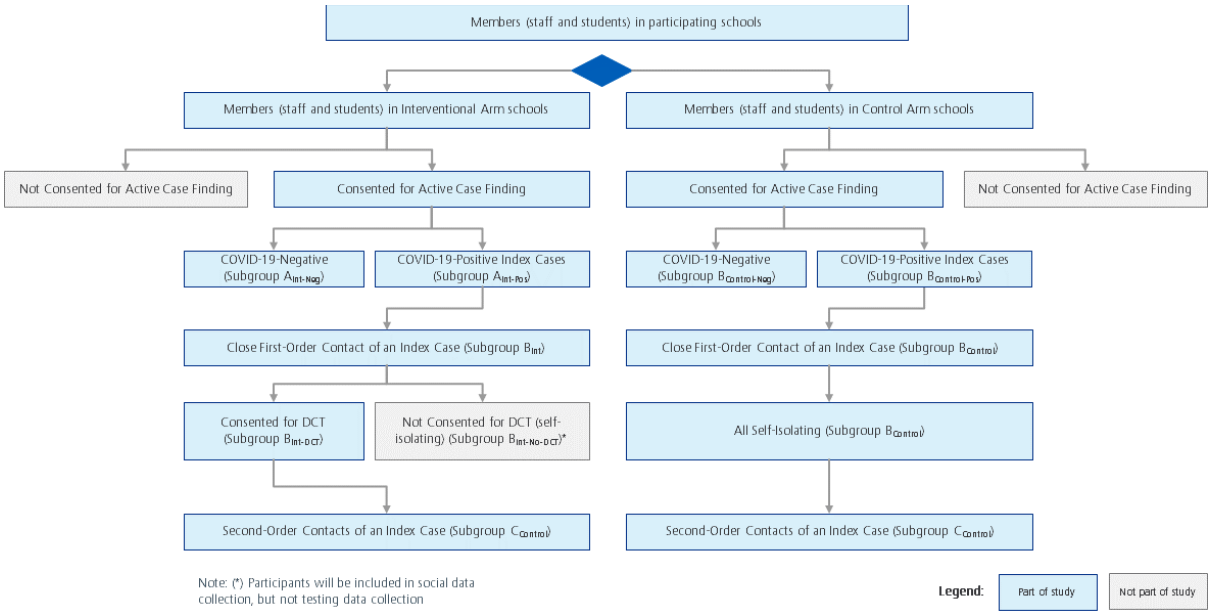


Figure 2: Schematic of study design and participation sub-groups

Consideration was given to a stepped-wedge study design where schools would introduce daily contact testing in waves. This was not pursued as part of this protocol due to the operational feasibility of this design.

Consideration for comparator testing regimes and groups of varying prevalence as part of the evaluation were considered but will not be part of this phase.

3.2 Inclusion and Exclusion Criteria for Schools

- **Inclusions**
    - Secondary school / further education college
    - Willing and able to follow the study protocol
    - Willing and able to undertake PCR testing of contacts in the event the school is allocated to the control group
    - Commits to maintain contact management in line with national standards
    - 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 data base.
    - Willing and able to support baseline data collection requirements (e.g., provision of school register, bubble allocation data, etc.)
    - Willing to communicate regularly to Participants via Participant Information Sheets and other communication materials
    - Willing and able to provide a dedicated DHSC-funded Research Assistant to support data collection
- **Exclusions**
    - The school's contact management policy does not conform to national standards
    - Inability to support in-school LFD testing (i.e. not part of the NHS Test and Trace Asymptomatic Testing Site network)

3.3 Non-Consenting Individuals in the Interventional Arm

Within the intervention arm, individuals not participating in DCT will self-isolate in the event they are a first-order contact. They will be asked to participate in elements of the qualitative work to enable better understanding of factors affecting uptake and pre and post-test behaviours.

3.4 Lateral Flow Device Testing

LFD antigen testing will be via two delivery models:

1. Supervised anterior nares swabbing, and device use within a school's 'Asymptomatic Testing Site (ATS)' model. The workforce for this will be trained according to national NHS T&T standard process.
2. Home or Self-testing will be made available once reliable operational delivery models are developed, and subject to the relevant regulatory approvals being received.

3.5 qRT-PCR Testing

The purpose of the qRT-PCR test component is to determine the number of first-order contacts which are positive with PCR but negative with LFD during DCT. This will determine the false negative rate of DCT. First-order contacts will be prioritised in the daily testing schedule in the school to ensure they are tested at the beginning of the day.

The swabbing method for qRT-PCR swabbing will be throat-and-nose as per standard NHS T&T practice. If throat-and-nose swabbing is not tolerated, anterior nares swabbing may be used. Schools / participants should record which swabbing method is used each day. Participants should self-swab under supervision in alignment with national NHS T&T guidance.

qRT-PCR swab samples will be transported to PHE Porton Down, stored at -20^{o}C and processed in batches every two weeks. Results will be available to participants after this time. This process is being implemented to prevent participants (in either stud arm) from receiving information on their COVID-19 status that they will not receive as part of the real-world public health intervention. This will be communicated to potential participants via the Participant Information Leaflet and ICF prior to enrolment in the study.

qRT-PCR testing will not form part of scaled LFD-enabled testing of asymptomatic close contact groups in schools. As such, the evaluation framework for the study will not consider the acceptability, tolerability or operational performance of the qRT-PCR testing component.

3.6 Assessment of End-Points

Please see the glossary at the start of this protocol for definitions

Co-Primary End-Points

(i) **Number of school days missed among those eligible to be in school.**
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.

(ii) **Estimated number of in-school COVID-19 transmission events**
The number of positive cases will be obtained from the following sources:

1. Weekly LFD active case finding (Control and Intervention Arms)
2. Symptomatic individuals' NHS Test and Trace results obtained from Community Testing routine data (Control and Intervention Arms)
3. In-school LFD DCT testing (Interventional Arm).

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 data base. Additional links will be obtained by membership of school-reported contact groups. Onward transmission from the index case will be determined by the following:

- 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 2 SNPs.

- Plausible epidemiological link (e.g. membership of same close contact group)
- 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 End-Points

(iii) Number of positive first-order contacts missed by daily LFD testing (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.

(iv) Number of COVID-19 cases transmitted to the first-order contacts of index cases ("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 primary attack rate.

As above, genomic sequencing will be used, wherever possible, to exclude non-direct transmission events.

(v) Number of COVID-19 cases transmitted to the second-order contacts of index cases ("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:

i. 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, and records kept by the school of any participants who become symptomatic and test positive via standard NHS Test and Trace community testing.

ii. Where the second-order contact is not a consented participant in this study (e.g., household contact of first-order contact), analysis of routine NHS Test and Trace data 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.

(vi) **Number and proportion of school attendees testing COVID-19 positive in weekly active case finding.**
LFD results and school attendance registers will be used to calculate 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.

(vii) **Proportion of student and staff who accept an offer of weekly active case finding testing with LFD devices.**
Schools will maintain consenting records to allow participation rates to be calculated.

(viii) **Proportion of student and staff first-order contacts who accept an offer of daily contact testing with LFD devices.**
Schools will maintain consenting records to allow participation rates to be calculated.

(vii) **Behavioural outcomes for pupils, parents and staff:** acceptability and feasibility of testing, self-reported perceptions and behaviour

3.7 Identification of Second-Order Contacts

As discussed above, the rate of COVID-19 positivity in the second-order contacts of index cases (i.e. the contacts of first-order contacts) will be an endpoint used to assess the public health effectiveness of DCT for school populations. Several methods will be used to identify the second-order contacts of index cases:

- **In-school secondary contacts:** As part of their existing COVID-19 management policy schools are required to segment their population into distinct 'bubbles' (e.g., year group), membership of which is unique. Members of one bubble should not be interacting with members of another. As a result, all the contacts of a member of a specific bubble should also be members of the same bubble.
  In the event of a positive index case within a bubble, the school will identify those bubble members it considers to be close contacts of the index case (this will often not be the entire bubble). These close contacts (i.e. 'first-order contacts' in the context of this study) are subject to self-isolation or DCT depending on their arm.
  All other members of the index case's bubble will be considered second-order contacts for the purposes of this study. Membership of each bubble will be provided by participating schools at the start of the study, and should not vary during the study.

- **Household contacts of first-order contacts:** Another group of second-order contacts are individuals who live in the same household as a first-order contact. These may attend the same school or may not. These individuals will be 'identified' by querying routinely collected NHS Test and Trace testing data for individuals with the same residential address as any first-order contact. The method to identify household contacts will only identify household contacts who are in Test and Trace systems.

