




BMJ Open Evaluating the controlled reopening of nightlife during the COVID-19 pandemic: a matched cohort study in Sitges, Spain, in May 2021 (Reobrim Sitges)

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ABSTRACT

Objectives To assess the impact of relaxing the state of alarm restrictions on SARS-CoV-2 infections at 14 days among people attending reopened nightclub venues.

Design Matched cohort study with a paired control group (1:5 ratio).

Setting Five small nightclubs with indoor areas and outdoor terraces, in a nightlife-restricted area in Sitges, Spain, on 20 May 2021. Wearing masks was mandatory, drinking was allowed and social distance was not required.

Participants Volunteers were selected through a convenience sampling. To attend the event, participants were required to be older than 17 years, with a negative rapid antigen diagnostic test (Ag-RDT) on the same afternoon, without a positive reverse-transcription PCR (RT-PCR) or Ag-RDT and/or symptoms associated with COVID-19 in the previous 7 days, to not having knowingly been in close contact with someone infected in the previous 10 days and to not have knowingly had close contact with someone with a suspicion of COVID-19 in the previous 48 hours. A control group was paired by exact age, gender, residence municipality, socioeconomic index, previous SARS-CoV-2-confirmed infection and vaccination status, in a 1:5 ratio, from the primary care electronic health records.

Primary outcome Evidence of infection at electronic health records by SARS-CoV-2 at 14-day follow-up.

Results Among the 391 participants (median age 37 years; 44% (n=173) women), no positive SARS-CoV-2 cases were detected at 14 days, resulting in a cumulative incidence estimation of 0 (95% CI 0 to 943) per 100 000 inhabitants. In the control group, two cases with RT-PCR test were identified, resulting in a cumulative incidence of 102.30 (12.4 to 369) per 100 000 inhabitants.

Conclusions Nightlife attendance under controlled conditions and with a requirement for a negative Ag-RDT was not associated with increased transmissibility of SARS-CoV-2 in a pandemic context of low infection rates. In such circumstances, secure opening of the nightlife sector was possible, under reduced capacity and controlled access by Ag-RDT, and environments

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Reobrim Sitges was a matched cohort study with convenience sampling and with a paired control group.
- ⇒ Participants underwent rapid antigen diagnostic tests (Ag-RDTs) on the afternoon of the same day prior to accessing the event.
- ⇒ Evidence of infection by SARS-CoV-2 at 14 days was obtained from the electronic health records.
- ⇒ Follow-up Ag-RDTs 6 days after the intervention minimised unregistered infections in the participants who attended the event, with only 12% loss to follow-up.
- ⇒ The background context of low infection rates at the time of the study and the timing of the study during a previous phase of the pandemic (before the emergence and dominance of new variants) limit the generalisability of these findings.

where compliance with sanitary measures are maintainable.

INTRODUCTION

The SARS-CoV-2 pandemic had infected 186 million people and caused over 4 million deaths worldwide by 12 July 2021, with wide variability between countries and regions.¹ SARS-CoV-2 transmission mostly occurs by direct contact or through droplets and aerosols from an infected person located within 2 m range and with exposure time of over 15 min.^{2 3} Indoor, poorly ventilated and crowded spaces⁴ where people gather are hotspots for transmission of the virus.⁵

The COVID-19, caused by SARS-CoV-2, has an incubation period that varies from 2 to 14 days. Among the symptomatic people,

50% develop symptoms within 5.1 days and 75% within 11.5 days.⁶

The gold standard diagnostic test for SARS-CoV-2 is the real-time reverse-transcription PCR (RT-PCR), which detects viral RNA, presenting good results in terms of reliability, sensitivity and specificity.⁷ Although RT-PCR can detect positive cases from the beginning of the infection in symptomatic and asymptomatic people, the need for well-equipped labs with specialised professionals increases the total delivery times and costs.⁸ In contrast, the lateral flow immunochromatographic rapid antigen diagnostic tests (Ag-RDTs) for SARS-CoV-2 can detect viral proteins and provide results in situ within 30 min. Although its sensitivity is below WHO recommendations, Ag-RDTs still offer the possibility of quick, easy and inexpensive SARS-CoV-2 detection in individuals who have high viral loads and hence are at high risk of transmitting the infection to others,⁹ which is the relevant issue for most public health measures.¹⁰

