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MAJOR ARTICLE

A Randomized Controlled Trial to Study the Transmission of SARS-CoV-2 and Other Respiratory Viruses During Indoor Clubbing Events (ANRS0066s ITOC Study)

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(See the Editorial Commentary by Conly and Loeb on pages 1656–8.)

Background. In the context of the circulation of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) B.1.617.2 (Delta) variant, vaccination re-authorized mass indoor gatherings. The "Indoor Transmission of coronavirus disease 2019 (COVID-19)" (ITOC) trial (ClinicalTrials.gov, NCT05311865) aimed to assess the risk of transmission of SARS-CoV-2 and other respiratory viruses during an indoor clubbing event among participants fully vaccinated against COVID-19.

Methods. ITOC, a randomized controlled trial in the Paris region (France), enrolled healthy volunteers aged 18–49 years, fully vaccinated against COVID-19, with no comorbidities or symptoms, randomized 1:1 to be interventional group "attendees" or control "non-attendees." The intervention was a 7-hour indoor event in a nightclub at full capacity, with no masking, prior SARS-CoV-2 test result, or social distancing required. The primary outcome measure was the number of reverse transcriptase–polymerase chain reaction (RT-PCR)–determined SARS-CoV-2–positive subjects using self-collected saliva 7 days post-gathering in the per-protocol population. Secondary endpoints focused on 20 other respiratory viruses.

Results. Healthy participants (n = 1216) randomized 2:1 by blocks up to 10 815 attendees and 401 non-attendees, yielding 529 and 287 subjects, respectively, with day-7 saliva samples. One day-7 sample from each group was positive. Looking at all respiratory viruses together, the clubbing event was associated with an increased risk of infection of 1.59 (95% CI, 1.04–2.61).

Conclusions. In the context of low Delta variant of concern circulation, no evidence of SARS-CoV-2 transmission among asymptomatic and vaccinated participants was found, but the risk of other respiratory virus transmission was higher.

Clinical Trials Registration. ClinicalTrials.gov, NCT05311865.

Keywords. COVID-19; respiratory viruses; vaccination; indoor transmission.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) can be transmitted by droplets and aerosols from infected individuals, even during their incubation period and when asymptomatic [1, 2]. Transmission risk is higher in closed spaces with poor ventilation and a high density of people [3]. Therefore, the coronavirus disease 2019 (COVID-19) pandemic initially led to closure of indoor mass-gathering venues. Although those measures successfully stopped virus transmission, they dramatically impacted the cultural economy and well-being of those frequenting those places. Entertainment venues re-opened progressively using nonpharmaceutical interventions (NPIs), including face masks, social distancing, or SARS-CoV-2 testing before entry [4–6]. With the expansion of anti–COVID-19 vaccination, which is effective against severe disease, hospitalization and death, French health authorities replaced NPIs with a health pass in July 2021 that documented full vaccination, thereby allowing attendance at mass-gathering events. However, data on vaccination efficacy to limit SARS-CoV-2 transmissions, especially Delta variant of concern (VOC), and on virus shedding during breakthrough infections, were limited [7]. Moreover, during lockdowns, influenza virus and respiratory syncytial virus (RSV) cases were sharply lower in the context of massive NPIs [8]. However, no data were available on the risks of transmission in closed spaces and during mass-gathering events. This study was undertaken

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to evaluate the risks of SARS-CoV-2 (primary objective) and other respiratory virus (secondary objective) transmissions during an indoor mass-gathering nightclub event among volunteers fully vaccinated against COVID-19, without implementation of any other preventive measures.

METHODS

Study Design and Participants

This prospective, open-label, noninferiority, randomized (1:1) controlled trial was designed to take place during live indoor clubbing events on 17 October 2021, held in 2 nightclubs in Paris, France (the "Machine du Moulin Rouge" and "La Bellevilloise" see Supplementary Methods for a complete description). All participants were invited via mass media and special-interest groups to a dedicated website, where participants provided online consent, registered individually or as a group (up to 10 individuals), and booked an enrollment visit within 3 days preceding the event venue, to verify their eligibility and be given 2 self-saliva-collection kits. Adults aged 18–49 years, residing in the Paris region, fully vaccinated against COVID-19, with no relevant comorbidities, and not living with older or at-risk people were eligible. Participants reporting COVID-19–suggestive symptoms or pregnancy were excluded. Detailed inclusion and non-inclusion criteria are provided in the Supplementary Methods.