Within the scope of this study we do not intend (for operational reasons) to identify non-school, non-household contacts of first-order contacts. As first-order contacts are required to maintain self-isolation outside the school environment (even if they are undertaking DCT) this group should be minimal in size. However, it is an acknowledged limitation of the study. We also do not intend (for

similar reasons) to identify individuals within the school who are not a member of the same bubble as a first-order contact but have had close contact with them. We acknowledge this as another limitation of the study.

3.8 Assessment of Behavioural and Other Outcomes

Assessment of the behavioural components of the evaluation framework will include the following:

1. Survey of a) self-reported out of school activities and contacts (for comparison in test-negative, test-positive and self-isolating participants); b) views of testing (compared with self-isolation)
2. PPI input and qualitative research to understand views and experiences of and responses to testing of pupils, parents and school staff – teachers and others

Participants in both the Interventional and Control Arms will be invited to complete a very brief online survey; this will include all participants who are a first-order contact of a positive index case. Measurement will be on day 7 after notification of being the contact[7], using self-report measures of social contacts and other behaviours adapted from measures already in use. To promote honest self-reporting, an anonymous survey instrument will be used (as in the previous 'Agile Lighthouse' evaluation of DCT), which can be found in Appendix 2.

Outcome 2 focuses on gathering the perceptions, experiences and beliefs of those involved in the testing process, including pupils, parents, teachers and administrators. In collecting this data, it is crucial that the burden on teachers and school staff is reduced as far as possible during what is already an extremely challenging time for them. We have explored the potential for using existing research vehicles (e.g. the Pupil and Parent Panel omnibus survey), but these would not allow us to deliver the objectives of the present study. The bespoke data collections have therefore been streamlined to lower burden. The approaches that will be used are:

- User research carried out in two waves within both Phase 1 and Phase 2:
    - Wave 1: At the beginning of the testing period to explore the practicalities of delivering the protocol within the 'intervention arm' schools. This will be no more than ten interviews (anticipated approx. 20-30 minutes, no more than 1 participant per school site) with school staff (teachers and non-teachers) involved in management/implementation focusing on the process and expectations for the testing. Data will enable a view of the study implementation (allowing adjustments to be made if required) as well as the feasibility of wider rollout.
    - Wave 2: Follow-up interviews (anticipated approx. 20 minutes) with these participants towards the end of the study period to collect their reflections having experienced more of the testing, again focusing on the process and feasibility of wider roll-out.
- Interviews with pupils, parents and staff in a sample of the schools involved in the testing (both Interventional and Control arms), looking to understand in more depth experiences of the testing process, beliefs about testing, perceptions of positive and negative test results and potential improvements and issues affecting take-up and impact on behaviour. Participants will be invited to take part in recorded online or telephone interviews (20 to 30 minutes)

[7] For clarity, the day on which they are notified they are a contact is Day 0

outside of school opening hours, and will receive an online voucher as reimbursement for their time. The sample will include staff, parents and pupils from different schools, with different ages, ethnic and socioeconomic backgrounds, and with positive and negative test results. Recordings will be fully transcribed, anonymised and analysed for emerging themes.

Parent/Guardian consent for pupils' participation in social research will be obtained via schools prior to commencement of fieldwork. More detail on social research design is included in Appendix 7.

3.9 Sample Size

Advice on the appropriate sample size for this study has been sought from Professor Sarah Walker at the University of Oxford.

The challenge with setting a non-inferiority margin for transmission events is that the meaning of a non-inferiority margin is highly dependent on the control group event rate. For example, if the control group event rate is 20%, then, depending on the other advantages of the intervention, it may be reasonable to set a non-inferiority margin of 10%, i.e., to exclude increases of more than 10% absolute or 50% relative. But if the control group event rate is 1%, a 10% non-inferiority margin is very unlikely to be considered reasonable. However, choosing the wrong control rate can have enormous consequences for the power of a trial to determine non-inferiority within a pre-defined bound[8].

At present, it is extremely difficult to get any estimate of a control group event rate for transmission over the next 3 months, and hence it is impossible to pre-define what might be a meaningful non-inferiority margin, given the hypothesised benefits of the intervention. We therefore power the trial to determine superiority of the intervention on school attendance; if superiority is demonstrated on the primary endpoint, we will ask an independent committee to judge whether the 95% CI for the difference between intervention and control schools on transmission events is sufficiently close to no difference such that the benefits outweigh any potential risks.

The primary endpoint of the study is the number of missed days at school compared to the control group. The following scenarios will illustrate the effect of the intervention on school attendance

The number of Covid-19-associated missed days at school is dependent on the number of positive cases identified and the number of contacts of these cases that are self-isolating. Each positive case is self-isolated for 10 days. In the control group all first order contacts will also be self-isolated for 10 days. It is expected that this trial will occur in the summer term when the number of cases in a school will be low. For instance, it is expected that in the control group about 30% of children (and their parents) will consent to participate in regular weekly active case finding testing. For the purposes of the power calculation, it is assumed that the expected number of index cases identified is about 1 outbreak/month. Each index cases will lead to identification of 50 children in their bubble who will need to self-isolate each for 10 days. The number of index cases identified is a Poisson distribution with mean 1/month with each index cases leading to 510 missed school days.

In the intervention group, it is expected that a more complex set of interactions will occur. The ability to avoid self-isolation by DCT is likely to make participation in weekly active case finding testing more

8 Quartagrio *et al,* 'Handling an uncertain control group event risk in non-inferiority trials: non-inferiority frontiers and the power-stabilising transformation' (2020)

attractive with an increase in consent to voluntary weekly active case finding testing to 60%. This in turn will lead to the identification of more positive cases with initially an expected number of 2 different index cases identified per week. However, it is expected that 70% of children will volunteer for DCT and therefore only 15 children (25% of 50) will self-isolate. In addition, about 2 contacts will be identified by LFD testing as positive during DCT (5% of 35). It is expected that these 2 children will only have contacts within the bubble and therefore they will not lead to identification of more children. In all, each index cases will lead to the index case plus 14 children each self-isolating for 10 days leading to 170 days of missed school per index cases or 360 missed schools / month

In addition, the intervention will lead, over time, to a decrease in transmission and therefore detection of cases through an increased identification and isolation of true positives, itself arising from an increase of uptake of weekly active case finding testing. However, this decrease will be offset by the possible increase in in-school transmission by infectious children not undertaking DCT who attend school.

It is expected that the trial will start in the Summer term with 100 schools enrolled into each arm. However, it is likely that only 50% of enrolled schools will manage to sustain the trial leaving only 50 schools in each group.

	Control Group	**Intervention Group**
Number of schools successfully participating	50	50
Proportion of children consenting to mass testing	30%	40-60%
Initial number of outbreaks detected/school	1/month	2/month
Number self-isolating (incl. index case and) each for 10 days	51	10-30
Number of schools in each arm	50	50

*Including index case and 2 cases in each DCT bubble of 50 children test positive and therefore need 10 days of self-isolation

Table 1: Assumptions in Power calculation

The number of schools required in each arm to determine whether school attendance has been increased by the intervention will depend on the number of children volunteering for DCT and the increase in the proportion of children consenting for weekly active case finding testing.

Assuming that 30% of the control arm participate in weekly active case finding testing, the number of schools per arm for a two month study is shown in the following table (power of 80%, two-sided alpha (0.05))

Number (per index case) in intervention group self-isolating and not undertaking DCT	**Proportion if children consenting to weekly active case finding testing in intervention arm**		
	40%	**50%**	**60%**
7	10	12	14
8	11	13	15

9	11	14	18
10	12	15	21
11	13	17	24
12	14	19	29
13	15	22	36
14	18	26	45
15	18	30	58
16	20	35	79
17	23	43	112
18	26	53	170
19	29	67	
20	33	87	
21	38	117	
22	45	166	
23	53		
24	64		
25	78		
26	98		
27	125		

Table 2: Relationship between number of schools required per arm and study participation rates

3.10 Governance Framework

This will be a service evaluation with the research aspect and ethical approval will be sought through Public Health England's Public Health Research Ethics framework.

The Principle Investigator and Co-principle investigators are responsible for drafting, and approval of this protocol. Review will be through the Education Evaluation Steering Group (DfE, DHSC and PHE)

and Testing Initiatives Evaluation Board (membership includes independent academics - see Appendix 5).

Overall responsibility for the study rests with the Secretary of State at the Department of Health and Social Care. The Principal Investigator has responsibility for the day-to-day delivery of the study, and for that he/she will be accountable to the Independent Trial Steering Group (TSG) (see Appendix 3 for Terms of Reference). The Study PI will be a member of this group. Test results data will be monitored by an Independent Data Monitoring Committee (IDMC) (see Section 5.2), which will report into the Trial Steering Group. Terms of Reference of the IDMC can be found in Appendix 4.

Lists of membership of study governance bodies can be found in Appendix 6.

