Social communication skill attainment in babies born during the COVID-19 pandemic: a birth cohort study

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ABSTRACT

Introduction The SARS-CoV-2 (COVID-19) pandemic was managed with sustained mass lockdowns to prevent spread of COVID-19 infection. Babies born during the early stages of the pandemic missed the opportunity of meeting a normal social circle of people outside the family home.

Methods We compared 10 parentally reported developmental milestones at 12-month assessment in a cohort of 309 babies born at the onset of the pandemic (CORAL cohort) and 1629 babies from a historical birth cohort (BASELINE cohort recruited between 2008 and 2011).

Results Compared with a historical cohort, babies born into lockdown appeared to have some deficits in social communication. Fewer infants in the pandemic cohort had one definite and meaningful word (76.6% vs 89.3%), could point (83.8% vs 92.8%) or wave bye-bye (87.7% vs 94.4%) at 12-month assessment. Adjusted log-binomial regression analyses demonstrated significant differences in social communication in the CORAL cohort compared with the BASELINE cohort: one definite and meaningful word (relative risk (RR): 0.86 (95% CI: 0.80 to 0.92)), pointing (RR: 0.91 (95% CI: 0.86 to 0.96)) and waving bye-bye (RR: 0.94 (95% CI: 0.90 to 0.99)).

Discussion Parentally reported developmental outcomes in a birth cohort of babies born into lockdown during the COVID-19 pandemic may indicate some potential deficits in early life social communication. It must be noted that milestones are parentally reported and comparison is with a historical cohort with associated limitations. Further studies with standardised testing is required to validate these findings.

Conclusion Pandemic-associated social isolation may have impacted on the social communication skills in babies born during the pandemic compared with a historical cohort. Babies are resilient and inquisitive by nature, and it is hoped that with societal re-emergence and increase in social circles, their social communication skills will improve.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Before vaccination, the pandemic was managed with social isolation. We do not know how this impacted on development of babies born into the pandemic.

⇒ Two recent publications demonstrate a reduction in developmental skills compared with historical cohorts.

WHAT THIS STUDY ADDS

⇒ This is a pandemic birth cohort of babies born during the first 3 months of the pandemic and followed for their first year of life.

⇒ At 12 months, there is a reduction in parentally reported social communication developmental milestones compared with a historical cohort.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This research may help guide decisions of future policymakers in relation to infant development.

⇒ This study and others looking at child development highlight the need for further research into developmental patterns in babies and children born during the pandemic.

INTRODUCTION

Prior to vaccination, the SARS-CoV-2 (COVID-19) pandemic was managed with sustained mass lockdowns and adult mask wearing outside the home, to prevent spread of infection. Babies born during the early stages of the pandemic missed the opportunity of meeting a normal social circle of people outside the family home, including other babies and grandparents.1 Ireland spent the majority of period March 2020–April 2021 in maximal (level 5); no home visitors, stay at home except for essential purposes, exercise within 2–5 km of home, essential retail only, unable to sit in restaurants/cafes, work from home unless essential worker) lockdown and so babies spent most of the first year of their lives in social isolation. While social communication has been shown to be impaired in animal models that were isolated at a young age,2,3 few papers have been published exploring social communication development in children who had early life social isolation,4,5 particularly with respect to COVID-19-related isolation. A recent paper by Huang et al looked at developmental outcomes in 546 6-month-old and 285 12-month-old Chinese children who were assessed in March–May 2020, having lived 1–3 months of their lives during the pandemic.6 They demonstrated a deficit in communication and fine motor skills at 1 year. More recently, Shuffrey et al have demonstrated that 255 babies, born during the pandemic and aged 6 months old, have lower scores on the gross motor, fine motor, and personal-social subscores of
the Ages and Stages 3 Questionnaire compared with a historical cohort.7 In addition to social isolation, babies born during the pandemic have also had to overcome other, new developmental challenges. The development of language in babies is complex, with younger babies fixating on the eyes of carers during interactions while babies from 6 months of age tend to shift their gaze from the eyes to the mouth.8 It is unclear how exposure to a limited number of people and mask wearing will impact speech development.9

In this paper, we outline the parentally reported developmental outcomes at 12-month assessment in a ‘pandemic’ birth cohort of babies compared with a historical birth cohort.