The trial protocol was approved by the Scientific Ethics Committee of Île-de-France VII and the French Data-Protection Agency and was registered with Identifiant de Recherche Clinique et Biologique (IDRCB no. 021-A01473-38) and ClinicalTrials.gov (NCT05311865).

Randomization and Masking

Participants were enrolled in groups of 1 to 10 individuals who registered together. The groups were randomly assigned in a 1:1 ratio to the intervention or control group—henceforth, "attendees" or "non-attendees," respectively. The allocation sequence was computer-generated by means of permuted blocks of variable sizes, concealed from the research team, and randomization was achieved by means of a centralized secure system (SAS version 9.1; SAS Institute, Cary, North Carolina, USA). Study participants were informed of their randomization group by text message and email within 24 hours before the event day. Non-attendees were asked to not participate in any mass-gathering event. We maximized adherence to the randomization group by scheduling the event on a Sunday and providing financial compensation (voucher for cultural goods, such as concert tickets, books or magazine).

Data-Collection Questionnaires

Participants were asked to complete 4 questionnaires. The first, given after consenting to participate and before the event, collected sociodemographic characteristics, occupational activities, vaccine motivations, and regular attendance at outdoor festive events. Three subsequent surveys, given on days 3, 7, and 9 post-event, sought information on clinical symptoms.

Procedures

During the event, neither physical distancing nor mask wearing was required, bars were open, and singing and dancing were permitted. The event lasted 7 hours, from 4 PM to 11 PM. All artists and staff members had to test negative for SARS-CoV-2 by nasopharyngeal reverse transcriptase–polymerase chain reaction (RT-PCR) or rapid antigen-detection test (RADT) within the 3 days preceding the event.

All participants were given 2 self-saliva-collection kits. The first sample, collected on the event day (day 0), was returned by attendees arriving at the nightclub entrance, and mailed in prepaid envelopes by non-attendees; the second specimen, collected on day 7 (with a window ranging from day 6 to day 15) post-event, was mailed by all participants in prepaid envelopes. All samples were centralized and processed at the Virology Laboratory, Saint-Louis Hospital, Paris, France. All participants testing positive were contacted individually by a medical team member to collect clinical information and initiate contact-tracing. Participants with clinical symptoms appearing between days 0 and 15 were asked to contact their primary care physician and notify the researchers of any additional screening-test results. Participants received regular reminders (text messages and phone calls) until day 15 to send their samples.

RT-PCR on day-0 and day-7 saliva samples followed the extraction procedure using the Qiasymphony DSP Virus/pathogen mini-kit (Qiagen, Courtaboeuf, France). The RespiFinder 2SMART panel (PathoFinder, Maastricht, The Netherlands) was used to detect 20 seasonal respiratory viruses: influenza A, B, A(H1N1)pdm09; RSVs A and B; metapneumovirus; rhinovirus/enterovirus; adenovirus; parainfluenza 1–4; bocaparvovirus; and 6 human coronaviruses (human coronavirus [HC] HCoV-NL63, HCoV-HKU1, HCoV-OC43, HCoV-229E, SARS-CoV-2, and Middle East Respiratory Syndrome Coronavirus [MERS-CoV]). We previously showed that RT-PCR achieved 95% sensitivity on saliva samples compared with nasopharyngeal swabbing of a population of individuals attending COVID-19 community-screening centers [9].

Three AerosolSense systems (ThermoFisher, Waltham, Massachusetts, USA) at "Machine du Moulin Rouge" were installed to detect respiratory virus genomes in ambient air [10]: samples were tested using the BioFire RP2.1plus panel on a BioFire Torch System (BioMérieux, Craponne, France) to detect the same viruses as the saliva test. Detailed laboratory procedures are provided in the Supplementary Methods. Subtyping and molecular analysis of transmission clusters were carried out by whole-genome sequencing on a GridION system

(Oxford Nanopore Technologies, Oxford, UK) for SARS-CoV-2, and by Sanger sequencing of the VP4–VP2-coding regions of rhinovirus/enterovirus-positive samples, as previously described [11].