Prior to enrollment of potential participant schools into the study advice will be sought from the local Director of Public Health, wider local authority and PHE on their willingness for the school to participate.

In the event of a suspect outbreak in a school (defined as more than 4 positive tests in a week), the local DPH and HPT will be responsible (with cooperation from the study team) for outbreak response management. Local and regional public health and teaching officials (including head teachers and school governing bodies) may raise concerns and questions with the Trial Steering Group for operational matters and the IDMC for other matters.

3.11 Testing Devices and Consumables

The following testing devices will be used in the study:

- Lateral Flow Antigen Testing Device for Daily Contact Testing: Orient Gene Coronavirus Ag Rapid Test
- qRT-PCR: Standard NHS T&T PCR throat and/or nasal swabs

3.12 Study Implementation Phasing

The study will be implemented in a phased manner to ensure the operational delivery model and intervention have received user feedback on feasibility and appropriateness prior to roll out across all sites. The aim is to maximise the effectiveness of the DCT implementation and minimise unnecessary burden of schools or participants

- **Phase 1 – Mixed methods feasibility trial in all students and staff in 6 schools**
    - Confirm that the operational delivery model and data capture processes are viable and feasible for use at scale (or refine accordingly)
    - Gain user feedback (through PPI and focus groups/interviews) on all aspects of the trial and intervention procedures and materials (including guidance on how to interpret an LFD result), and refine procedures and materials accordingly
    - Gain user feedback on the tolerability of the proposed PCR testing regime, and refine accordingly
    - In this phase only the in-school assisted testing ATS delivery model will be available
- **Phase 2 – Deliver evaluation in full sample size of schools**

- Collect evidence against objectives in full sample of schools
- At the start of this phase only the in-school assisted testing ATS delivery model will be available. If the at-home self-test delivery model becomes available during Phase 2 schools will be notified and allowed to choose to deliver the active case finding component via at-home self testing.
- Separately, collect evidence on home self-test DCT as this option becomes available

3.13 User Experience Research in Phase 1

In Phase 1, user feedback will be solicited on the public health intervention (including communication materials, consent forms and patient information sheets) and research elements of the evaluation. This will be used to refine the study operational model prior to scaling the number of sites in Phase 2.

4. Testing Regimen and Public Health Intervention

Participation in both the weekly active case finding and DCT components of the study will be (separately) voluntary. There are two options for first-order close contacts in the operation of this study, depending on whether they are taking part in the DCT component or not:

1. Those taking part in the DCT component of the evaluation: people in the first-order close contact group of a positive index case are tested at the start of each day by anterior nares swab for LFD and on days 2 and 7 additionally with a throat-and-nose swab for qRT-PCR (anterior nares swabbing may be used if throat-and-nose swabbing is not tolerated)[9].

2. Those not taking part in the DCT component of the evaluation: People in the first-order close contact group of a positive index case self-isolate in line with current national guidance. This option should be available for anyone who wishes to self-isolate rather than participate in the 'Daily Contact Testing' study. It will not be described further in this document.

Informed Consent from staff members and students and/or their parent /guardian will be required to take part in the testing components of the study. An information leaflet will be used to describe the purpose and process of the study, and the risks and benefits associated with the use of lateral flow antigen tests.

The below (which will be followed in all participating schools) focuses on the process for testing and the public health intervention. This is also illustrated in Figure 3 and Figure 4 below.

4.1 Initial Active Case Finding

This applies for students/ staff undergoing routine Lateral Flow Antigen Testing Device (LFD) tests through the national programme of school asymptomatic testing. For schools enrolled as part of Daily Contact Testing, at least weekly LFD testing is a prerequisite. LFD antigen testing will be via supervised anterior nares swabbing, and device use will be assisted use within a school's ATS model. The workforce for this will be trained according to national NHS T&T standard process.

Active case finding LFD testing will be once a week for students and twice a week for staff.

The following actions will be taken depending on the result:

4.1.1 Negative LFD Result

All persons who test **negative** on the weekly antigen LFD testing may participate in activities in the school with appropriate social distancing, respiratory hygiene, hand washing and face coverings where appropriate in line with the national guidance:

https://www.gov.uk/government/collections/guidance-for-schools-coronavirus-covid-19

[9] For clarity, the day on which they are notified they are a contact is Day 0

4.1.2 Positive LFD Result

- The school should follow the national guidance (link above), in the same way as if the person with the positive test had become symptomatic whilst in school. The person in question must begin self-isolation in accordance with national guidance and Stay at Home guidelines[10].

- Residential schools must follow the national guidance for residential educational settings: https://www.gov.uk/government/publications/coronavirus-COVID-19-guidance-on-isolation-for-residential-educational-settings/coronavirus-COVID-19-guidance-on-isolation-for-residential-educational-settings.

- Participants testing positive will be given a home PCR testing kit. They should be instructed to take a PCR swab **that day** and return it as per the enclosed instructions. This sample will be subject to genomic sequencing to allow chains of transmission to be analysed.

4.2 Management of First-Order Contacts of a Positive Index Case

Schools are eligible for the study on the condition that national guidelines and advice for good contact management are maintained throughout, with a pragmatic approach to the non-mixing of contact groups, and national guidance for schools continues to be followed.

This part of the protocol applies to asymptomatic first-order close contacts of COVID-19 positive index cases in the school who have tested positive through:

- Weekly asymptomatic LFD testing within the school
- Asymptomatic testing via another non-school route
- Symptomatic qRT-PCR testing outside the context of the school's testing programme

Any first-order close contact group where a positive index case is detected (by any means) will be eligible for Daily Contact Testing on the basis that:

1. The index case is a student / staff member at that school. First-order contacts of index cases not based in the school are not eligible for DCT within this evaluation
2. The first-order contact has consented to partake of DCT
3. The first-order contact is not a household contact of a currently COVID-19 positive individual (including the index case)
4. The first-order contact is not symptomatic

As stated above, participating schools must commit to maintaining the same level of good contact management and national guidance for schools. A pragmatic approach should be taken to ensure individuals participating in DCT should not mix with individuals from other contact groups (even if those individuals are also undergoing DCT).

Symptomatic individuals must follow national guidance (link above) and self isolate whilst awaiting results of a qRT-PCR test.

[10] COVID-19: guidance for households with possible coronavirus infection - GOV.UK (www.gov.uk)

Note on timings of DCT / self-isolation compared to date of contact

Where the index case was identified via weekly asymptomatic LFD active case finding testing within the school, the date of their positive test will be treated as Day 0 for their first-order contacts' DCT / self-isolation regime (e.g., if an index case test's positive during weekly active case finding on Monday, Day 1 of their first-order close contacts' DCT regime would be Tuesday). When the index case was diagnosed outside of in-school testing, they will be asked during contact tracing when the last date of contact was with each of their named first-order contacts. This will allow the interval between the date of contact and the date of initiation of DCT / self-isolation (Day 1) to be calculated for the purpose of tracing chains of transmission.

4.2.1 Interventional (Daily Contact Testing) Arm

All those in the same first-order close contact group as the positive case will be offered the option of being tested by LFD at the start of every school day, until day 7 after being notified of being a contact[11]. Those who do not consent to daily testing will be subject to the process outlined in Section 4.4. LFD antigen testing will be via one of two delivery models:

1. Supervised anterior nares swabbing, with device use assisted within a school's ATS model. The workforce for this will be trained according to national NHS T&T standard process.
2. Once a suitable protocol is available, at-home self-anterior nares self-swabbing under supervision of the parent / guardian (in alignment with national NHS T&T guidance). Swab samples will be self-applied at home to the LFD device and the result self-read by students under supervision of the parent / guardian, or by the parent / guardian if the student does not feel confident to use the device themselves.[12]

Those that test **negative** on the LFD negative at the start of the school day will be allowed to attend school for that day until their next test is due. It will not allow them to avoid self-isolation outside the school setting, and this will be communicated to participants using accessible, standardised materials drawing on behaviour change techniques and developed with user feedback to ensure they are credible and motivating. Participants will be required to self-isolate on days where a test has not been performed (e.g. weekends). If a non-tested day occurs at the end of Daily Contact Testing, a further negative test will be required to complete and release from the Daily Contact Testing protocol.

Those that test **positive** on the LFD test should follow the national guidance (link above) as if they have developed symptoms whilst at school and self-isolate for 10 days. If during this time they develop symptoms, the individual is asked to notify the school so this can be recorded as part of the study. They will be given an additional home PCR testing kit. They should be instructed to take a PCR swab **that day** and return it as per the enclosed instructions. This sample will be subject to genomic sequencing to allow chains of transmission to be analysis. They should also continue with any outstanding 'day 2 and 7' qRT-PCR testing (see below), as this is a research component of the study[13]. Home qRT-PCR testing kits will be provided for this purpose to remove the need to come into school for testing.

