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The acceptability of testing contacts of confirmed COVID-19 cases using serial, self-administered lateral flow devices as an alternative to self-isolation

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Abstract

Introduction. Evidence suggests that although people modify their behaviours, full adherence to self-isolation guidance in England may be suboptimal, which may have a detrimental impact on COVID-19 transmission rates.

Hypothesis. Testing asymptomatic contacts of confirmed COVID-19 cases for the presence of SARS-CoV-2 could reduce onward transmission by improving case ascertainment and lessen the impact of self-isolation on un-infected individuals.

Aim. This study investigated the feasibility and acceptability of implementing a 'test to enable approach' as part of England's tracing strategy.

Methodology. Contacts of confirmed COVID-19 cases were offered serial testing as an alternative to self-isolation using daily self-performed lateral flow device (LFD) tests for the first 7 days post-exposure. Asymptomatic participants with a negative LFD result were given 24 h of freedom from self-isolation between each test. A self-collected confirmatory PCR test was performed on testing positive or at the end of the LFD testing period.

Results. Of 1760 contacts, 882 consented to daily testing, of whom 812 individuals were within 48 h of exposure and were sent LFD testing packs. Of those who declined to participate, 39.1% stated they had already accessed PCR testing. Of the 812 who were sent LFD packs, 570 (70.2%) reported one or more LFD results; 102 (17.9%) tested positive. Concordance between reported LFD result and a supplied LFD image was 97.1%. In total, 82.8% of PCR-positive samples and 99.6% of PCR-negative samples were correctly detected by LFD. The proportion of secondary cases from contacts of those who participated in the study and tested positive (6.3%; 95% CI: 3.4–11.1%) was comparable to a comparator group who self-isolated (7.6%; 95% CI: 7.3–7.8%).

Conclusion. This study shows a high acceptability, compliance and positivity rates when using self-administered LFDs among contacts of confirmed COVID-19 cases. Offering routine testing as a structured part of the contact tracing process is likely to be an effective method of case ascertainment.

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Keywords: contacts; COVID-19; DCT; lateral flow testing; SARS-CoV-2; testing.

Abbreviations: BAME, black and minority ethnic; CI, confidence interval; ct, cycle threshold; CTAS, contact tracing and advice service; DBS, demographic batch tracing service; DCT, daily contact testing; HES, hospital episode statistics; IMD, index of multiple deprivation; IQR, interquartile range; LFD, lateral flow device; REGG, Research Ethics and Governance Group; SGSS, second generation surveillance system; UKHSA, UK Health Security Agency.

Two supplementary figures and four supplementary tables are available with the online version of this article.

INTRODUCTION

At the time of performing this study in December 2020, all contacts of confirmed cases of COVID-19 in England were required to isolate for 10 days from the date of their last exposure and were not routinely tested for SARS-CoV-2 unless they developed symptoms [1]. In August 2021, vaccinated contacts and those under 18.5 years were no longer required to isolate, although as of December 2021 it was strongly advised that vaccinated contacts take daily lateral flow device (LFD) tests as an alternative to self-isolation. All COVID-19 contacts have been offered a single PCR test, irrespective of symptoms, since March 2021 [1].

Evidence suggested that although people modify their behaviours, full adherence to self-isolation guidance in England was suboptimal, which may have impacted transmission rates [2, 3]. Strategies for improving self-isolation compliance have been proposed, including provision of financial or other incentives and penalties for breaking isolation. However, such strategies may not consider the wider economic, social and well-being impacts of isolation [4, 5]. 'Test to enable' strategies are designed to isolate those with infection while reducing or avoiding self-isolation for those without infection. Implementing a 'test to enable' approach could therefore lessen the impact of self-isolation on exposed individuals without infection and reduce onward transmission by improving case ascertainment for asymptomatic, paucisymptomatic and pre-symptomatic individuals and, potentially, adherence to self-isolation [6–10]. Indeed, a recent study reported that 16.3 % of isolating contacts of confirmed cases were PCR positive for SARS-CoV-2 RNA, suggesting that a structured approach to testing contacts of confirmed cases can support improved case ascertainment [11].