METHODS
The BASELINE (Babies After SCOPE: Evaluating the Longitudinal Impact using Neurological and Nutritional Impact) Study, the first longitudinal birth cohort study in Ireland, recruited babies born in Ireland between 2008 and 2011.10 Recruitment for BASELINE occurred in one of two ways: babies were recruited antenatally from first-time mothers (BASELINE-stream 1) and postnatally from mothers of mixed parity (BASELINE-stream 2). Detailed demographic and epidemiological data were collected at birth, 12 and 24 months (early life environment, diet, growth, development and health). More details about recruitment, protocol and prior results of the BASELINE Study can be found in this paper10 and online (www.baselinestudy.net and www.birthcohorts.net).

The CORAL (Impact of Corona Virus Pandemic on Allergic and Autoimmune Dysregulation in Infants Born During Lockdown) Study is a longitudinal prospective observational study of allergy, immune function and neurodevelopment in a population of term Irish infants born during the first 3 months of the COVID-19 pandemic, March–May 2020.11 12 A total of 3773 infants were born in the two participating major maternity hospitals in Dublin from March to May 2020. Invitations were sent to the families of 3065 term babies who were eligible for inclusion. Exclusion criteria were pre-birth PCR-proven SARS-CoV-2 infection in a parent or co-dwelling person, intravenous antibiotics in the neonatal period, multiple births or major congenital anomaly. A total of 354 infants were recruited postnatally to the CORAL Study and mothers did not need to be first-time parents. Babies had a clinical review along with lateral flow COVID-19 antibody screening at 6 and 12 months of age. Detailed epidemiological information was collected at recruitment and at each 6-month review.

In both cohorts, the following 10 skills were assessed: crawl, side step along furniture, stand alone, pick up tiny objects with thumb and index finger (pincer grip), put one brick upon another (stack bricks), finger feed, know their own name, has one definite and meaningful word, point at objects and wave ‘bye-bye’. Questions were based on the parental report section of the Griffiths Scales of Mental Development Version 2, 0–2 years,13 valid across cultures and therefore appropriate for these cohorts.14 In the BASELINE birth cohort, babies were assessed as close to their 1 year birthday as possible. On the assessment day, parents were asked ‘can your child do the following (Yes/No)?’ and the 10 skills were listed.

The CORAL birth cohort was sent developmental questionnaires with the following instruction ‘We request that these questionnaires be completed as soon as possible. The aim is to gather the details of your child’s development as close to their first birthday as we can’. They were asked ‘At their 1 year birthday, could your child do the following (Yes/No)?’ and the 10 skills were listed.

Comparisons were made between the term babies (birth at 37 weeks’ gestation or older) from the CORAL and BASELINE cohorts whose parents completed the questions regarding developmental milestones. Appropriate descriptive statistics (eg, means, SDs, proportions) were used to describe the two cohorts and t-tests and proportions tests as appropriate were used to explore potential differences between the cohorts. Attainment of each skill was stratified by age that questionnaire was completed in both cohorts to look at how response varied with age of completion. For each of the developmental milestones, multivariable log-binomial regression analysis, adjusted for age at questionnaire completion (in days), gender, gestational age in weeks, birth order (first or other) and maternal educational attainment, was also used to explore potential differences between the two cohorts. Relative risks (RRs) and 95% Confidence Intervals (CIs) for the CORAL cohort relative to the BASELINE cohort, in addition to p values, are reported. The primary analysis was complete case analysis. However, the age at assessment was missing for 145 of 1938 cases (8 CORAL and 137 BASELINE), and a sensitivity analysis was conducted using the mean age at assessment for each cohort for the missing values. Finally, a subgroup analysis was carried out comparing the BASELINE-stream 2 group with the CORAL cohort as they were similar for proportion of first-time mothers. Stata V.16.1 (StataCorp, Texas, USA) was used for all analyses.

RESULTS
Three hundred fifty-four babies, born between March and May 2020, were recruited to the CORAL Study.11 A total of 2173 babies were recruited to the BASELINE Study. Three hundred nine CORAL and 1629 BASELINE term babies (1186 BASELINE-stream 1 and 443 BASELINE-stream 2) completed 12-month assessment and were included in analysis (online supplemental figure 1).