The health and social crises subsequent to the COVID-19 pandemic have forced many governments to deploy new social policies and legal restrictions, mostly focused on reducing the spread of COVID-19. In Spain, restrictions to mobility and economic activity (with temporary closure of restaurants, hotels and nightlife activities) began with the first state of alarm in March 2020.¹¹ At the time of writing of the first draft of this paper, September 2021, some restrictions on capacity limitations and opening hours still prevail. The balance between health and economy is still under study in the more flexible stage at this time: bars, restaurants, pubs, discotheques and concert venues were still on the tightrope, claiming for secure measures to allow them to flounder.

Herd immunity, mainly through mass vaccination, is the key goal to restoring social and economic activities in this sector. In Catalonia, on 5 May 2021, 30.5% of the population had received at least one dose, and 13.6% had completed vaccination.¹² Due to age prioritisation, only 6.9% of Catalanian people aged 18–24 years old and 11%

aged 25–49 years had some vaccination, thus constituting age ranges where legal measures were still prominent in controlling virus transmission.

Some studies have been carried out in Catalonia to assess the impact of relaxing legal restrictions on various types of social activities, including indoor gigs and dining passes in restaurants; although just two articles have been published to date,^{13 14} press conferences have disseminated some results on three initiatives.¹⁵ None of these studies detected any increased risk associated with the exposures.

The aim of the present study was to assess the impact of relaxing the state of alarm restrictions on SARS-CoV-2 infections at 14 days among people attending reopened nightclub venues.

METHODS

Reobrim Sitges was a matched cohort study, performed in a nightlife-restricted area in Sitges (Barcelona, Spain) on 20 May 2021.

The volunteers attending the event were recruited by convenience sampling promoted mainly through social networks by participating entities (council, guild, venues) and registered through the official city council website. Inclusion and exclusion criteria for all exposure groups (formed by study volunteers and staff groups) are defined in [table 1](#). Participants underwent their Ag-RDTs in scheduled intervals the afternoon of the event day in Sitges. The Ag-RDT was performed by trained health professionals following manufacturer's instructions (AllTest, Ref. ICOV-502, Japan). The manufacturer's reported sensitivity and specificity were 96.4% and 99.9%, respectively.

The nightlife event took place from 23:00 on 20 May to 03:00 on 21 May, in a restricted street section, including five nightclubs with indoor areas (capacity 42–98 people) and outdoor terraces (capacity 15–35 people), with controlled registered access exclusively for participants. Mask was mandatory (surgical or FFP2), except while

Table 1 Inclusion and exclusion criteria for study participants (volunteers and staff groups) attending the nightlife mass gathering event

Inclusion criteria	Exclusion criteria
1. Aged over 17 years	1. Declaring to have had a positive RT-PCR or Ag-RDT in the last 7 days
2. Living in Sitges area and Barcelona	2. Presenting symptoms associated with COVID-19 in the last 7 days (according to Catalan Health Department protocols ^{32 33})
3. Having a personal card from the Catalan public healthcare system	▶ at least one of these: fever, persistent cough, shortness of breath, anosmia, ageusia
4. A negative Ag-RDT the same afternoon (provided by the organisation)	▶ at least two of the following: sore throat, a cold, fatigue, myalgia, headache, vomiting or diarrhoea stomachache
	3. Having had close contact with someone infected in the last 10 days
	4. Having had close contact with someone suspected to have COVID-19 in the last 48 hours

Ag-RDT, rapid antigen diagnostic test; RT-PCR, reverse-transcription PCR.