Outcomes

The primary outcome was the number of SARS-CoV-2–positive RT-PCR results on day 7 (with a 7-day window) post-event, self-collected saliva samples, according to viral RNA kinetics and the same sampling timing as previously described [12–14]. Those results were analyzed for the per-protocol population (complete case analysis), which included all randomized eligible participants without any major protocol deviations. Major protocol deviations were as follows: missing day-7-saliva RT-PCR results, day-7-saliva swab obtained outside the day 6-to-day-15 window, and attendees who did not come. The main analysis yielded the absolute positivity-rate differences (95% confidence interval [CI]) between attendees and non-attendees. The secondary outcomes were the saliva-carriage conversion rate between days 0 and 7 for SARS-CoV-2 and other seasonal respiratory viruses and AerosolSense machine detection of SARS-CoV-2 and other respiratory viruses in ambient air.

Statistical Analyses

We hypothesized that, among a population fully vaccinated against COVID-19, event attendance in a closed venue would not engender an increased risk of SARS-CoV-2 acquisition compared with non-attendees. To determine the SARS-CoV-2 incidence rate in the general population, based on 100–300 positive tests per week per 100 000 people, the detectable excess risk would be 4- to 3-fold (respectively) for 2000 attendees and 2000 non-attendees (ratio 1:1). Because study participants were randomized by block to avoid to artificially separating participants who had reserved as a group, we considered that this randomization introduced a clustering effect. We simulated its impact, considering an increased risk of infection within groups of participants who came to the event together. Considering that the secondary attack rate within those groups would be decreased by 80% by vaccine protection, we could assume that the intracluster correlation would be negligible and that the design effect would be close to 1. With a planned participant attrition rate of 10% for the primary outcome on day 7, we decided to randomize 2200 attendees and 2200 non-attendees. Sensitivity analyses were computed to determine the robustness of our findings and compare results of attendees and non-attendees not participating in another event (Supplementary Methods).

Categorical data are expressed as number (percentage) and continuous data as median (interquartile range [IQR]). Statistical analyses were computed using R version 4.0.3 software (R Foundation for Statistical Computing, Vienna, Austria).

We also planned a preapproved, protocol-design adaptation in the case of fewer inclusions. A decision algorithm was applied that first preserved randomization and mass gathering in a full-capacity venue (see Supplementary Methods). This design adaptation could engender asymmetric randomization and the use of only 1 venue.

Role of the Funding Source

The funders played no role in the study design or conduct of the trial, data collection, data analysis, writing of the report, or the decision to submit for publication.

RESULTS

Recruitment of Participants and Study Protocol Adaptation

Between 19 September and 13 October 2021, 3863 individuals registered on the dedicated website; 2744 provided online consent and booked an appointment, and 1216 were eligible for randomization (Figure 1). We had to resort to the preapproved protocol-design adaptation (see scenario 4, Supplementary Methods) to modify randomization to the 2:1 ratio, with 1 nightclub at full capacity ("Machine du Moulin Rouge"): 815 were assigned to be attendees and 401 to be non-attendees. Among attendees, 655 (80.4%) attended but 126 (19.2%) had major protocol deviations (samples not sent, deteriorated, or could not be analyzed), which resulted in a primary per-protocol analysis of 529 attendees with day-7-saliva samples. Among non-attendees, 114 (28.4%) had major protocol deviations, leaving 287 participants with day-7-saliva samples for primary outcome assessment.

The median age of primary-analysis participants was 28 (IQR: 25–33) years; 52.9% were males (Table 1); 12.0% of participants were healthcare workers. The first questionnaire showed that the study population was familiar with such events: 541 (66.3%) usually go clubbing more than 1 time per month and 676 (82.8%) considered the opening of nightclubs as important as other gathering events. The median (IQR) group-reservation size was 2 (1–3) persons. Attendees spoke more than 5 minutes with 2.7 individuals in their group and 1.3 persons outside their group. Mean time spent at the event was 4.2 hours. Among the 287 randomized non-attendees, 235 (81.9%) stayed home. Among the 36 participants who did not stay at home, 16 individually attended other indoor parties, 8 of which comprised more than 50 individuals.