On average, CORAL babies weighed 3.5 (SD: 0.5) kg at birth and BASELINE babies weighed 3.5 (SD: 0.5) kg (p=0.33). In both cohorts, there were slightly fewer female babies; 45.6% (141 of 309) of the CORAL babies were female compared with 48.8% (795 of 1629) BASELINE babies (p=0.30). There was evidence of a difference in average gestational age with CORAL babies born on average at 39.3 (SD: 1.3) weeks and BASELINE babies at 39.7 (SD: 1.2) weeks (p<0.01). There was a significant difference between the proportion of first-born babies; 44.7% (138 of 309) of CORAL babies were first born compared with 83.9% (1364 of 1629) of BASELINE babies (p<0.01). The CORAL cohort had a higher proportion of mothers educated to or attending tertiary-level education (postgraduate certificate or higher), 94.4% (292 of 309) compared with 87.8% (1431 of 1629) (p<0.01). Questionnaire was completed at mean age of 400 (SD: 24) days in CORAL babies compared with 381 (SD: 19) days in babies in the BASELINE cohort (p<0.01) (table 1).

Attainment of each skill was stratified by age that questionnaire was completed in both cohorts to look at how response varied with age of completion (online supplemental table 1). In both cohorts, for some skills, parental responses were notably different for those who completed the questionnaire when their babies were <380 days of age versus those whose babies were 380+ days old. In the pandemic cohort, there is a possibility of recall bias, or some parents may have completed the questionnaire based on skills attained at the age of completion of the questionnaire, rather than skills attained at the child’s first birthday.
birthday. In all models, we included an adjustment for age at questionnaire completion (in days).

Table 2 shows the reported proportions for each skill assessed and the adjusted log-binomial regression analysis. Of note, fewer infants from the CORAL birth cohort had one definite and meaningful word (76.6% compared with 89.3%), could point (83.8% compared with 92.8%) and wave bye-bye (87.7% compared with 94.4%). More CORAL cohort babies were able to crawl (97.4% compared with 91%). Log-binomial regression analyses, adjusted for age in days at questionnaire completion, gender, gestational age in weeks, birth order and maternal educational attainment, showed significant differences in having one definite and meaningful word (RR: 0.86; 95%CI: 0.80 to 0.92), pointing (RR: 0.91; 95%CI: 0.86 to 0.96), waving bye-bye (RR: 0.94; 95%CI: 0.90 to 0.99) and crawling (RR: 1.06; 95%CI: 1.03 to 1.09) in the CORAL cohort compared with the BASELINE cohort (Table 2 and figure 1). A sensitivity analysis imputing mean age at assessment for missing values showed almost identical results (results not shown).

Furthermore, a subgroup analysis comparing BASELINE-stream 2 with the CORAL cohort showed similar results (see online supplemental material).

There was no evidence of a difference in results between CORAL infants (n=12) who had COVID-19 infection in their first year of life and the 297 babies who did not. However, due to the small number of children who got infected, there was lack of power to detect significant differences.

**DISCUSSION**

This report of developmental outcome in a birth cohort of babies born into mass lockdown and living their whole lives in the post-COVID-19 era adds to the literature on pandemic-associated child development described above.⁶ ⁷ Evidence from our study suggests some deficits in early life social communication; however, we acknowledge that there are limitations to this study.

Fewer babies from the COVID-19 CORAL birth cohort had achieved one definite and meaningful word, the ability to point and the ability to wave bye-bye compared with babies from a comparable historical cohort. The development of social communication is dependent on social engagement, and low levels of community engagement of infants and their caregivers have been associated with developmental delay in a non-pandemic setting.¹ A study looking at the effect of language development in infants who spent their early life in institutional care and were subsequently placed in foster care demonstrated improved language outcomes if placed before the age of 24 months compared with a later stage,² thus highlighting the importance of early life on language development and the potential for improvement in language attainment. Two