[11] For clarity, the day on which they are notified they are a contact is Day 0

[12] Initially only the in-school assisted ATS model will be available to schools. Once the at-home self-test delivery model has been finalised, participating schools will be notified and given the opportunity to switch.

[13] For clarity, the day of their diagnosis is Day 0

As a research component of the study, Interventional Arm participants should also provide concurrent throat-and-nose swabs for qRT-PCR (on days 2 and 7 after being notified of being a close contact anterior nares swabbing may be used if throat-and-nose swabbing is not tolerated)[13]. Home qRT-PCR testing kits will be provided for this purpose by the school. Participants will be instructed that they should confirm to the school that they have taken each of the day 2 and 7 qRT-PCR tests. If the school does not receive confirmation of this by a pre-agree point in the day, they will follow up my telephone to request the test is taken. Failure to take a qRT-PCR test on days 2 and 7 (or taking it on another day) will not be considered a protocol violation.

qRT-PCR samples will be run in batches every two weeks, after which point the results will be available to participants.

Additional positive cases identified in a first-order close contact group during testing will restart the Daily Contact Testing protocol for the existing close contact group to Day 0. They should also be asked for any additional first-order close contacts, who would be eligible to start daily contact testing from that day.

4.2.3 Control (Isolation of Contacts) Arm

All those identified in the same first-order close contact group as the positive case, who would have been eligible (as part of one of the interventional arms of the study) for Daily Contact Testing should self-isolate for 10 days.

As a research component of the study, Control Arm participants should also provide concurrent throat-and-nose swabs for qRT-PCR on days 2 and 7 after being notified of being a close contact (anterior nares swabbing may be used if throat-and-nose swabbing is not tolerated)[13]. Home qRT-PCR testing kits will be provided for this purpose by the school. Participants will be instructed that they should confirm to the school that they have taken each of the day 2 and 7 qRT-PCR tests. If the school does not receive confirmation of this by a pre-agree point in the day, they will follow up my telephone to request the test is taken. Failure to take a qRT-PCR test on days 2 and 7 (or taking it on another day) will not be considered a protocol violation.

qRT-PCR samples will be run in batches every two weeks, after which point the results will be available to participants.

If an individual becomes symptomatic, they must follow national guidance and continue to self-isolate whilst awaiting results of a qRT-PCR test. The subject must restart their self-isolation period in line with national guidance.

4.3 Household Contacts

Household members of a positive index case are those who live in the same household as the positive case. These individuals should self-isolate in line with the national guidance and will not be able to enrol into the DCT component of this study: https://www.gov.uk/government/publications/covid-19-stay-at-home-guidance.

4.4 Management of those who do not Consent to DCT

Participation in the study will be voluntary, and potential participants will be provided with information on the risks and benefits as part of the consenting process. Those first-order contacts of positive cases who do not wish to be tested daily or who are unable to be tested for any reason must self-isolate in accordance with national guidance and Stay at Home guidance[14] until 10 days after the they were notified of being a contact of tested positive. As a result, they will not be exposed to incremental infection risk compared to the counterfactual of the whole close contact group self-isolating.

4.5 Symptomatic Individuals

If any person develops symptoms at any time during the study, they must immediately self-isolate and order a qRT-PCR home test through the national Test and Trace symptomatic testing process[15]. They should follow Stay at Home guidance[7].

4.6 Multiple Positive Cases in a School

The management of local outbreaks in a school will be managed according to the exiting national process. The school will contact the DfE coronavirus helpline (dfe.coronavirushelpline@education.gov.uk / 0800 046 8687) for initial risk assessment and this will be escalated to PHE Health Protection Teams for advice managing large or complex outbreaks. The study team will also be notified. If the HPT, DPH or the school wants to stop the trial and instruct a contact group to self-isolate they should discuss this with the Trial Steering Committee. The Trial might be able to provide extra genomic analysis to determine the extent of the outbreak and help inform decision making. If DCT is stopped the IDMC should be informed.

[14] COVID-19: guidance for households with possible coronavirus infection - GOV.UK (www.gov.uk)
[15] https://www.gov.uk/get-coronavirus-test

4.7 Process Flow for Schools Evaluation (Intervention and Control)

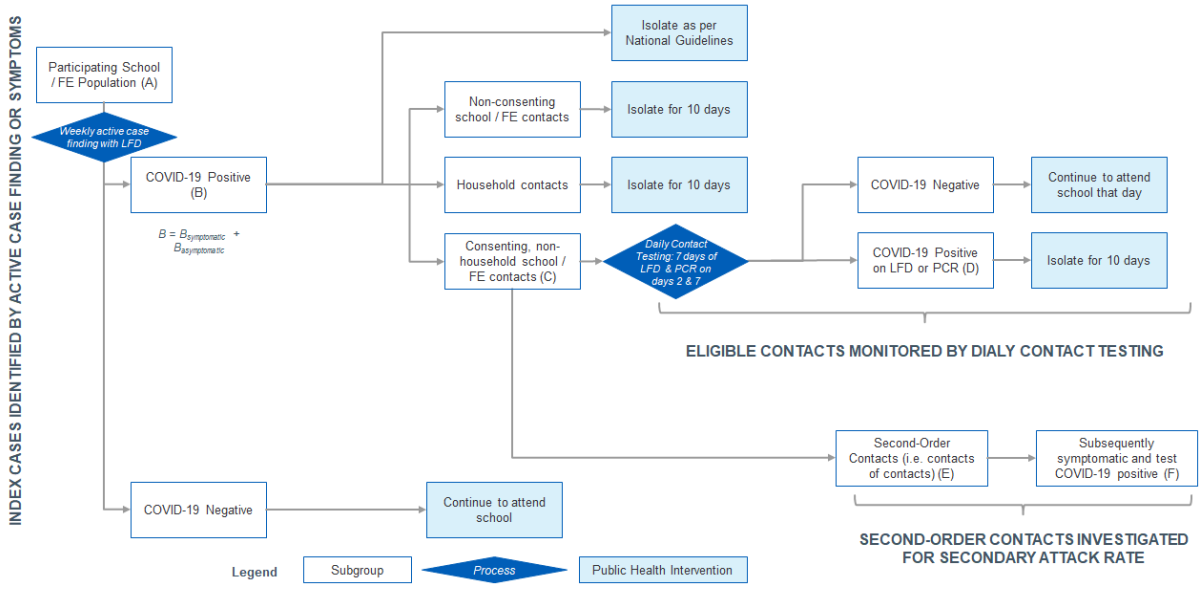


Figure 3: Process flow for schools DCT evaluation interventional arm

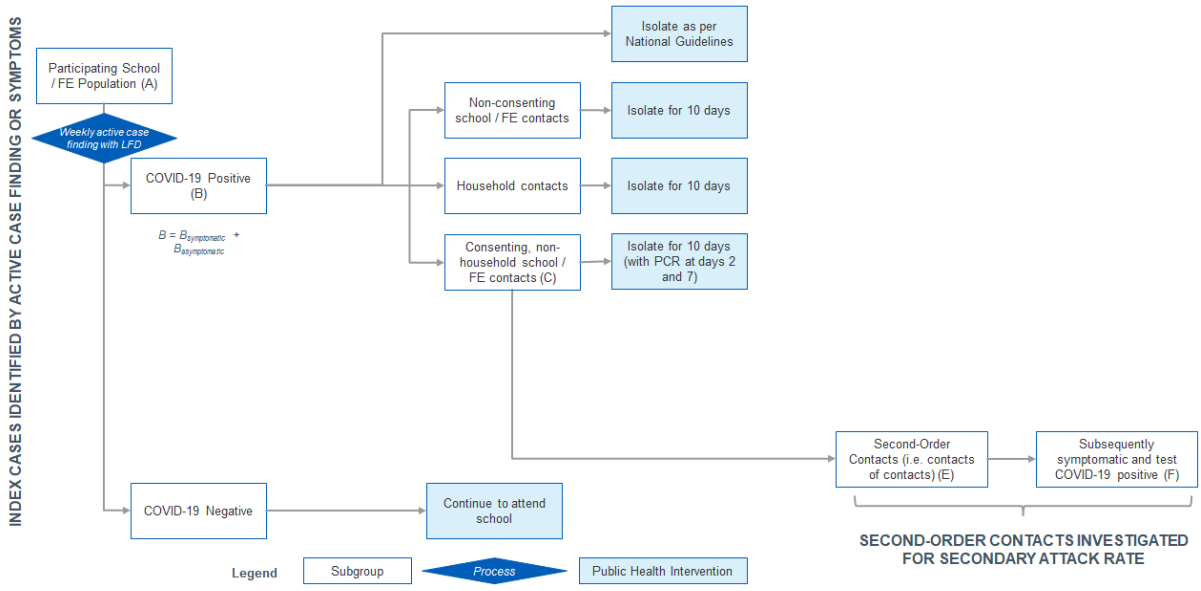


Figure 4: Process flow for schools DCT evaluation control arm

4.8 Note on PPE

For the routine weekly active case finding PPE applicable to asymptomatic testing is appropriate. For the daily testing of contacts of a case PPE applicable to the testing of symptomatic individuals must be used.