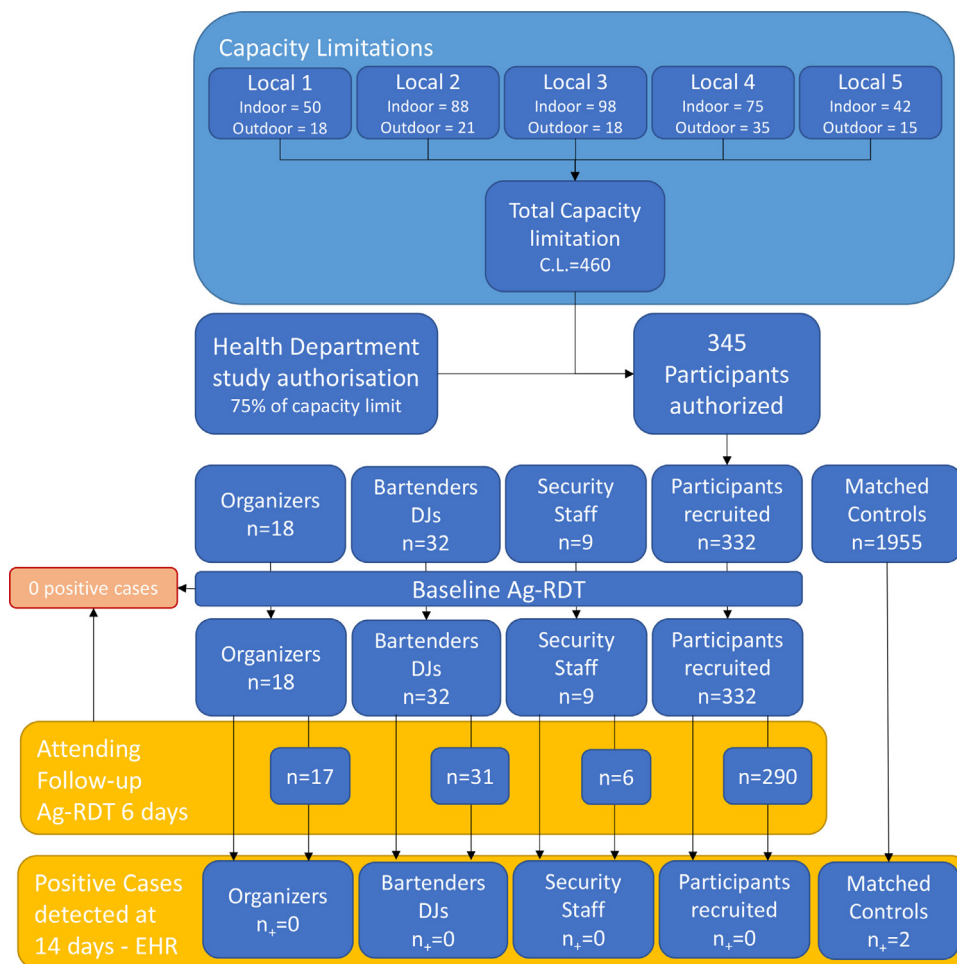


Figure 1 Participant flow chart. Ag-RDT, rapid antigen diagnostic test; EHR, electronic health record.

drinking or smoking. Drinking was allowed indoors and outdoors. Social distancing was not required. Hydroalcoholic gel and panels reminding about COVID-19 safety standards and their participation in the study were distributed throughout the entire area. No special ventilation measures were required. A follow-up Ag-RDT on day 6 after the event was performed on participants.

The control group was obtained through secondary data from the primary care electronic health records (PC-EHRs), by a pseudonymised paired extraction of individuals not attending the social event. Pairing was executed by exact age, gender, residence municipality, socioeconomic index, previous SARS-CoV-2-confirmed infection and vaccination status (at least one dose administered), in a 1:5 ratio.

Sample size was conditioned on capacity limitations established at 75% of the venue's usual limits (according to and authorised by the health department within the context of this study), resulting in 400 volunteers. Considering the 14-day cumulative incidence of COVID-19 occurring in the health district (Gerència Territorial Metropolitana Sud) on 29 April 2021 (210/100 000 inhabitants¹²), significant differences would be found observing a 14-day incidence in the intervention group of

1.38% (six positive cases), with a significance level of 0.05 and power of 0.8.

A participant flow chart is shown in [figure 1](#).