### Table 1 Demographic comparisons between the CORAL (n=309) and full BASELINE (n=1629) cohorts

<table>
<thead>
<tr>
<th>Demographic</th>
<th>CORAL cohort n=309</th>
<th>BASELINE cohort n=1629</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age, mean (SD)</td>
<td>39.3 weeks (1.3)</td>
<td>39.7 weeks (1.2)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Mean weight at birth (SD)</td>
<td>3.5 kg (0.5)</td>
<td>3.5 kg (0.5)</td>
<td>0.33</td>
</tr>
<tr>
<td>Proportion of females (n/N)</td>
<td>45.6% (141/309)</td>
<td>48.8% (795/1629)</td>
<td>0.30</td>
</tr>
<tr>
<td>Proportion of first born (n/N)</td>
<td>44.7% (138/309)</td>
<td>83.9% (1364/1629)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Proportion of maternal tertiary education (n/N)</td>
<td>94.4% (292/309)</td>
<td>87.8% (1431/1629)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Mean age at assessment (SD)</td>
<td>400 (24) days</td>
<td>381 (18) days</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

*Proportions test or Student’s t-test as appropriate.

BASELINE, Babies After SCOPE: Evaluating the Longitudinal Impact using Neurological and Nutritional Impact; CORAL, Impact of Corona Virus Pandemic on Allergic and Autoimmune Dysregulation in Infants Born During Lockdown.

### Table 2 Adjusted log-binomial regression analysis for skill attainment between the CORAL and BASELINE cohorts—complete case analysis

<table>
<thead>
<tr>
<th>Developmental milestone</th>
<th>CORAL cohort (n=309) Reached milestone % (n)</th>
<th>BASELINE cohort (n=1629) Reached milestone % (n)</th>
<th>Adjusted log-binomial regression models† (n=1793) Relative risk (95% CI)</th>
<th>P value*</th>
<th>Regression diagnostics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stand alone</td>
<td>Yes: 65.7 (203/309)</td>
<td>Yes: 66.3 (1080/1629)</td>
<td>1.00 (0.91 to 1.11)</td>
<td>p=0.99</td>
<td>AIC: 1.87</td>
</tr>
<tr>
<td></td>
<td>No: 34.3 (96/309)</td>
<td>No: 33.7 (549/1629)</td>
<td></td>
<td></td>
<td>AIC: 1.81</td>
</tr>
<tr>
<td>Side steps</td>
<td>Yes: 89.6 (277/309)</td>
<td>Yes: 86.9 (1416/1629)</td>
<td>1.03 (0.98 to 1.09)</td>
<td>p=0.18</td>
<td>AIC: 1.99</td>
</tr>
<tr>
<td></td>
<td>No: 10.4 (32/309)</td>
<td>No: 13.1 (213/1629)</td>
<td></td>
<td></td>
<td>AIC: 0.59</td>
</tr>
<tr>
<td>Crawl</td>
<td>Yes: 97.4 (300/309)</td>
<td>Yes: 91.0 (1482/1629)</td>
<td>1.06 (1.03 to 1.09)</td>
<td>p=0.01</td>
<td>AIC: 2.00</td>
</tr>
<tr>
<td></td>
<td>No: 2.6 (8/309)</td>
<td>No: 9.0 (157/1629)</td>
<td></td>
<td></td>
<td>AIC: 0.61</td>
</tr>
<tr>
<td>Stack bricks</td>
<td>Yes: 72.0 (221/307)</td>
<td>Yes: 78.3 (1276/1629)</td>
<td>0.93 (0.85 to 1.02)</td>
<td>p=0.10</td>
<td>AIC: 1.95</td>
</tr>
<tr>
<td></td>
<td>No: 28.0 (86/307)</td>
<td>No: 21.7 (353/1629)</td>
<td></td>
<td></td>
<td>AIC: 0.59</td>
</tr>
<tr>
<td>Finger feeds</td>
<td>Yes: 99.9 (306/309)</td>
<td>Yes: 98.7 (1608/1629)</td>
<td>1.00 (0.99 to 1.01)</td>
<td>p=0.92</td>
<td>AIC: 2.00</td>
</tr>
<tr>
<td></td>
<td>No: 0.1 (1/309)</td>
<td>No: 0.3 (5/1629)</td>
<td></td>
<td></td>
<td>AIC: 0.65</td>
</tr>
<tr>
<td>Pincer</td>
<td>Yes: 99.7 (307/308)</td>
<td>Yes: 99.4 (1620/1629)</td>
<td>1.00 (0.99 to 1.01)</td>
<td>p=0.72</td>
<td>AIC: 2.00</td>
</tr>
<tr>
<td></td>
<td>No: 0.3 (1/309)</td>
<td>No: 0.6 (10/1629)</td>
<td></td>
<td></td>
<td>AIC: 0.69</td>
</tr>
<tr>
<td>Knows name</td>
<td>Yes: 98.7 (305/309)</td>
<td>Yes: 98.8 (1610/1629)</td>
<td>1.00 (0.98 to 1.01)</td>
<td>p=0.64</td>
<td>AIC: 2.00</td>
</tr>
<tr>
<td></td>
<td>No: 1.3 (4/309)</td>
<td>No: 1.2 (21/1629)</td>
<td></td>
<td></td>
<td>AIC: 0.57</td>
</tr>
<tr>
<td>One definite and meaningful word</td>
<td>Yes: 76.6 (232/309)</td>
<td>Yes: 89.3 (1455/1628)</td>
<td>0.86 (0.80 to 0.90)</td>
<td>p=0.01</td>
<td>AIC: 1.99</td>
</tr>
<tr>
<td></td>
<td>No: 23.4 (71/309)</td>
<td>No: 11.7 (163/1628)</td>
<td></td>
<td></td>
<td>AIC: 0.65</td>
</tr>
<tr>
<td>Finger points</td>
<td>Yes: 83.8 (258/308)</td>
<td>Yes: 92.8 (1512/1629)</td>
<td>0.91 (0.86 to 0.96)</td>
<td>p=0.01</td>
<td>AIC: 2.00</td>
</tr>
<tr>
<td></td>
<td>No: 16.2 (51/309)</td>
<td>No: 7.2 (47/1629)</td>
<td></td>
<td></td>
<td>AIC: 0.67</td>
</tr>
<tr>
<td>Waves bye-bye</td>
<td>Yes: 87.7 (271/309)</td>
<td>Yes: 94.4 (1537/1629)</td>
<td>0.94 (0.90 to 0.99)</td>
<td>p=0.02</td>
<td>AIC: 2.00</td>
</tr>
<tr>
<td></td>
<td>No: 12.3 (38/309)</td>
<td>No: 5.6 (92/1629)</td>
<td></td>
<td></td>
<td>AIC: 0.68</td>
</tr>
</tbody>
</table>