5. Results and Data Management

5.1 Data Collection and Flows

Schools will keep their own records to help monitor who has consented, the tests taken and the results. The schools' records are to help with management of DCT and contact tracing. Some of this information will be shared with DHSC, and will include personal identifiable information. On transfer from the schools, the Data will then be stored on DHSC and NHS Digital IT infrastructure.

The LFD testing data captured through the digital mechanisms will follow the normal process including upload to NPEX and stored by NHS Digital.

Data generated by the pilot will be held, recorded, stored, and accessed on DHSC and NHS Digital IT infrastructure. Transfer of data from schools to DHSC will be encrypted using Egress which is the secure working space which has been chosen by the CISO team at DHSC to send information securely.

5.2 Data Management

Personal data generated by the study will be stored on DHSC IT infrastructure. Data Protection Impact Assessments (DPIA) will be completed. Data analysis will be conducted by NHS T&T staff, under supervision from academics at the University of Oxford.

5.3 Results Data Monitoring

During the trial the combined results of all schools in the trial will remain blinded to all except the statistical centre and the Independent Data Monitoring Committee (IDMC). The IDMC will review the overall quality, safety and efficacy of the data and make recommendations to the Trial Steering Committee on whether the trial protocol should be altered. If they have evidence beyond reasonable doubt that one strategy is clearly superior (or inferior) to another arm and that the result is likely to change public health practice, they should immediately report the unblinded data and their recommendation to the Trial Steering Committee.

Statistical Analysis of primary and secondary end-points

Conventional statistical analysis will be undertaken. Analysis will be undertaken for the primary objective at a per-school basis with comparisons to the population of control schools. Absent school days (both total and COVID-related) will be presented as a proportion of pupils (with binomial confidence intervals). Unadjusted transmission events will be measured as the incidence of all COVID-19 positive cases determined by both Pillar 2 and school directed testing. Transmission events will also be categorised as 'more likely' if they either have a similar genetic sequence (the cut off to be determined) or as a member of the same pre-defined school bubble.

Secondary analysis

The performance of DCT will be made at the level of each primary contact. The performance of the DCT will be compared to PCR using conventional exact binomial statistics. The extent of secondary transmission events will be analysed using Poisson statistics and the results

stratified according to the LFD and PCR results of the DCT-contact. The results can also be adjusted according to the day that the LFD becomes positive and the CT value of the PCR result.

Appendix 1 – DCT Evaluation Framework

Below is shown the Evaluation Framework for the NHS Test Trace Programme of Evaluation of Daily Contact Testing. Individual pilots or studies run within this programme address a subset of these dimensions / questions.

- **Operational Feasibility**
    - How acceptable is the testing regime to those being tested?
    - What operational burden does it place on the host institution?
    - What are the implications for scaling up?
- **Scientific Knowledge**
    - What is the operational performance of the testing technology in this setting? Do we see concordance between new technologies and dual swab PCRs?
    - Are the assumptions used in previous modelling of the effectiveness of new testing technologies born out in real-world practice?
- **Public Health Effectiveness**
    - What is the uptake of testing? How does that vary by socio-demographic factors?
    - What effect does testing have on the spread of infection within the bubble / host institution? Does it increase or decrease compared to self-isolation? Could any modifications to the testing intervention improve its effectiveness?
- **Behavioural Factors**
    - Why do people choose or decline to take part in testing?
    - What factors affect whether people complete the regime of tests as intended?
    - How do people respond to positive and negative test results? How do they alter their behaviour?
- **Broader Social/Economic Benefit**
    - What impact does this have on people's daily activities (for example being at work or school)?

Appendix 2 – Self-Reported Behaviours Survey Instrument

1. Recent activities

a. Thinking about yesterday, please tick all the things you did:

   a. Went to school
   b. Went out to go to a shop, cafe or any other place outside my home (not school)
   c. Spent time outdoors (not at school) with people I do not live with (for example, in the park, playing, walking)
   d. Spent time indoors (not at school or online) with friends or family I do not live with
   e. Went out for any other reason (please say what this was for)
   f. None of these

   If you went to school yesterday please answer this question:

   How often did you do the following?
   [responses = Much less than usual, Less than usual About the same as usual More than usual, Much more than usual]

   Wore a face covering
   Spent time with people in my bubble
   Spent time with people not in my bubble
   Washed my hands

b. Thinking about the last 7 days, please say how often you have done each of these things: [options = never, once or twice, a few times, most days)

   a. Went to school
   b. Went out to go to a shop, cafe or any other place outside my home (not school)
   c. Spent time outdoors (not at school) with people I do not live with (for example, in the park, playing, walking)
   d. Spent time indoors (not at school or online) with friends or family I do not live with
   e. Went out for any other reason (please say what this was for)
   f. None of these

c. Comparing the last 7 days with the week before that - did you have more or less close contact with people you do not live with (indoors and for more than 15 minutes) last week?

   - Much more contact
   - Slightly more contact
   - About the same
   - Slightly less contact
   - Much less contact

2. Test result

a. During the past week, have you had any tests for coronavirus?
YES / NO

[If Yes]

Did you have a positive test result for any test? (This means that the test showed you did have COVID.)

YES/NO

[If Yes]

When did you test positive?

[Responses: Today, yesterday, 2-3 days ago, 4-5 days ago, 6-7 days ago]

Next question for those in DCT group only

b. How confident are you that your test results were accurate?
- Completely confident
- Very confident
- Fairly confident
- Not very confident
- Not at all confident

3. Preferences for testing

If you have been in contact with someone testing positive for coronavirus the usual option is to self-isolate by staying at home for 10 days.

A new option is to carry out daily tests for up to 7 days, which means that every day you have a negative test you can carry on with your normal activities and do not need to self-isolate.

Which option do you prefer?

- Strongly prefer 10 day self-isolation option
- Somewhat prefer 10 day self-isolation option
- No preference for either option
- Somewhat prefer daily testing option
- Strongly prefer daily testing option

4. **Demographics**

What school do you attend?

How old are you?

What is your gender?

- Male
- Female
- Prefer to self-describe
- Prefer not to say

Appendix 3 – Terms of Reference for Independent Trial Steering Group (TSC)

The role of the TSC

The role of the TSC is to provide overall supervision for the trial to ensure that the project is conducted to the rigorous standards set out in the Department of Health and Social Care's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. It should be noted that the day-to-day management of the project is the responsibility of the Principal Investigator, and as such the Principal Investigator may wish to set up a separate Project Management Group (PMG) to assist with this function.

The main features of the TSC are as follows:

- To provide advice, through its Chair, to The Department for Education, the Department for Health and Social Care and the Chief Investigator on all appropriate aspects of the trial
- To concentrate on progress of the trial, adherence to the protocol, patient safety (where appropriate) and the consideration of new information of relevance to the research question
- The rights, safety and well-being of the participants are the most important considerations and should prevail over the interests of science and society
- To ensure appropriate ethical and other approvals are obtained in line with the project plan
- To agree proposals for substantial protocol amendments and provide advice regarding approvals of such amendments
- To provide advice to the investigators on all aspects of the trial.

Constitution of the TSC

- The members of the TSG will be appointed by the Department of Health and Social Care and the Department for Education
- Independent * members must make up a minimum of 75% of the TSC membership.
- The minimum quorum for any TSC meeting to conduct business is 67% (two thirds) of the appointed membership.
- Only appointed members will be entitled to vote, and the Chair will have a casting vote
- The Chair and members must sign and maintain a log of potential conflicts and/or interests
- Attendance at TSC meetings by non-members is at the discretion of the Chair
- The primary TSC reporting line is via the Chair to the Department of Health and Social Care and the Department for Education

** Independence is defined as follows:*

- *Not part of the same institution as any of the applicants or members of the project team. This means holding neither a substantive nor honorary contract with said institution.*
- *Not related to any of the applicants or project team members.*

- *For the Chair only; not an applicant on a rival proposal.*
- *It is recognised that independence status may change during the duration of the trial.*

Composition Requirements of the TSC

- An Independent* Chair
- An Independent* statistician
- At least one PPI member
- Others with expertise relevant to the project, such as an infectious disease epidemiologist and an expert in running studies in educational settings
- The TSC may invite observers to meetings

TSC meetings

- The TSC should meet at least monthly
- TSC meetings should be scheduled to follow shortly after IDMC meetings so that reports from that group can be considered if appropriate
- Minutes of meetings should be sent to all members, the Department of Health and Social Care, the Department for Education and the Principal Investigator and be retained in the study master file.