Asymptomatic, rapid antigenic tests using LFDs for SARS-CoV-2 are now widely available in the UK and have been used for testing in workplaces, schools and health and social care settings [12]. However, at the time of this study, LFDs were not commonly in use and it was important to understand if LFD use was acceptable to people. It has been reported that the sensitivity of LFD testing is lower than PCR (57.5–78.8%); however, the sensitivity has been reported to improve to >90 % when tested using samples with higher viral loads [13, 14]. LFDs provide some added benefits compared to PCR, with a rapid turn-around time (usually less than 30 min), low cost and delivery outside of a routine laboratory environment. These features may help increase accessibility to testing for harder to reach groups and allow for a programme of repeated testing, improving the overall case ascertainment [8, 9]

Here we describe an investigation into the feasibility and acceptability of a self-administered daily 'test to enable' programme for contacts of confirmed COVID-19 cases using the Innova LFD antigen test during the first 7 days of isolation. On receipt of a negative LFD result, asymptomatic adult participants were exempt from self-isolation for a 24 h period. The study was designed to identify barriers and strengths to a 'test to enable' approach for contacts of confirmed cases of COVID-19, to inform the implementation of serial testing of contacts using LFDs as part of England's NHS Test and Trace strategy.

METHODS

Recruitment

Asymptomatic adult contacts (>18 years) exposed to a confirmed COVID-19 case within the preceding 48 h were identified from NHS Test and Trace records and invited to participate by NHS Test and Trace staff using a specific recruitment script (Figs 1 and S1, available in the online version of this article). Contacts who completed contact tracing via the call centre route were recruited at the end of their contact tracing interview. Contacts who self-completed contact tracing via a digital route were contacted after completing their contact tracing form and were recruited. Recruitment was performed Monday to Friday, 08.00 to 16.00 h, between 11–23 December 2020 and 4–12 January 2021. A non-probability sample with target size of 800 was sought based on the volume of daily calls performed by recruiters, with no limit on daily recruitment. Individuals contacted by the NHS Test and Trace recruitment team were asked for their reasons for consenting or declining the testing offer based on predefined categories.

Specimen collection and LFD result reporting

Consenting participants were posted six Innova LFDs (2×3 packs) and a PCR self-sample postal swab kit. Participants were required to self-complete six daily LFD tests during the first 7 days post-exposure and self-report daily results together with a digital image of their LFD result to the UK Health Security Agency (UKHSA; formerly Public Health England) using a secure online portal developed in Snap Survey (Snap Professional version 11), which mirrored the government point of care test portal (www.gov.uk/report-covid-19-result). Participants were required to submit daily LFD results, an image of the test, identifiers, symptoms and the date the kit arrived. Reminder messages were sent to all participants with a valid mobile number using the Notify messaging service (https://www.notifications.service.gov.uk) to provide information on kit dispatch and LFD reporting, to encourage PCR submission and to provide PCR results. On receipt of a negative LFD result, asymptomatic participants were exempt from self-isolation for a 24 h period.

Self-collected nasal PCR swabs were returned to the same UKHSA laboratory (UKAS ISO 15789) using an approved, trackable postal route, either on receipt of a positive LFD result or at the end of the 7 day testing period if all LFD results were negative. SARS-CoV-2 RT-PCR testing at UKHSA Colindale was carried out using RT-PCR assays targeting the Orf1ab and E genes [15],