*Results highlighted in bold have statistically significant differences between groups.
† Log-binomial regression models for each skill, adjusted for age at assessment in days, gender, gestational age in weeks, birth order (first or other) and maternal educational attainment.
AIC, Akaike Information Criterion; AUC, area under the curve; BASELINE, Babies After SCOPE: Evaluating the Longitudinal Impact using Neurological and Nutritional Impact; CORAL, Impact of Corona Virus Pandemic on Allergic and Autoimmune Dysregulation in Infants Born During Lockdown.
pandemic-related studies demonstrated differences between communication/social-personal interaction in babies developing during the pandemic compared with historical controls. Based on these papers and our study, there is a temporal relationship between the pandemic period and infant development, which could lead one to speculate as to the reason for these findings. Stringent lockdown, used to control the COVID-19 pandemic, has led to babies and their families spending more time at home than babies from previous years. We recently demonstrated that families of babies in the CORAL cohort had a median of one social contact outside the home at birth, increasing to four when the babies reached 6 months of age. This may have impacted on parents’ experience of raising a child during the pandemic, as many parents noted that they were isolated. In addition, we found that social isolation restrictions lead to 25% of infants not having met a child their own age by their first birthday, which will have led to a reduction in social peer interaction. Because of lockdown measures, it is likely that COVID-19 era babies heard a narrower repertoire of language and saw fewer unmasked faces speaking to them. As babies spent most of the lockdown in their familiar home neighbourhood, they were less likely to encounter new items of interest which might prompt pointing. These findings may also be linked to one or both parents (due to home working) and siblings (out of school and day care) being in close proximity and anticipating babies’ needs before the need for pointing arises. There was also a reduction in the babies’ ability to wave bye-bye which is likely due to a reduction in number of opportunities where babies can learn to wave bye-bye due to reduced social contacts. However, it is worth noting that the overall relative risk reductions in this study are small and it is hoped that these infants will catch up with their pre-pandemic peers quickly once restrictions are lifted. In comparison with the two previous pandemic-related studies, a significantly higher proportion of babies in the CORAL cohort were able to crawl but there was no comparable difference in any other gross motor skills. Infants are likely to have spent more time at home and on the ground exploring their environment rather than out of the home in cars and strollers.