The responsibility for calling and organising TSC meetings lies with the Principal Investigator, in association with the Chair.

The Role of the Chair of TSC

The Chair's responsibilities include:

- Liaising with the Principal Investigator to arrange a meeting to finalise the protocol and to set up a schedule of meetings to align with the project plan
- Establishing clear reporting lines.
- Being familiar with relevant guidance documents and with the role of the IDMC if appropriate.
- Providing an independent*, experienced opinion if conflicts arise between the needs of the research team, the participating organisations and/or any other agencies
- Leading the TSC to provide regular, impartial oversight of the study, especially to identify and pre-empt problems
- Ensuring that changes to the protocol are debated and endorsed by the TSC;
- Being available to provide independent* advice as required, not just when TSC meetings are scheduled

- Commenting in detail (when appropriate) regarding the continuation, extension or termination of the project. NB: The TSC Chair does not need to be a content expert him/herself but needs to ensure that enough content expertise is available for the group to perform its oversight function effectively.

Appendix 4 – Terms of Reference for Independent Data Monitoring Committee (IDMC)

The role of the IDMC

The IDMC's main role is as follows:

- It is the only body involved in the trial that has access to the unblinded comparative data
- The role of its members is to monitor these data and make recommendations to the Trial Steering Committee (TSC) on whether there is there evidence beyond reasonable doubt that one arm is superior to another arm such that it is likely to change public health or educational practice.
- The safety, rights and well-being of the trial participants are paramount
- The IDMC considers the need for any interim analysis advising the TSC regarding the release of data and/or information
- The IDMC may be asked by the ISSG to consider data emerging from other related studies
- There are also rare occasions when the IDMC chair might be asked, by the chair of the TSC to provide advice based on a confidential interim or futility analysis if serious concerns are raised about the viability of the study or if the research team are requesting significant extensions.
- Criteria should be agreed at which continuation of the trial is considered futile and the DM(E)C would only indicate if these had been passed or not as this would limit the potential for un-blinding.

Constitution of the IDMC

- Members of the IDMC will be appointed by the Department of Health and Social Care and the Department for Education
- Only appointed members will be entitled to vote, and the Chair will have a casting vote
- The minimum quoracy for a meeting to conduct business is 67% (two thirds) of appointed members
- The Chair and members must sign and maintain a log of potential conflicts and/or interests
- Attendance at IDMC meetings by non-members is at the discretion of the Chair
- The primary IDMC reporting line is via the Chair to the TSC.

Composition Requirements of the IDMC

- All IDMC members are to be independent*
- Membership of the IDMC will be four members, comprising experts in the field, e.g. a clinician with experience in infectious disease epidemiology, an expert in working with educational settings and an expert trial statistician.

IDMC Meetings

- Responsibility for calling and organising IDMC meetings lies with the Principal Investigator, in association with the Chair of the IDMC. The project team should provide the IDMC with support for organising and minuting meetings and a comprehensive report, the content of which should be agreed in advance by the Chair of the DMC.
- The IDMC should be presented with an interim analysis of the trial data prior to the return of the majority of pupils to school.
- The IDMC should determine their meeting frequency, but must meet to consider the interim analysis before the full return of pupils to school.
- Minutes of meeting should be sent to all members, DfE, DHSC, the TSC and the study master file. It should be noted that the minutes may have 'in camera' items redacted from some copies.

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**Independence is defined as follows:*

- *Not part of the same institution as any of the applicants or members of the project team. This means holding neither a substantive nor honorary contract with said institution.*
- *Not related to any of the applicants or project team members.*
- *For the Chair only; not an applicant on a rival proposal.*
- *It is recognised that independence status may change during the duration of the trial.*

Appendix 5 – Terms of Reference of Testing Initiatives Evaluation Board

Testing Initiatives Evaluation Board | Terms of Reference

NHS Test and Trace

Intent	The Testing Initiatives Evaluation Board provides expert review of scientific, clinical and operational findings and conclusions from evaluation activities across the programme, and considers the impact these outputs could have on policy				
Purpose	• Provide scientific, clinical and operational insights for design of new evaluations • Maintain watching brief on evaluation approach to current and upcoming pilots; this may entail requesting further information on data sources, methodologies and timeframe for delivery • Consider emerging findings and scrutinise methodologies and conclusions, critically challenge where needed, provide quality assurance for evaluation products of the programme • Appraise the impact that evaluation outputs could have on policy for mass and serial testing • Approve programme products for publication				
Standing Agenda	• Introductions • Minutes • Pipeline of Testing pilots • Scheduled reviews of selected evaluations • AOB • Other items added as appropriate				
Reporting to	SAGE			Meeting Chair	Susan Hopkins
Frequency	Weekly	Work day	Tuesday	Coordination	Sarah Tunkel
Duration	90 minutes	Delivery Medium	Virtual	Secretariat	Alan Edwards
Minutes of Meeting	• Circulated by email and uploaded into Teams				

Name	Role
Susan Hopkins	Chief Medical Advisor, *Chair*
Tom Fowler	Director PHCO, *Deputy Chair*
Sarah Tunkel	Deputy Director, Evidence & Knowledge, *Convenor*
Dame Sue Hill	Chief Scientific Officer, NHS England and NHS Test and Trace
Steve Calder	Director, Intelligence
Sarah Hartley	Director, Use Cases
Toby Lambert	Deputy Director, Testing Policy
Sidonie Kingsmill	Director, Customer Experience
Neil Ashworth	Director, Delivery Channels
Sara Seigel	Senior Partner, Deloitte
Johanna Hutchinson	Director of Data & Data Science, JBC
Joe Hillier	Deputy Director, Evidence & Evaluation
Alex Green-Wilkes	Deputy Director, Mass Testing Communications
Alex Sienkiewicz	Director PHE Porton Down
Isabel Oliver	PHE, Director, National Infection Service
Richard Amlot	PHE, Behavioural Science Unit
Andrew Howe	PHE, Trace
Janet Atherton	Public Health Advisor to Contain
Graeme Tunbridge	Director of Devices, MHRA
Janine Jolly	Group Manager, Devices Safety and Surveillance, MHRA
Nicola Steedman	Scottish Government
Brid Farrell	Director of Testing Programme, Northern Ireland
Rob Orford / Fliss Bennee	Welsh Government
Greg Fell	DPH, Sheffield
Ruth Tennant	DPH, Solihull
Chris Holmes	Programme Director for Health & Medical Sciences, Turing Institute

NHS Test and Trace

Name	Role
Sir Muir Gray	Formerly Director of UK National Screening Committee
James Rubin	Kings College London
Dame Theresa Marteau	University of Cambridge
Calum Semple / Iain Buchan	University of Liverpool
John Edmunds	London School of Hygiene & Tropical Medicine
Timothy Peto	University of Oxford
Sheila M Bird	Royal Statistical Society / MRC Biostatistics Unit
Sir Ian Diamond	National Statistician, ONS
Iain Bell	Director General, Population and Public Policy, ONS

NHS Test and Trace

Information Flow

No.	Decisions / Outcomes / Outputs
1	Meeting minutes
2	Updated action log
3	Recommendations on new evaluations
4	Recommendations on changes to evaluation protocols
5	Sign off on studies that can be published

No.	Inputs	Owner	Details
1	Advise on policy direction using evidence base from pilots		
2	Feed into the pilot review and roll out process to ensure these continually improve		
3	Actions & notes from previous meeting		

Appendix 6 – Membership of Study Governance Bodies

6.1 Education Evaluation Steering Group

Philippa Gilmour	DHSC
Joseph Hillier	DHSC
Sarah Tunkel	DHSC
Stephen Finer	DHSC
Karl Olsen	DHSC
Tom Fowler	DHSC
Katia Yazigi	DHSC
Steve Grudgings	DHSC
Peter Marks	DHSC
Helen Slater	Department for Education
Richard Lumley	Department for Education
Amy Morgan	Department for Education
Osama Rahman	Department for Education
Oliver Clifton-Moore	Department for Education
James Henry	Department for Education
Dougal Hargreaves	Department for Education
Christopher Gray	Department for Education
Stevie Jones	Department for Education
Jane Pettican-Boyes	Department for Education
Lavani Devarajan	Department for Education
Elizabeth Castle	Department for Education
Aashya Zina	Department for Education
Vicky Petrie	Department for Education

6.2 Trial Steering Group

Prof Martin Llewelyn, University of Sussex	Independent Chair
To be recruited by Chair	Independent Statistician
To be recruited by Chair	PPI Member

6.3 Independent Data Monitoring Committee

Prof Neil French, University of Liverpool	Clinician (infectious disease epidemiology expert)
To be recruited by Chair	Clinical Trial Statistician
To be recruited by Chair	Educational Expert

Appendix 7 – Further details on social research instruments

7.1. User research

The aim of this research activity is to understand the user journey for Daily Contact Testing within intervention arm participants. We need to identify any residual risks to effective delivery and mitigate these before rolling out the trial. We also need to understand how the DFE can communicate effectively to ensure take-up for DCT in these settings is high.