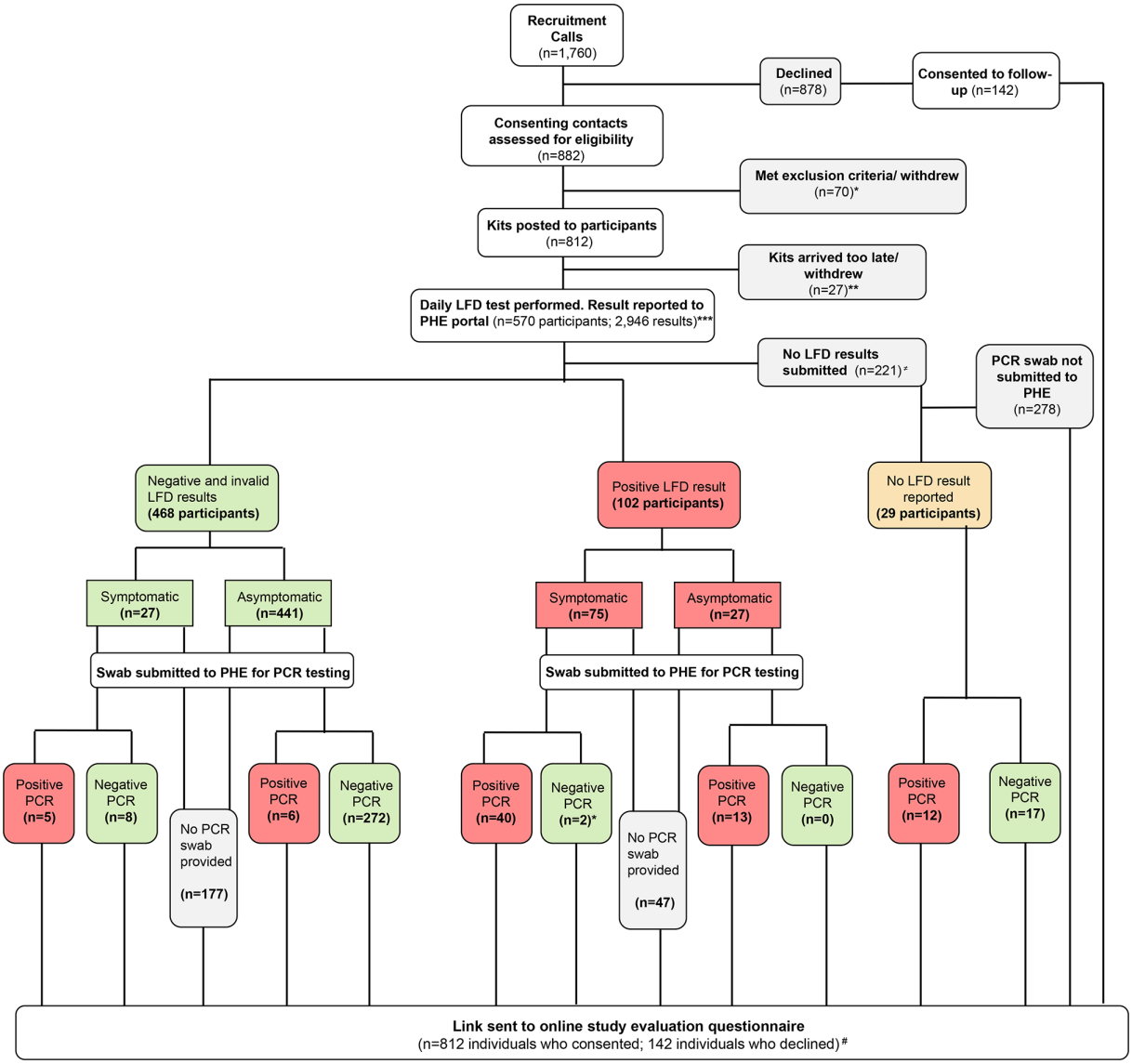

Fig. 1. Flow chart of study participation. *In total, 68 participants were excluded due to exposure >48 h prior, one excluded as non-England resident and one withdrew after giving consent. **Twenty-seven participants notified the study team that their kit arrived too late to participate or did not arrive and were excluded. ***Reported LFD results were excluded if: duplicate entries (*n*=221; 7.5%), blank entries (*n*=189; 6.4%), no identifiers (*n*=27) and reporting by an ineligible non-participant (*n*=13). ᶻFive participants did not report a result but informed the study team that an eligible household member would be reporting using their testing kit. In total, 216 participants did not report a result but did not contact the study team to provide a reason. #Evaluation questionnaire data analysis is presented separately, by Martin *et al.* [16].

RT-PCR testing carried out in other clinical laboratories used different commercially available tests. Reporting of PCR and LFD results was compliant with Health Protection notification regulations and NHS Test and Trace.

Data linkage

Identifiers from the NHS Test and Trace Contact Tracing and Advice Service (CTAS) webtool were linked to data collected by recruiting agents and to LFD and PCR results. Linkage was deterministic, based on a combination of CTAS ID (Test and Trace ID), name, date of birth, telephone number, postcode and NHS number. Enrichment of NHS number and ethnicity was performed using the NHS demographic batch tracing service (DBS) and Hospital Episode Statistics (HES), respectively. An index of multiple deprivation (IMD) was derived from the postcode of residence. UKHSA's main laboratory surveillance system, SGSS, and CTAS were interrogated using participant identifiers to obtain non-study PCR test results.

Data analysis

All data with the exception of secondary attack rates were analysed in Stata version 15. Associations were determined by chi squared and rank sum tests, with $P<0.05$ used to show observed differences between groups. Sample size was not determined by statistical power considerations and this should be considered when interpreting study results.

Secondary attack rates

Secondary attack rates were calculated (in R 4.0.3) for participants who developed COVID-19 as determined by confirmatory PCR, during the study period, using a denominator of all contact case episodes (without deduplication) and a numerator of all case positive contact episodes matched to those contacts with onset within 2–14 days of exposure (without deduplication). A comparator group of all adult cases (with a valid date of birth) reported to NHS Test and Trace who had previously been asymptomatic contacts but were not included in the study, who were exposed to a confirmed case of COVID-19 between 8 and 22 December 2020 or 3 and 8 January 2021 inclusive was used.

Ethical considerations

Research governance approval for this study was granted by UKHSA Research Ethics and Governance Group (REGG) – reference NR0235 on 10 December 2020, with informed consent obtained from participants during recruitment and implied ongoing consent by submission of results or PCR swabs. All data were handled and stored in accordance with UKHSA information governance and securities policies. The study was open to all eligible participants and specific professional groups were not automatically excluded; employers were advised to carry out local risk assessment to support decision-making for employee inclusion in the study.