SARS-CoV-2 Detection

Day-7 SARS-CoV-2 RT-PCR results were positive for 1 of the 529 attendees and 1 of the 287 non-attendees. Among day-0 RT-PCR results, 1 attendee's sample was positive, but none were positive among non-attendees. Unfortunately, the attendee with the day-0 positive RT-PCR did not provide a day-7-

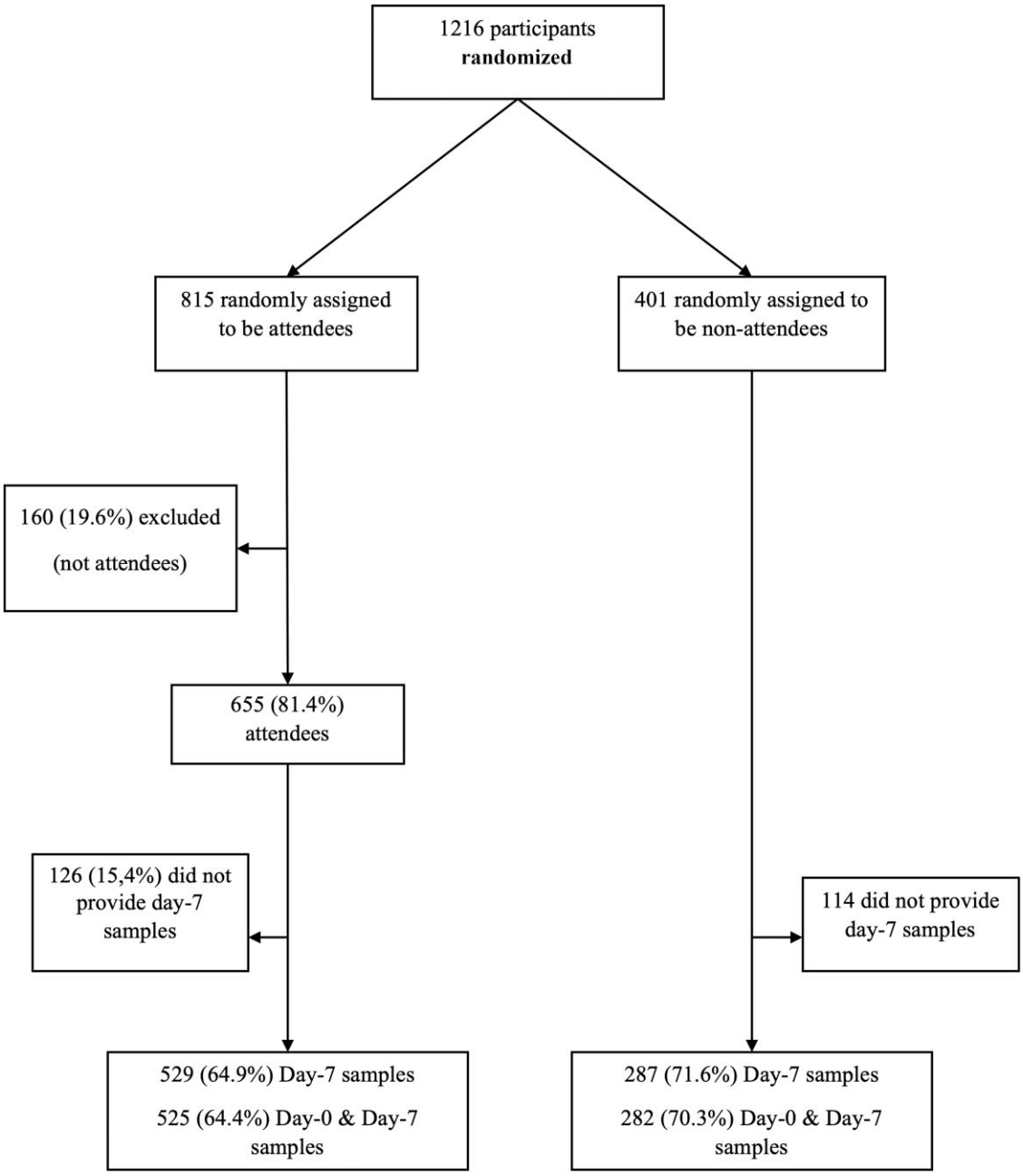

Figure 1. Flow chart.

saliva sample. All SARS-CoV-2 belonged to the Delta (B.1.617.2) lineage.