Main objectives as follows:

1. Understand the user journey of DCT within secondary school and college settings, including how this varies in different institutions
2. Identify any risks or blockers that will stop DCT being implemented.
3. Inform learning from Phase 1 of the trial to improve the implementation of Phase 2. In phase 2, to inform policy recommendations about the use of DCT in secondary schools and colleges.
4. Ensure policy relating to testing in special schools reflects the needs, experiences and challenges of special schools

Participants

Staff (teaching and non-teaching) at participating intervention arm institutions involved in management / implementation of Daily Contact Testing.

Two waves of user research interviews will be delivered in phase 1 and a further two waves in phase 2. Interviews will be conducted at the start of the trial and near to the end of the trial.

In Phase 1 we expect to conduct a user research interview in all consenting schools (c. 5 initial and 5 follow up interviews). In phase 2 we will conduct ten initial interviews and follow up interviews. No more than one research interview will be conducted per school, to minimise research burden.

Targeting

Schools will be selected based on the available pool of volunteers to maximise potential insight. For phase 1 we expect this to be all consenting schools. For phase two we will select schools to approach for user research interviews where there is most scope for differing experiences that we can learn from: e.g. different school types; different levels of disadvantage; etc.

Delivery mechanism

Online or telephone interviews, no longer than 20-30 minutes.
Staff participants will be recruited through consenting schools, via the lead contact between the school and the trial administrators. We expect that consenting schools will confirm an appropriate person to be interviewed and contact details for that person will be shared with the research team.

User research topics

Decision making and participation

- Initial reaction to the trial invitation
- Reasons for joining the trial and decision-making process
- Understanding of DCT (what is it?; why is it being trialled? etc)

DCT delivery (planned / enacted)

- Logistics of delivery in the school (e.g. all activities undertaken in-house, sub-contracted out, or mixture; number of testing centres; location of testing)
- Process of delivering testing in the school
- Process of what happens when there is a positive DCT result
- Experiences of reporting testing data results

DCT engagement

- Communication about DCT with pupils, parents, and staff - including how consent is being managed, any post-result conversations / discussions with pupils
- Any challenges helping pupils through testing
- Experiences with self-isolating vs DCT participating pupils (e.g. any insight into reasons for preferring self-isolation; school's preference; etc.)

Anticipation / reflections

- Anything expected to work well / that worked more smoothly than anticipated
- Any expected / experienced key pain points
- Views on what could be changed to work effectively
- Expected obstacles, if any, to scaling DCT: for schools, for pupils

7.2. In-depth qualitative interviews

The aim of this research activity interviews is to generate rich detail on the experience of testing, perspective / attitudes towards the testing (and DCT in particular), and behavioural responses to test results. In-depth interviews are designed to explore *why* participants hold particular perspectives or act in particular ways. They are not designed to be generalisable, but instead create a more holistic understanding of participants' experiences in the intervention or control schools.

<u>Participants</u>

The following sub-groups will be recruited as interviewees:

- Close contacts, intervention DCT
- Close contacts, intervention self-isolation
- Close contacts, control
- Parents, intervention DCT
- Parents, intervention self-isolation
- Parents, control
- Staff, intervention

Note that close contacts could be staff members, not just pupils, depending on positive cases.

Final total of interviews conducted will be dependent on number of cases found and number of consenting participants, but are aimed to be as follows:

- 12-15 each - Close contacts, DCT; Parents, DCT
- 8-12 each – Close contacts, intervention self-isolation
- 8-12 each - Close contacts, control; Parents (intervention self-isolation & control); Staff, intervention

Targeting

Our selection of interviewees will be limited by where positive COVID cases arise (and thus who are close contacts), but in principle we will recruit interviewees to get a mix of gender, ethnicity and education setting types (ensuring representation of schools serving minority ethnic and low income communities) to better understand any idiosyncratic issues for different sub-populations.

Delivery mechanism / recruitment

For close contacts and parents, recruitment will be brokered a letter home to parents asking for consent to participate. The same letter will be used for the DCT 7 day survey and in-depth interviews, to minimise burden. Staff will be recruited via a request through their schools.

Participants will be invited to take part in recorded online or telephone interviews (20 to 30 minutes) outside of school opening hours and will receive an online voucher as reimbursement for their time.

Main interview topics

For all close contacts:

- Information and advice received
- Support received
- Willingness to share close contact details
- Preference for daily testing vs self-isolation
- Experiences of DCT / self-isolation
- Behaviour during DCT / self-isolation
- [Intervention only] Reasons for opting for DCT or self-isolation

For parents (in addition to relevant elements of above):

- Willingness to consent to testing
- Perspectives on safety of testing

For staff (in addition to relevant elements of above):

- Classroom impact of testing - DCT participants attending vs isolating; potential workforce burden impacts on wider school activity

Interview schedules

All interviews will be preceded by a standard introduction the research, explanation of the process and participants' rights.

Close contacts, Intervention Daily Contact Testing sample

I would like to start by asking you about your experiences of daily testing for COVID-19.

- What made you agree to carry daily testing instead of self-isolating?
- What is good about self-isolation? What is not so good about self-isolating?
- What is good about daily testing? What is not so good about daily testing?
- What happened on the day you were told you had been in contact with someone with the virus?

Experiences of testing

- What happened on the first day that you took a test? Can you tell me about anything that changed?
- Were there any times that you didn't get tested?
- What happened on those days?
- What was the most difficult part of having to be tested daily?
- What did you do to help you overcome any problems?

Behaviour during testing

- How did you feel when you received a negative test result? How did it affect your life?
- What, if anything, did you do differently at school on the days you got a negative test?
- Can you tell me about anything you do differently outside school on the days you got a negative test?
- Can you tell me about anything you do differently at home on the days you got a negative test?
- Did you take more or less precautions to reduce infection on the days you got a negative test?
- Why / why not?

[This section only for DCT participants required to self-isolated because of a positive test]
How did you feel when you received a positive test result? How did it affect your life? There's loads of guidance to do with self-isolation, and we know people can find some of it tricky.

- What does the term self-isolation mean to you?
- What steps did you take?
- Can you tell me about any times when you had to leave the house?
- Can you tell me about any times when you had visitors?
- Can you tell me about any times it was hard to stick to the guidance?
- What was the most difficult part of having to self-isolate?
- What did you do to help you overcome any problems?
- What would have helped you to be able to follow the advice around self-isolating?
- Do you think having to self-isolate had any impact on your health, wellbeing or education in anyway?

What, if anything, did you do differently in the home while you were self-isolating?

- Did you take any extra precautions to reduce infection in the home?
- Why/why not?

What support did you have to help you with daily testing and self-isolation?

- What did you think of the support?
- What support did you need? / what was missing?

What information or advice did you and your family have about daily testing and self-isolation?

- Where did you look for information or advice?
- What information did you find most reliable?
- What did you think about the information you found?
- Was anything unclear or confusing?
- Was anything missing?

Have you had to take a test or self-isolate before?

[IF YES]

- How did your experiences of daily testing and self-isolation compare with any other times you have been in contact with a positive case?
- What was different?
- What was better/worse?

If you were told that you had been in contact with a positive case in the future, would you choose to do daily testing again or to self-isolate instead?

- What might influence this decision? What could be done to make it better / easier for people to test/isolate?

If you had a positive test in the future and you knew that your contacts would be able to have daily testing (instead of self-isolating), would this affect how willing you are to share their contact details?

Is there anything else you would like to say?

Close contacts, Intervention self-isolating sample

Can you start off by telling me about your experiences of having to self-isolate for 10 days?

- What made you decide to carry out self-isolation instead of 7 days daily testing?
- Did you have any concerns about daily testing that made you choose self-isolation?
- Did you have any concerns about self-isolating?
- What happened on the day you were told you had been in contact with someone with the virus?

There's loads of guidance to do with self-isolation, and we know people can find some of it tricky.

- What does the term self-isolation mean to you?
- What steps did you take?
- Can you tell me about any times when you had to leave the house?
- Can you tell me about any times when you had visitors?
- Can you tell me about any times it was hard to stick to the guidance?
- What was the most difficult part of having to self-isolate?
- What did you do to help you overcome any problems?
- What would have helped you to be able to follow the advice around self-isolating?
- Do you think having to self-isolate had any impact on your health, wellbeing or education in anyway?