RESULTS

Study population

In total, 1760 contacts of confirmed cases of COVID-19 were telephoned and asked if they would undertake daily self-testing using LFDs as an alternative to self-isolation; 882 consented to daily contact testing (DCT; 50.1%) and 878 declined (49.9%; Fig. 1). Individuals completing the call centre journey (n=171) were more likely to consent to take part in the study than those contacted for recruitment after completing contact tracing via the autocompletion route (n=719; 66 % vs. 52%).The most common self-reported motivations for consenting were a duty to take part (33.8%), the assurance of daily testing (30.4%) and not wanting to self-isolate (26.0%; Table S1). Reasons for declining were varied, but 39.1% (n=343) declined due to self-reporting a positive PCR result, awaiting a PCR result or already being part of a routine testing programme (Table S2). Verifiable PCR results with specimen dates prior to date of interview were obtained for 462 individuals who declined, of whom 281 (32.0%) had tested positive between interview and the 14 days prior to exposure (167 who gave this as their reason for declining). Around a third of contacts declined the testing offer citing reasons regarding the practicalities and commitment of daily testing, with only 1.0% declining due to concerns with LFD performance (n=9).

There were no significant differences in age, sex or geographical distribution between individuals who consented or declined (Table 1). Participants of Asian ethnicity and individuals residing in the two most deprived IMD deciles were more likely to decline, giving observed differences between individuals who consented or declined ($P\leq0.01$). Self-reported motivations for declining participation did not vary significantly between IMD deciles (P=0.267) or ethnic groups (P=0.476; data not shown).

Timeliness of recruitment and reporting

Contacts recruited after self-completing contact tracing digitally (n=1,553; 88.2%) were selected for inclusion if exposed in the previous 2 days. Those recruited during the contact tracing interview (n=207; 11.8%) were representative of contacts completing the call centre journey, with the median time between exposure and recruitment of 4 days [interquartile range (IQR) 2–6 days]. Contacts recruited through the call centre journey were more likely to consent to serial testing (68% vs. 48% of those who completed digitally).

In total, 812 recruited participants (92%) eligible for inclusion with an exposure within the previous 48 h were posted a serial testing kit (Fig. 1; reasons for exclusion are given in Fig. 1). On average postage took 1.9 days (95% confidence interval: 1.8–2.0 days; n=521), giving a median time between exposure and reporting of first LFD result of 3 days (IQR 2–4 days); for participants recruited after completing the call centre journey this increased to 4 days (IQR 3–6 days).

LFD results

Between 11 December 2020 and 20 January 2021, 2946 LFD results were reported, of which 2505 (85.0%) were eligible for inclusion (Fig. 1; reasons for exclusion are given in Fig. 1). In total, 565 of 812 participants who were posted a kit reported at least one LFD result (69.6%), with five individuals providing their kit to an eligible family member who reported at least one result and

Table 1. Socio-demographic characteristics of contacts of confirmed cases of COVID-19 (n=1,760) who consented and declined to take part in serial self-testing

		Consented (n=882)* **Proportion [95% CI] (no.)**	**Declined (n=878)**** **Proportion [95% CI] (no.)**	***P*-value**
Sex	Female	**51%** [48–55%] (452)	**47%** [44–50%] (412)	0.07
	Male	**49%** [45–52%] (430)	**53%** [50–56%] (466)	
Age	Mean 95% CI Range	42 years [41–43 years] 18–82 years	41 years [40–42 years] 13–94 years	0.97
Geography	East Midlands	**10%** [8–12%] (90)	**6%** [5–8%] (57)	
	East of England	**20%** [17–22%] (174)	**21%** [19–24%] (186)	
	London	**14%** [12–17%] (126)	**17%** [15–20%] (152)	
	North East	**4%** [3–6%] (38)	**4%** [3–5%] (35)	
	North West	**11%** [9–13%] (96)	**13%** [11–15%] (116)	0.10
	South East	**16%** [13–18%] (137)	**14%** [11–16%] (119)	
	South West	**7%** [6–9%] (64)	**6%** [5–8%] (55)	
	West Midlands	**9%** [7–11%] (80)	**10%** [8–12%] (85)	
	Yorkshire and Humber	**9%** [7–10%] (76)	**8%** [6–10%] (71)	
Ethnicity	Asian	**4%** [3–5%] (33)	**12%** [10–14%] (86)	
	Black	**2%** [1–3%] (19)	**2%** [1–3%] (12)	
	Mixed	**3%** [2–4%] (25)	**1%** [0.4–2%] (9)	<0.001
	White	**89%** [9–13%] (731)	**81%** [9–14%] (576)	
	Other	**2%** [1–3%] (14)	**4%** [3–6%] (30)	
Index of multiple deprivation	1 - Most deprived	**6%** [4–7%] (52)	**10%** [8–12%] (89)	
	2	**8%** [6–10%] (69)	**12%** [9–14%] (101)	
	3	**12%** [10–14%] (105)	**11%** [9–13%] (96)	
	4	**10%** [8–12%] (87)	**12%** [10–14%] (102)	
	5	**10%** [8–12%] (92)	**11%** [8–13%] (92)	<0.001
	6	**13%** [11–15%] (112)	**11%** [9–13%] (98)	
	7	**10%** [8–12%] (90)	**8%** [6–10%] (71)	
	8	**10%** [8–12%] (86)	**9%** [7–11%] (78)	
	9	**11%** [9–13%] (96)	**9%** [7–11%] (80)	
	10 - Least deprived	**10%** [8–12%] (92)	**8%** [6–10%] (69)	