Detection of Other Respiratory Viruses

Among day-0-saliva samples, 16 attendees' and 95 non-attendees' specimens could not be analyzed. The remaining 945 samples contained 151 detected respiratory viruses: 84 of 639 (13.1%) from attendees versus 50 of 306 (16.4%) from non-attendees. The most frequent viruses identified in attendees' (Table 2) and non-attendees' samples, respectively, were as follows: 51 of 639 (8%) versus 27 of 306 (8.8%) enterovirus/rhinovirus, 20 of 639 (3.1%) versus 8 of 306 (2.6%) HCoV-229E, and 9 of 639 (1.4%) versus 8 of 306 (2.6%) HCoV-OC43. On the event day, the AerosolSense in at least 2 locations collected from ambient air enterovirus/rhinovirus, HCoV-229E, and HCoV NL63/HKU1, but not HCoV-OC43 or SARS CoV-2. RSV was found in ambient air but not detected in attendees' saliva, while adenovirus was collected from ambient air and only 1 day-0-saliva sample. The day after the event, AerosolSense filters had entrapped the same viruses but in fewer places.

Table 1. Sociodemographic Characteristics of Participants Randomly Assigned to Be Nightclub-Concert Attendees or Non-attendees

Parameter	All Participants (N = 816)	Attendees (n = 529)	Non-attendees (n = 287)	*P*
Males	432 (52.9)	278 (52.6)	154 (53.7)	.77
Age, y	28.0 [25.0–33.0]	29.0 [25.0–33.0]	28.0 [25.0–32.0]	.40
Employment				.36
Healthcare workers	98 (12.0)	69 (13.0)	29 (10.1)	
Executive	328 (40.2)	214 (40.5)	114 (39.7)	
Students	156 (19.1)	105 (19.8)	51 (17.8)	
Unemployed	45 (5.5)	25 (4.7)	20 (7)	
Other	189 (23.2)	116 (21.9)	73 (25.4)	
Clubbing-night frequency per month				
<1/mo	275 (33.7)	187 (35.3)	88 (30.7)	.22
1–2/mo	359 (44)	232 (43.9)	127 (44.3)	
>2/mo	182 (22.3)	110 (20.8)	72 (25.1)	
≥1 SARS-CoV-2 test (since January 2020)	796 (97.5)	512 (96.8)	284 (99)	.139
≥1 positive	180 (22.1)	113 (21.4)	67 (23.3)	
Currently taking precautionary measures against COVID-19				
Yes, completely	133 (16.3)	88 (16.6)	45 (15.7)	.95
Yes, somewhat	430 (52.7)	280 (52.9)	150 (52.3)	
No, rather not	206 (25.2)	130 (24.6)	76 (26.5)	
Not at all	47 (5.8)	31 (5.9)	16 (5.6)	

Results are expressed as median [interquartile range] or n (%).

Abbreviations: COVID-19, coronavirus disease 2019; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

Because of numerous rhinovirus/enterovirus-positive samples, VP4–VP2 regions were subjected to Sanger sequencing to determine species and type, and whether transmission cluster(s) existed among those samples (Supplementary Results, Supplementary Table 4, and Supplementary Figure 2). Among the 138 positive saliva specimens, 62 were successfully sequenced and were classified as rhinoviruses A (n = 33), B (n = 8), or C (n = 17); enterovirus D68 (n = 1); and Coxsackievirus (n = 3). Among rhinovirus-infected attendees, 5 putative transmission clusters were identified: 3 intervention attendees and 2 non-attendee controls (Supplementary Results and Supplementary Figure 2).

Among the 707 attendees and non-attendees, respectively, who provided day-0- and day-7- saliva samples, attack rates for at least 1 respiratory virus were 13.0% versus 8.2%, leading to a risk ratio of 1.59 (95% CI, 1.04–2.61; $P = .047$) (Table 3). That result was confirmed by a mixed-effects regression-model analysis that identified factors related to respiratory infection, with an odds ratio of 1.88 (95% CI, 1.00–3.55; $P = .05$) (Supplementary Table 1). Sensitivity analyses considering only non-attendees who did not participate in any indoor events confirmed that result (Supplementary Table 2).