Variables

The main outcome was a confirmed case (PCR, Ag-RDT and serology) of SARS-CoV-2 infection at 14-day follow-up. As a secondary outcome, the number of positive Ag-RDTs performed in person at 6 days in the exposure group was considered. The main outcome for the exposure group was gathered from both the 6-day follow-up Ag-RDT and any registry in the PC-EHR at 14-day follow-up and for the control group only from PC-EHR.

All other variables were obtained from PC-EHR: age, gender, MEDEA socioeconomic deprivation index¹⁶ (classifying individuals into septiles), previous SARS-CoV-2-confirmed infection and previous vaccination: first and second intake, date and vaccine commercial brand (BioNTech-Pfizer/Moderna/Oxford AstraZeneca/Janssen-Johnson&Johnson).

This information was collected for all participants, who were classified according to their role as organisers, security personnel, club workers or volunteers.

Statistical analysis

All variables were described and compared by participant role groups. Median, IQR, mean and SD were calculated for continuous variables, and absolute and relative frequencies were described for categorical variables. Homogeneity in distribution across roles was tested using Kruskal-Wallis or χ^2 tests and complete case analysis. As pairing was performed by the exact characteristics, no description is provided for the controls (presenting the same values as study participants).

Cumulative incidence was calculated for study participants as the number of positive cases at 14 days divided by the total of individuals exposed, transformed into cases per 100 000 inhabitants and with CIs estimated by the exact method.

Patient and public involvement

The Associació d'Establiments d'Oci Nocturn de Sitges (Association of Nightlife Premises of Sitges) and the Federació Catalana de Locals d'Oci Nocturn (Catalan Federation of Nightclubs) proposed and promoted the initiative and developed the initial proposal together with the Sitges Council. The Catalan Public Health Agency was contacted to adapt it to a formal study design and develop it, with the aforementioned entities participating in the conception and dissemination. The results were returned immediately to the entities for their dissemination.

RESULTS

No positive Ag-RDTs were detected at baseline. The final exposure group included 391 participants (332 volunteers, 9 security staff, 32 bartenders/DJs, 18 organisers) who accessed the restricted nightlife area. Participants had a median/mean age of 37/37.5 years, 50% were between 23 and 50 years (table 2). A total of 55.8% (n=218) were male, and there was an under-representation of extreme Catalan socioeconomic ranges (especially the least deprived, with a 4.1% in front of the 28.6% in the general population). About 9.0% (n=35) had previously been infected by SARS-CoV-2, 10.7% (n=42) had at least one vaccination dose and 19.7% (n=73) had been vaccinated as well as infected.

Staff groups were significantly different from volunteers in terms of age (organisers were significantly older), gender (due to a 100% male security personnel) and socioeconomic status (55.5%—five of security personnel came from most deprived areas). Although not significant, security personnel and bartenders/DJs had lower vaccination and previous infection percentages. As the control group was matched by exact characteristics, it presented exactly the same distribution for all variables except for the outcomes.

Volunteers stayed in the restricted nightlife venue area for a mean of 177 min (minimum—maximum: 59–210 min). Three hundred seventy-three (88%) participants attended the 6-day Ag-RDT, all of them with negative results.

No positive SARS-CoV-2 cases were detected at 14 days in the exposure group (estimated cumulative incidence (95% CI): 0 (0 to 943)/100 000 inhabitants) and two positive RT-PCR cases in the control group (cumulative incidence of 102 (12.4 to 369)/100 000 inhabitants).

DISCUSSION

Key results

The Reobrim Sitges nightlife study loosening state of alarm restrictions in small clubs resulted in no positive SARS-CoV-2 test results among participants at the 14-day follow-up, while two positive cases were detected in the control group without statistically significant differences. This study adds new evidence to other studies assessing the impact of reopening the social and cultural nightlife.