*Data completeness for those who consented was 100% for sex, 99.6% for age, 100% for geography and IMD (excluding one non-England case), and 93.2% for ethnicity.
†Data completeness for those who declined was 100% for sex, 99.5% for age, 100% for geography and IMD (excluding two non-England cases), and 81.2% for ethnicity.

were retrospectively included in the study. Individuals from BAME (Black, Asian and Minority Ethnic) groups were less likely to report a result after consenting to take part (*P*=0.01; Table S3).

In total, 102 individuals reported at least one positive result (17.9%), 464 (81.4%) reported only negative results and four (0.7%) reported only negative and invalid results (Fig. 1). Seventy-five individuals who tested positive (74%) and 27 who tested negative (6%) self-reported symptoms (13 negative and six positive by PCR, eight no PCR result). A convenience sample of 1221 LFD images (54.6% of 2236 records with an image) were checked by two independent reviewers for concordance with self-reported results (Fig. S2). In total, 97.1% of images were concordant (*n*=1187; 1132 negative and 55 positive results), 26 images were

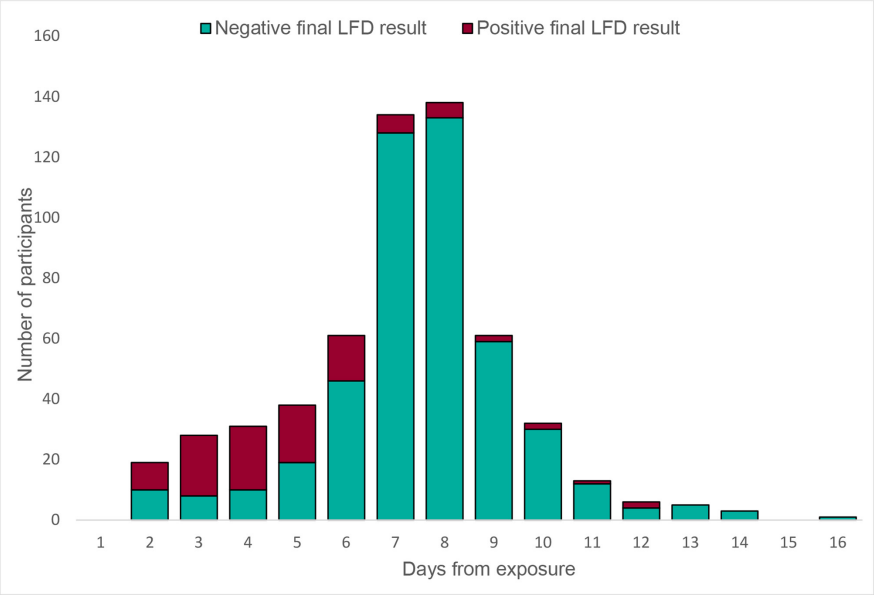

Fig. 2. Number of days post-exposure participants took their final LFD test (*n*=570), indicating the duration of reporting and number of people who reported up to day 7 as directed.

unreadable (2.1%) and eight results were discordant (0.8 %; seven positive reported as negative, one negative reported as positive). The seven positive results were from five individuals; all were faintly positive, and 3/5 individuals subsequently reported a positive LFD and PCR on receiving a stronger result 1–3 days later.

Reporting period

Of the 570 individuals who reported daily LFD results, 272 (47.7%) reported to the end of the 7 day period (day 7 or 8 from exposure; Fig. 2). The median period from date of exposure to last LFD result reported for individuals testing negative was 8 days (IQR 7–8 days; range 2–16 days). For individuals with a positive LFD result the median period was 5 days (IQR: 3–6 days; range 2–12 days). Individuals were directed to stop LFD testing on receiving a positive result. The proportion of individuals reporting a positive LFD result decreased with the number of tests a participant performed. In total, 50.6% of individuals who submitted only one LFD result were positive (*n*=39/77), while only seven individuals tested positive on their sixth LFD test. And 80.1% of the 468 individuals reporting only negative or invalid results (*n*=375) submitted their final result 7 days after exposure or later. Overall, 259 individuals who reported only negative and invalid results reported six results (Fig. 3).