While all participants were asymptomatic on day 0, 351 (59.5%) attendees developed symptoms during follow-up, as did 164 (55.8%) non-attendees. The mixed-effects regression analysis to identify factors associated with respiratory symptoms revealed that employment, participation in a cultural event during the last 15 days, or saliva detection of at least 1 respiratory virus were independently associated with the presence of symptoms. Participation in our intervention was not found to be significantly associated (Supplementary Table 3).

DISCUSSION

To our knowledge, no randomized controlled trial to assess the risk of SARS-CoV-2 and other respiratory virus transmissions among a population fully vaccinated against COVID-19 in an indoor mass gathering has been published; the ITOC trial fills that void. Participants were able to attend a mass-gathering nightclub event at full capacity for 7 hours, with no prior testing, no masking, no social distancing, and optimized ventilation. Only 1 new SARS-CoV-2 infection in each group was confirmed based on day-7 self-collected saliva samples, and no cluster was identified. Notably, at the time of the event in October 2021, the 14-day cumulative incidence rate was low (51/100 000 per week) in the Paris region, where the SARS-CoV-2 Delta VOC was circulating [15]. Vaccination became available to any adult in June 2021, so most participants had received their second dose less than 6 months previously [16].

Our results add to a growing body of evidence of SARS-CoV-2 transmission in mass-gathering, indoor events and on the conditions for venue re-opening. All previous studies relied on testing, mask wearing, and hand sanitizing to prevent SARS-CoV-2 transmission. Large-scale studies in Spain, the United Kingdom, or Germany were observational and

Table 2. Detection of Viral Genome in Ambient Air by AerosolSense (ThermoFisher) and Saliva From Attendees

	Day of the Event				Day After the Event		
	Ambient Air in the Venue				Ambient Air in the Venue		
Virus	Stage	Corner of the Dance Floor	Central Bar	Attendees With Positive Day-0 Saliva Samples (n = 639[a])	Stage	Corner of the Dance Floor	Central Bar
Rhinovirus/enterovirus	+	+	+	51	–	–	–
Coronavirus							
HCoV-229E	+	+	–	20	–	+	–
HcoV-OC43	–	–	–	9	–	–	–
NL63/HKU1	+	+	–	2	–	–	+
SARS-CoV-2	–	–	–	1	–	–	–
MERS-CoV	–	–	–	0	–	–	–
Influenza							
Influenza A	–	–	–	0	–	–	–
Influenza B	–	–	–	0	–	–	–
(H1N1)pdm 09	–	–	–	0	–	–	–
Respiratory syncytial virus	+	–	–	0	–	–	–
Metapneumovirus	–	–	–	1	–	–	–
Adenovirus	–	+	–	1	–	+	–
Parainfluenza 1–4	–	–	–	4	–	–	–
Bocavirus	–	–	–	2	–	–	–

[a]Numbers of day-0 samples.

Abbreviations: MERS-CoV, Middle East respiratory syndrome coronavirus; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

Table 3. Comparative Respiratory Virus Attack Rates in Patients With Day-0–Negative and Day-7–Positive Saliva Samples for a Given Virus

	Intervention		Control			
Respiratory Virus on Day 7	No. Event/Total	AR, %	No. Event/Total	AR,%	RR [95% CI]	*P*
All viruses[a]	68/525	13.0	23/282	8.2	1.59 [1.04–2.61]	.047
Coronavirus OC43	7/519	1.3	4/275	1.5	0.93 [.26–5.30]	1.000
Coronavirus 299E	17/510	3.3	5/274	1.8	1.83 [.77–8.61]	.263
Rhinovirus/enterovirus	36/481	7.5	11/255	4.3	1.74 [.95–3.89]	.113

[a]Influenza A, B, and (H1N1)pdm09, respiratory syncytial virus, metapneumovirus, rhinovirus/enterovirus, adenovirus, parainfluenza 1–4, bocavirus, and coronavirus (NL63/HKU1, OC43, 229E, SARS-CoV-2, MERS-CoV).