Comparison with previous studies

To date, most articles studying COVID-19 in mass gathering events either reported retrospective analyses of SARS-CoV-2 transmission^{17–19} or described mitigation plans and measures applied during mass gathering events.^{20 21} Only one controlled trial was published in Catalonia.¹³

Revollo *et al*¹³ present a randomised controlled trial assessing the impact, in terms of SARS-CoV-2 infections, of attending a live gig in a medium-sized concert hall (capacity for 900 people) in Barcelona, in December 2020. One thousand forty-seven individuals aged 18–59 years with a negative Ag-RDT on the same day, no comorbidities and declaring not to have had a positive COVID-19 diagnosis during the last 14 days were randomly assigned to the experimental group and attended the indoor event (at 50% of venue's capacity; n=465), or sent home (control group, n=495). With a mean staying time of 2:40 hours, 8 days after the event no positive RT-PCR tests were found in the intervention group, whereas two (<1%) individuals in the control arm had a positive Ag-RDT and RT-PCR results. Common elements in this study are: sample size, use of Ag-RDT as inclusion criterion, age ranges, freedom of movement with no social distance and use of masks (although FFP2 and surgical masks were allowed in this study). Both studies obtained similar results, although in this study, (a) drinking was allowed in the entire perimeter and (b) the event was held in venues with indoor capacities below 100 people without indoor air quality control and with larger outdoor areas.

In March 2021, an observational study assessed the impact of attending a live gig in a large concert hall in Barcelona: 4584 attendees (below 30% of the hall's 17 000 person capacity) with negative Ag-RDT simultaneously enjoyed the experience in three isolated groups. No social distancing and wearing of FFP2 masks were required and independent drinking areas were established. The result was a cumulative incidence at 14 days of 131 infections per 100 000 inhabitants. This, compared with the age-adjusted estimation of 296/100 000 observed

Table 2 Sample characteristics and outcomes, overall and by subgroup

	n	Missing	Global	Organisers (n=18)	Security personnel (n=9)	Club workers (n=32)	Study participants (n=332)	P value
Age: median (IQR)	391	0	37.00 (23.00–50.00)	54.00 (48.25–57.00)	41.00 (38.00–46.00)	29.00 (25.00–40.25)	35.50 (23.00–50.00)	<0.001
Age: mean (SD)			37.54 (15.53)	51.67 (8.60)	41.44 (6.95)	33.06 (10.53)	37.10 (15.99)	<0.001
Gender: n (%)	391	0						0.017
Women			173 (44.25)	8 (44.44)	0 (0.00)	10 (31.25)	155 (46.69)	
Men			218 (55.75)	10 (55.56)	9 (100.00)	22 (68.75)	177 (53.31)	
MEDEA deprivation index: median (IQR)	374	17	-0.32 (-0.32 to 0.48)	-0.32 (-0.32 to -0.14)	0.64 (0.48–1.07)	-0.32 (-0.32 to 0.64)	-0.32 (-0.32 to 0.48)	0.022
MEDEA deprivation index: mean (SD)			0.04 (0.59)	-0.03 (0.64)	0.79 (0.49)	0.09 (0.67)	0.02 (0.58)	0.015
MEDEA deprivation index categories: n (%)	391	0						<0.001
Least deprived septiles (28.6%)			16 (4.09)	0 (0.00)	0 (0.00)	1 (3.12)	15 (4.52)	
Most deprived septiles (28.6%)			98 (25.06)	3 (16.67)	5 (55.56)	9 (28.12)	81 (24.40)	
3 central septiles (42.8%)			260 (66.50)	13 (72.22)	1 (11.11)	21 (65.62)	225 (67.77)	
No MEDEA			17 (4.35)	2 (11.11)	3 (33.33)	1 (3.12)	11 (3.31)	
Previous infection: n (%)	391	0	35 (8.95)	3 (16.67)	0 (0.00)	2 (6.25)	30 (9.04)	0.477
Previous infection date: median (IQR)	35	356	2 Nov 2020 (17 Aug 2020–8 Jan 2021)	13 Jan 2021 (4 Nov 2020–17 Jan 2021)	–	19 Jan 2021 (2 Jan 2021–5 Feb 2021)	15 Oct 2020 (12 Aug 2020–3 Jan 2021)	0.256
First vaccination: n (%)	391	0	42 (10.74)	1 (5.56)	0 (0.00)	2 (6.25)	39 (11.75)	0.456
Vaccine 1 company: n (%)	42	349						
BioNTech/Pfizer			17 (40.48)	1 (100.00)	–	0 (0.00)	16 (41.03)	
Moderna			8 (19.05)	0 (0.00)	–	2 (100.00)	6 (15.38)	
Oxford/AstraZeneca			17 (40.48)	0 (0.00)	–	0 (0.00)	17 (43.59)	
Second vaccination: n (%)	391	0	23 (5.88)	1 (5.56)	0 (0.00)	2 (6.25)	20 (6.02)	0.900
Vaccine 2 company: n (%)	23	368						
BioNTech/Pfizer			15 (65.22)	1 (100.00)	–	0 (0.00)	14 (70.00)	
Moderna			7 (30.43)	0 (0.00)	–	2 (100.00)	5 (25.00)	
Oxford/AstraZeneca			1 (4.35)	0 (0.00)	–	0 (0.00)	1 (5.00)	
Vaccinated and infected: n (%)	391	0	73 (18.67)	4 (22.22)	0 (0.00)	3 (9.38)	66 (19.88)	0.225
Follow-up Ag-RDT at 6 days: n (%)	391	0						0.069
Negative result			344 (87.98)	17 (94.44)	6 (66.67)	31 (96.88)	290 (87.35)	
Not attending			47 (12.02)	1 (5.56)	3 (33.33)	1 (3.12)	42 (12.65)	
Extra tests at 14 days: n (%)	18	373						–
RT-PCR			13 (72.22)	–	2 (100.00)	2 (100.00)	9 (64.29)	
Ag-RDT			5 (27.78)	–	0 (0.00)	0 (0.00)	5 (65.71)	
Test results at 14 days: n (%)	18	373						–
Negative result			18 (100.00)	–	2 (100.00)	2 (100.00)	14 (100.00)	