Concordance between LFD and self-swab PCR

In total, 55/102 participants self-reporting a positive final LFD test (53.9%) returned a study PCR swab; 53 individuals were PCR positive for SARS-CoV-2, of whom 37 self-reported becoming symptomatic in the previous 14 days and 15 self-reported remaining asymptomatic on the laboratory request form. Two results were negative; however, one individual reported concordant negative LFD and PCR results after previously testing positive. The median time between reporting a positive LFD result and receipt of a PCR swab in the laboratory was 2 days (IQR 1–3 days).

In total, 291/468 participants who reported only a negative or a combination of negative and invalid LFD results returned a PCR swab at the end of the 7 day LFD testing period; 280 samples from individuals were PCR negative (96.2%; *n*=280/291) and 11 were PCR positive for SARS-CoV-2 (3.8%). Also, 55% of the 11 individuals with a positive PCR result and negative LFD result self-reported being symptomatic, compared with 3% of individuals with negative PCR and LFD results (*n*=9/280). The median time between the last negative LFD result being reported and the swab being received at the lab was 3 days (IQR 2–5 days). Overall, 82.8% of PCR-positive samples tested in the UKHSA laboratory were also positive by LFD self-testing and 99.6% of PCR-negative samples were correctly detected as negative by LFD, for the 61% of participants submitting LFD results and a study PCR swab (Table 2).

The median Ct (cycle threshold) value for study PCR-positive samples from individuals who had tested negative on LFD (*n*=11) was 24.0 (range 16.9–32.1) for the ORF1ab gene and 25.5 (range 16.9–33.5; one swab negative for ORF1ab) for the E gene target,

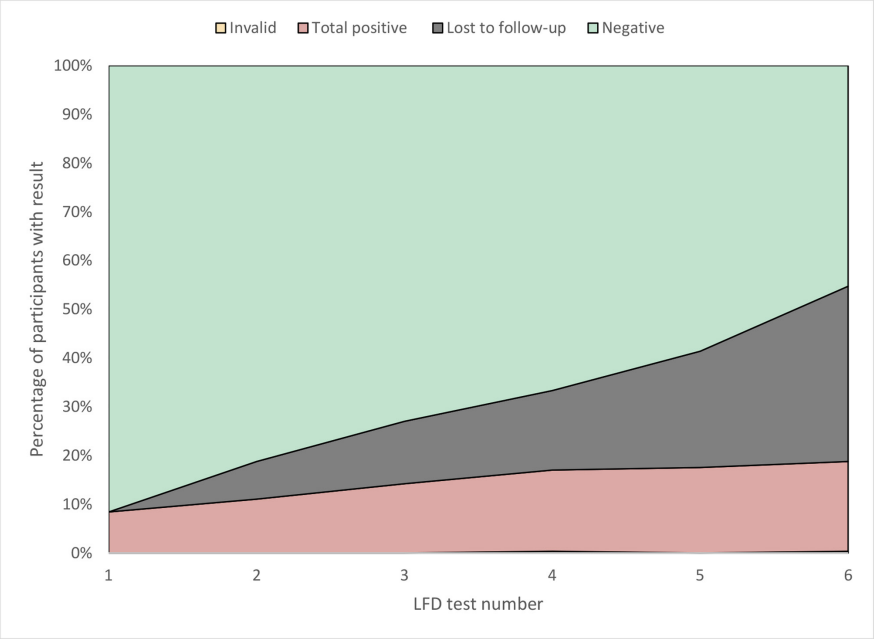

Fig. 3. Results reported by participants (*n*=570) by number of tests and test number. Participants were directed to submit for the first 7 days post-exposure, not to submit six tests. Individuals submitting to the end of their 7 day period are unlikely to have submitted six LFD results due to the timeliness of recruitment and postage. Participants reporting fewer than six LFD tests have subsequent missing tests reported as lost to follow-up. Participants testing positive were advised to stop testing, and therefore participants testing positive but with no subsequent tests are reported as 'Total Positive' for the duration of the six-test period.

which was higher than for those individuals who had tested positive on both LFD and PCR [ORF1ab: 20.8 (range: 14.0–35.7); E gene target: 20.0 (range: 13.8–34.2); Table S4].