Abbreviations: AR, attack rate; CI, confidence interval; MERS-CoV, Middle East respiratory syndrome coronavirus; RR, risk ratio; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

showed little risk of transmission [6, 17–19]. Only 2 studies were randomized and controlled. The PRIMA-CoV study on 1140 participants, conducted in December 2020 in Spain, was a randomized controlled, open-label trial that assessed the effectiveness of comprehensive preventive interventions for a mass-gathering, live, indoor concert with low population density: systematic same-day RADT screening, compulsory N95 facemask wearing, and adequate site ventilation [6]. In France, the larger, prospective, randomized controlled SPRING trial evaluated SARS-CoV-2 transmission during a live concert in May 2021, with systematic RADT within the 3 days preceding the event, medical mask-wearing, optimized ventilation, and no social distancing. All of these study results demonstrated no enhanced transmission risk during live indoor events. However, every participant had to present a negative RADT or RT-PCR result, which is hardly applicable in a real-life context, where tests are expensive, have limited access, and are not convenient to perform at the last moment. Moreover, masking and social distancing are difficult to maintain constantly because of poor adherence, rendering these events less financially profitable. To our knowledge, event entry not conditioned on the SARS-CoV-2 test result was never explored previously. A strength of the ITOC trial is that it was held under real-life conditions with fully vaccinated participants during a period of Delta VOC circulation. Vaccination can limit transmission in 2 ways: whereas it has individual benefits of lowering the risks of become infected, severely ill, requiring hospitalization, and dying, study results suggest that it also provides collective benefits in limiting virus proliferation and shedding, even during vaccine-breakthrough infections [7, 20]. Pertinently, our

extremely rare SARS-CoV-2 detection would tend to confirm rare shedding among vaccinated persons. Our results also add to those of the Comcort study [21], which found a higher risk of Delta VOC infection for nightclub and private-gathering attendees (adjusted OR: 3.4). However, those earlier observational studies were not conducted when the young French population was fully vaccinated, and their questionnaire did not differentiate private gatherings from effectively ventilated venues.

Another strength of our study is that it also examined other respiratory viruses, with similarities in transmission similar to those of SARS-CoV-2. Most previous studies on virus transmission (not SARS-CoV-2) were based on mathematical and laboratory studies, suggesting possible airborne transmission, whose route has not been examined in randomized clinical trials [22]. We found a 1.59 relative risk of respiratory virus transmission among attendees compared with non-attendees. Unlike SARS-CoV-2, rhinovirus/enterovirus and HCoV 229E were detected in ambient air and among attendees, suggesting that airborne transmission could have been the main transmission route in the nightclub. Airborne transmission could also explain why the infection did not spread only among interacting participants of the same block or those from different randomization blocks. Finally, when comparing SARS-CoV-2 transmission with that of other respiratory viruses—all disseminated by airborne transmission—the fact that we found no evidence of transmission could also support our hypothesis that vaccination can lower SARS-CoV-2 transmission.

Our study has several limitations. Fewer persons were enrolled than initially planned. It had an original study design that randomized participants to exposure and not to treatment. The risk–benefit balance had to be carefully weighed based on little evidence of indoor SARS-CoV-2 transmission at mass-gathering events, vaccination efficacy against transmission, and emerging VOCs. Unfortunately, conducting the study in the context of a novel emerging disease was hampered by several external factors—principally, the low incidence rate at the time of the event, which lowered the study's statistical power. The real-time evolution of policies regarding mass-gathering events is another impacting factor. The trial was designed when clubs were still closed. A health pass, requiring proof of vaccination or recent infection, but no need for prior testing, enabled clubs to re-open 3 months before our intervention. That change could partly explain why the inclusion rate was lower than expected.

Herein, we described the results of an innovative trial designed to assess the risk of airborne virus transmission, including SARS-CoV-2, in a real-life setting. We believe it can be used as a proof-of-concept study, as we actively cooperated with several organizations, representative of civil society and the music industry, without any experience in epidemiological research.

To conclude, our results indicated no evidence of SARS-CoV-2 transmission or cluster infections in the context of low Delta VOC circulation, and among recently vaccinated participants, but found an enhanced risk of transmission of other respiratory viruses. More research in real-life settings is needed to characterize that risk, to avoid systematic shutdown of mass-gathering events.

Supplementary Data

Supplementary materials are available at *Clinical Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Notes

Author Contributions. J. Z., L. B. L. N., J. G. d. B.: conceptualization. P. C.: data curation. J. Z., L. B. L. N., J. G. D. B.: investigation. P. C.: methodology. C. D.: supervision. M. N., J. Z., L. B. L. N., J. G. D. B.: writing the original draft. C. D., P. C.: writing and editing. All authors have read and approved the final manuscript.

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