Can you tell me anything you did differently in the home during the 10/14 days that you were in self-isolation?

- Did your family take any extra precautions to reduce infection in the home?
- Why/why not?

What information or advice did you and your family have about self-isolating?

- Where did you look for information or advice?
- What information did you find most reliable?
- What did you think about the information you found?
- Was anything unclear or confusing?
- Was anything missing?

What support did you have to help you to self-isolate?

- What did you think of the support?
- What support did you need? / what was missing?

If you were informed that you had been in contact with a positive case again, would you be willing to complete seven days testing / isolating instead of self-isolation for 10/14 days?

- Why?
- What might influence this decision?
- What could be done to make it better / easier for people to test/isolate?

Is there anything else you would like to say?

Close contacts, control sample

Can you start off by telling me about your experiences of having to self-isolate for 10 days?

- Did you have any concerns about self-isolating?
- What happened on the day you were told you had been in contact with someone with the virus?

There's loads of guidance to do with self-isolation, and we know people can find some of it tricky.

- What does the term self-isolation mean to you?
- What steps did you take?
- Can you tell me about any times when you had to leave the house?
- Can you tell me about any times when you had visitors?
- Can you tell me about any times it was hard to stick to the guidance?
- What was the most difficult part of having to self-isolate?
- What did you do to help you overcome any problems?
- What would have helped you to be able to follow the advice around self-isolating?
- Do you think having to self-isolate had any impact on your health, wellbeing or education in anyway?

Can you tell me anything you did differently in the home during the 10/14 days that you were in self-isolation?

- Did your family take any extra precautions to reduce infection in the home?

- Why/why not?

What information or advice did you and your family have about self-isolating?

- Where did you look for information or advice?
- What information did you find most reliable?
- What did you think about the information you found?
- Was anything unclear or confusing?
- Was anything missing?

What support did you have to help you to self-isolate?

- What did you think of the support?
- What support did you need? / what was missing?

If you were informed that you had been in contact with a positive case again, would you be willing to complete seven days testing / isolating instead of self-isolating for 10/14 days?

- Why?
- What might influence this decision?
- What could be done to make it better / easier for people to test/isolate?

Is there anything else you would like to say?

Parents, intervention Daily Contact Testing sample

I would like to start by asking you about your experiences of *[PUPILNAME]* doing daily testing for COVID-19.

- What made you agree for *[PUPILNAME]* to carry daily testing instead of self-isolating? What were some of the factors that influenced your decision?
- What are your feelings about self-isolation?
- What are your feelings about daily testing?

Experiences of testing

- What happened on the day you were told *[PUPILNAME]* had been in contact with someone with the virus?
- What happened on the first day that they took a test? Can you tell me about anything that changed?
- Were there any times that *[PUPILNAME]* didn't get tested? What happened on those days?
- What was the most difficult part of *[PUPILNAME]* having to be tested daily?
- What did you do to help you overcome any problems?

Behaviour during testing

- Did you and *[PUPILNAME]* discuss the test process and their test results much? What did you talk about?
- How did you feel when *[PUPILNAME]* received a negative test result?
- Do you notice *[PUPILNAME]* do anything differently at school, outside school, or at home on the days they got a negative test?
- Did you do anything differently on the days *[PUPILNAME]* got a negative test result?

[This section only for parents of DCT participants required to self-isolated because of a positive test]
How did you feel when *[PUPILNAME]* received a positive test result? How did it affect your life?
What does the term self-isolation mean to you?
Can you tell me about your experiences of *[PUPILNAME]* having to self-isolate?

- What steps did you take?
- What was the most difficult part of having to self-isolate?
- What did you do to overcome any problems you had?
- What would have helped you overcome any problems that you had?
- Do you think having to self-isolate had any impact on *[PUPILNAME]'S* health, wellbeing or education in anyway?

There's loads of guidance to do with self-isolation, and we know people can find some of it tricky.

- Can you tell us about any times that you *[PUPILNAME]* had to leave the house?
- Can you tell us about having visitors?

What, if anything, did you do differently in the home while *[PUPILNAME]'s* were self-isolating?

- Did you take any extra precautions to reduce infection in the home?
- Why/why not?

What information or advice did your family have about daily testing and self-isolation?

- Where did you look for information or advice?
- What information did you find most reliable?
- What did you think about the information you found?
- Was anything unclear or confusing?
- Was anything missing?

Have you had to take a test or do self-isolation before?

[IF YES]

- How did your experiences of daily testing and self-isolation compare with any other times you have been in contact with a positive case?
- What was different?
- What was better/worse?

If you were told that *[PUPILNAME]* had been in contact with a positive case in the future, would you choose to do daily testing again or to self-isolate instead?

- What might influence this decision? What could be done to make it better / easier for people to test/isolate?

If you had a positive test in the future and you knew that your contacts would be able to have daily testing (instead of self-isolating), would this affect how willing you are to share their contact details?

Is there anything else you would like to say?

Parents, intervention self-isolation sample

I would like to start by asking you about your experiences of *[PUPILNAME]* having to self-isolate for 10 days.

- What made you decide to carry out self-isolating instead of 7 days daily testing?
- What are your feelings about self-isolating?
- What are your feelings about daily testing?
- What happened on the day you were told *[PUPILNAME]* had been in contact with someone with the virus?

There's loads of guidance to do with self-isolation, and we know people can find some of it tricky.

- What does the term self-isolation mean to you?
- What steps did you and *[PUPILNAME]* take?
- Can you tell me about any times when *[PUPILNAME]* had to leave the house?
- Can you tell me about any times when you had visitors?
- Can you tell me about any times it was hard to stick to the guidance?
- What did you do to help you overcome any problems?
- What would have helped you to be able to follow the advice around self-isolating?
- Do you think having to self-isolate had any impact on *[PUPILNAME]'S* health/wellbeing/education in anyway?

What information or advice did your family have about daily testing and self-isolation?

- Where did you look for information or advice?
- What information did you find most reliable?
- What did you think about the information you found?
- Was anything unclear or confusing?
- Was anything missing?

If you were told that *[PUPILNAME]* had been in contact with a positive case in the future, would you choose to do daily testing again or to self-isolate instead?

- What might influence this decision? What could be done to make it better / easier for people to test/isolate?

Is there anything else you would like to say?

Parents, control sample

I would like to start by asking you about your experiences of *[PUPILNAME]* having to self-isolate for 10 days.

- What are your feelings about self-isolating?
- What happened on the day you were told *[PUPILNAME]* had been in contact with someone with the virus?

There's loads of guidance to do with self-isolation, and we know people can find some of it tricky.

- What does the term self-isolation mean to you?
- What steps did you and *[PUPILNAME]* take?
- Can you tell me about any times when *[PUPILNAME]* had to leave the house?
- Can you tell me about any times when you had visitors?

- Can you tell me about any times it was hard to stick to the guidance?
- What did you do to help you overcome any problems?
- What would have helped you to be able to follow the advice around self-isolating?
- Do you think having to self-isolate had any impact on *[PUPILNAME]'S* health/wellbeing/education in anyway?

What information or advice did your family have about daily testing and self-isolation?

- Where did you look for information or advice?
- What information did you find most reliable?
- What did you think about the information you found?
- Was anything unclear or confusing?
- Was anything missing?

If you were told that *[PUPILNAME]* had been in contact with a positive case in the future, would you choose to do daily testing again or to self-isolate instead?

- What might influence this decision? What could be done to make it better / easier for people to test/isolate?

Is there anything else you would like to say?

Staff, intervention arm schools

Have you been involved in delivering testing at the school?

[IF YES]

- Can you tell me about you experiences?
- To what extent has being involved in testing impacted on your other duties?

What information or advice did you receive about daily testing?

- What information and guidance did you receive from the school about daily testing?
- Did you look for additional information or advice? What information did you find most reliable?
- To what extent was it clear why daily testing was being undertaken?

How would you describe the impact of testing at your school?

- Did anything unexpected happen?
- Is there anything you think has gone particularly well?
- Is there anything you think has gone badly, or that you would do differently?
- What was your reaction when you heard about daily testing being implemented at the school?
- To what extent has your view changed?

Impacts of testing on behaviour

- Do you know anyone in the school who was taking daily tests?
- How do you feel about having pupils in school who had been identified as a contact of a positive case, but tested negative themselves? Why?
- Did you do anything differently at school while the daily testing has been going on?

Overall, to what extent do you think daily testing is suitable for your schools?

- Are there any clear benefits you think are important?
- Are there any clear drawbacks you think are important?
- Is there anything you think is specific to your school, or your type of school, that makes daily testing more or less effective?

Is there anything else you would like to say?