SGSS and CTAS systems were also interrogated to determine if individuals requested confirmatory testing through an approved alternative route. Sixty individuals who had submitted at least one LFD result obtained a PCR test via an alternative route during their testing period (7 days from exposure) of which 48 were temporally linked to LFD results and were included. Inclusion of these data in the concordance calculation demonstrated 83.1% of PCR-positive samples were detected by LFD and 99.7% of PCR-negative samples were correctly reported as negative by LFD for 397 participants with matching data (Table 2).

Overall, the PCR positivity for participants who consented to the study and undertook a PCR was 20.9% (83/397), which was comparable to the positivity rate for participants who declined to take part in serial testing but had an identifiable positive PCR result in SGSS or CTAS (20.0%; *n*=124/620).

Table 2. Concordance between LFD and PCR results for individuals who completed a study PCR swab (*n*=346) and individuals who completed a PCR test via any route (*n*=51)

		PCR					
		Study PCR swabs			All PCR swabs		
		Positive	Negative	Total	Positive	Negative	Total
LFD	Positive	53 (82.8%)	1 (0.4%)	54	69 (83.1%)	1 (0.3%)	72
	Negative	11 (17.2%)	281 (99.6%)*	292	14 (16.9%)	313 (99.7%)*	327
Total		64	282	346	83	314	397

*One individual reported a negative LFD on the day they took a negative PCR swab, but the individual had reported five consecutive positive LFDs in the 5 days prior to this negative result. This result is reported as concordant.

Table 3. Secondary attack rates for contacts of confirmed cases of COVID-19 who tested positive for SARS-CoV-2 on study PCR swabs (*n*=84*)

Group	Cases	Contacts of cases	Contacts who became cases	Secondary attack rate	SAR confidence interval (95%)	Day window† (exposure date is 0)
Study group	84†	160	10	6.3%	3.4–11.1%	2–14
Study group December	28	54	3	5.6%	1.9–15.1 %	2–14
Study group January	56	106	7	6.6%	3.2–13.0 %	2–14
Comparison group	18070	35167	2657	7.6%	7.3–7.8 %	2–14
Comparison group December	10581	21147	1640	7.8%	7.4–8.1 %	2–14
Comparison group January	7489	14020	1017	7.3%	6.8–7.7 %	2–14

*Contacts from 82 cases. Two cases have two records, both are included to give a denominator of 84. One study case is excluded as their case first symptomatic date is a week before their contact date.
†Exposure date is day 0.

Activities and secondary attack rates

Overall, 160 contacts were reported to NHS Test and Trace from 64 of the 83 participants who tested positive on PCR after submitting at least one LFD result. Nineteen participants did not report any contacts. Information on activities carried out was also collected for 83 participants. In total, 15.7% reported attending an educational setting, 9.6% a retail setting, 7.2% a healthcare setting and 41% any other workplace setting. Only 2.4% reported a hospitality event and 1.2% a personal care event.

Secondary attack rates were calculated for participants who submitted at least one LFD result and received a positive PCR result and compared these to secondary attack rates for a comparator group of all contacts reported to NHS T and T over the same study period who met the same inclusion criteria as study participants, who subsequently became cases (Table 3). There were no differences in the overall secondary attack rates for the study group [6.3%; 95% confidence interval (CI): 3.4–11.1%] compared with a comparator group (7.6%; 95% CI: 7.3–7.8%). For contacts taking part in the study who tested positive, 96.8% of their contacts were household contacts compared with 94.0% of contacts for cases in the comparator group.

DISCUSSION

The aim of the study was to investigate the feasibility and acceptability of using LFD testing as an alternative to self-isolation. We showed that daily testing using LFDs was acceptable to contacts of cases of COVID-19 reported to England's NHS Test and Trace system and that there was likely to be public health benefit in routinely offering tests to contacts to increase case ascertainment in individuals who may not access or who do not qualify for testing under England's previous testing strategy [1].

Uptake of daily testing was encouraging, with 882 (51.1%) of those contacted for recruitment accepting the offer of serial LFD testing. This was higher than previously reported when contacts of cases were offered a PCR swab (39.5% [11]), which may reflect the additional freedoms awarded by serial testing as part of a test to enable strategy. It is important to note that in both studies a substantial proportion of those who declined self-reported that they had already been tested for SARS-CoV-2, had booked a test or were part of a testing programme, which indicates that testing acceptability is high. Interestingly, 4% of participants declined as they had already tested negative, which is similar to that observed when contacts were offered a PCR swab (8.2% [11]) and highlights the risk that an early negative result may be providing false re-assurance to individuals who may assume that a negative result will be valid for their full incubation period. Better information on interpretation of negative results may be needed if routine testing of contacts is implemented. Despite controversies in the media about the performance of LFD tests, concerns around test performance or the practicalities of daily testing were not a major issue in this study.