While neurodevelopment is part genetically mediated, parental education and social exposure have a significant role to play. Teasing out the direct effect of early enrichment is extremely difficult. The pandemic may allow us to assess the impact of environmental and social exposures on infant development over time. Whether this will be short lived, with rapid recovery post-lockdown, or whether there will be longer term effects remains to be seen.

This study carried out during the height of the COVID-19 pandemic has very clear limitations. It was not possible to have a comparable cohort for the same time period as all of Ireland was in level 5 lockdown, as was most of the world. We used data from an Irish historical birth cohort. The babies in this cohort was in level 5 lockdown, as was most of the world. We used a comparable cohort for the same time period as all of Ireland had a similar proportion of first-child effect, we also compared the CORAL cohort with a subset of the baseline cohort. These factors were adjusted for in all logistic regression models. In addition, to rule out the ‘first child effect’, we also compared the CORAL cohort with a subset of the baseline cohort (stream 2; supplemental results) which had a similar proportion of first-time mothers, and demonstrated similar results. Parental report instruments have been shown to be an effective and efficient tool for physicians to screen for developmental delays, therefore parents were asked about 10 developmental skills. However, this was not a standardised developmental assessment but was based on parentally reported developmental milestones. The pandemic and historical cohorts were asked the developmental question in a slightly different way. Parents were asked to complete the 12-month assessment questionnaire as close as possible to child’s first birthday; however, in the pandemic cohort (due to practical factors), this was carried out at a later stage and this introduced the chance for recall bias. Further studies with standardised testing are required to validate these findings. Comparative developmental assessment with standardised questionnaires (carried out by both birth cohorts) will be conducted at 24 months of age to see if differences in social communication skills are observed.

Pandemic-associated social isolation appears to have impacted on social communication skills in babies born during the pandemic compared with a historical cohort. Babies are resilient and inquisitive by nature, and it is very likely that with societal re-emergence and increase in social circles that their social communication skills will improve. However, this cohort and others will need to be followed up to school age to ensure that this is the case.

Correction notice This article has been corrected since it first published. The open access licence type has been changed to CC BY 17th May 2023.

Collaborators CORAL Study group: Liam O’Mahony (APC UCC), Naomi McCallion (Rotunda Hospital Dublin and Department of Paediatrics and Child Health, RCSI), Martin White (The Coombe Hospital and Department of Paediatrics and Child Health, RCSI), Marguerite Lawler (Children’s Health Ireland and Department of Paediatrics and Child Health, RCSI), Aideen Byrne (Children’s Health Ireland), John Fitzsimons (Children’s Health Ireland), Orla McMenery (Children’s Health Ireland).

Contributors SB co-designed the developmental aspect of the CORAL Study, collected data, analysed data and wrote the paper (suby@rcsi.ie). HS collated data, assisted in analysis and edited the paper. RF recruited participants, collected data and edited the paper. FB provided statistical input and edited the paper. DMM is the PI of the BASELINE Study. She provided input on CORAL developmental study design, data interpretation and edited the paper. JH is PI of the CORAL Study. He conceived and designed the CORAL Study and the developmental substudy, made the original clinical observation regarding social skills in infants, recruited participants, collected data, made data interpretation and wrote the paper. He is the guarantor of the work.

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Competing interests JH is a board member of Clemens Von Pirquet Foundation. No other conflicts declared.

Patient consent for publication Parental/guardian consent obtained.

Ethics approval This study involves human participants and ethical permission was granted by the National COVID-19 Ethics Committee (20-NREC-COV-067). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplemental information. Not applicable.

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