Self-testing kits were sent to 812 individuals by UKHSA for home LFD testing and PCR validation. Overall, 570 (70.2%) participants returned at least one LFD result, but it is likely that compliance was underestimated as delays to postage, especially around the Christmas period, negatively impacted the study. Twenty-seven recruited participants directly contacted the study team to withdraw due to delays in receiving kits, while 65 anonymous respondents reported in the study evaluation questionnaire that they were unable to participate as the kit arrived too late [16]. The timeliness of recruitment and kit delivery is a considerable barrier to offering a daily contact testing alternative to self-isolation. It is important to note that individuals submitting to the end of their 7 day period would have been expected to submit fewer than six LFD results based on the time lag between exposure and first result. However, many participants completed the six LFD tests irrespective of the 7 day testing period.

These data suggest that daily LFD testing was acceptable with high compliance with self-reporting LFD results. However, it is advisable to explore any barriers for individuals who did not return LFD results to the UKHSA portal to help improve compliance. In particular, barriers to uptake need to be further explored in those from BAME groups and from lower IMD deciles who were less likely to consent to serial testing and less likely to report a result if posted a test kit, but who are at a higher risk of infection from COVID-19 [17].

Overall, 102/570 participants reported a positive result via LFD, giving a positivity rate of 17.9%; this is comparable to that reported when contacts of cases were offered a single PCR swab (16.3% [11]). Concordance between the Innova LFD and PCR was similar or higher than previously reported for positive results (83.1% vs. 58.9–76.8%) and negative results (99.7% vs. 99.7–99.9%), and higher than previously reported for untrained members of the public self-administering testing (58% [13, 14, 18]). However, it's important to note that a previous study found the differences in sensitivity between expert and non-expert reviewers diminished over time with repeated exposure to performing LFDs, as in serial testing [14, 18]. LFD failed to detect 11 PCR-positive cases of whom five were symptomatic, so it is important to encourage contacts who become symptomatic to access PCR testing. Given that testing was performed for only the first 7 days post-exposure, it is possible that an individual who was symptomatic but LFD negative on their last LFD test may have subsequently tested positive on a later LFD test. All study PCR swabs were analysed using the same PCR assay, procedures and platforms for those testing negative on LFD but positive on PCR; median Ct values were higher by 3.2–5.5 cycles. Other studies have noted that Ct values are an important determinant for detection of SARS-CoV-2 [19].

Self-testing is trust based and puts an onus on the contact to perform the test correctly and report the result. Although only a subset of participants did a confirmatory PCR, we observed good concordance, suggesting tests were being performed correctly. Furthermore, blinded analysis of images by two reviewers found just eight discordant results reported from six individuals. One result was clearly negative and may have been misreported as positive. The seven positive results reported as negative were very faintly positive and instructions for contacts may need to be made clearer to ensure accurate interpretation of results.

CONCLUSION

This study shows a high acceptability and compliance with self-testing among many contacts of confirmed COVID-19 cases. Therefore, offering routine testing as part of the contact tracing process is likely to be an effective method of case finding, and daily testing with release from self-isolation, if negative, may improve adherence with self-isolation. Offering a structured programme of testing of contacts of cases still requires some additional questions to be addressed, specifically which testing strategy is most effective. Further work is needed to understand any impact of daily testing on secondary transmission.

Limitations of the study

Sample size was not determined by statistical power considerations and this is an important limitation that should be considered when interpreting the findings. The study was designed to investigate the feasibility and acceptability of a test to enable study, with further research planned to use more robust methodologies to look at associations. Secondary attack rates in particular should be interpreted with caution due to small numbers, with estimates of uncertainty for secondary attack statistics subject to random variation when underlying cohorts are small. Only close contacts who are named by the case are captured by contact tracing. These attack rates should be considered minimum estimates both because only those contacts who access testing can subsequently be identified as a case and because the matching process used to detect when a contact goes onto become a case within NHS Test and Trace is highly specific. Secondary attack rates are also likely to underestimate the number of contacts, given the predominance towards the reporting of household contacts, which may be a result of the study being performed during a period of lockdown in England. A large proportion of contacts who became cases had reported activities outside of the household during their infectious period to NHS Test and Trace but declared no contacts in these settings to NHS T and T. The study was carried out when the alpha variant dominated in England and therefore testing performance may vary if other emerged or emerging variants expand. Days 8, 9 and 10 did not require LFD testing and therefore potentially a small proportion of late-onset asymptomatic infection would not have been identified in this study.

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Conflicts of interest
The author(s) declare that there are no conflicts of interest

Ethical statement
Research governance approval for this study was granted by UKHSA Research Ethics and Governance Group (REGG) – reference NR0235 on 10 December 2020. All necessary participant consent was obtained.

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