Ag-RDT, rapid antigen diagnostic test; RT-PCR, Real-time Reverse-Transcription Polymerase Chain Reaction.

in the city of Barcelona for the same period, had no significant impact due to the event,¹⁴ in line with our results.

As mentioned previously, the press has published other experiences such as the ‘Obrir Girona’ initiative,¹⁵ from 23 April to 22 May 2021 in Girona, assessing the impact of reactivating a broader range of social activities under ‘very low infection capacity’ conditions. Social activities included dinners in restaurants, an electronic music gig (250 attendees at full capacity, wearing masks—drinking allowed in independent room—with no social distancing) and a pop gig (1000 attendees at 56% capacity, wearing masks—drinking allowed at outdoor bar—with no social distancing). ‘Very low infection capacity’ was considered if participants were vaccinated in the last 6 months, had overcome COVID-19 in the last 3 months or had a negative Ag-RDT in the last 36 hours. Of the 1350 participants, only 3 had a positive test between day 7 and 14 after the events.²² Remarkably, the study inclusion criteria for participants relied on Ag-RDT screening and also considered recent vaccination or infection as an indicator of low infection capacity. Despite its heterogeneity in social activities and locations, the observed low incidence rate supports their low infection capacity criterion.

Other projects have been undertaken in the Netherlands and UK to examine how events can be reopened with reduced risk.^{23 24} Fitzgerald *et al*²⁵ explored the management of COVID-19 restrictions to operate safely in licensed premises. Physical distancing, which was not required in this study, was one of the more challenging aspects. A pilot study in Liverpool explored nightclubs reopening in semicontrolled settings.²⁶ Despite differences in the methodology, the results were in line with ours; an exploratory modelling of transmission risk at nightclubs suggests that primary transmissions are reduced by 53% through testing on the day.

Informally, if these unpublished results were correct, social activities in Catalonia under sanitary controlled access would have resulted in 9 people infected at 14 days out of 6739 participants to date. However, press information has attributed to the three extraordinarily authorised festivals in Catalonia in July 2021, with an infection risk around 1.7 times higher than expected.^{27 28} Without an official published report, the inefficiency of the Ag-RDT control process in one of the events, and the relaxation in the use of masks after several hours in an environment considered to be safe, along with the appearance of more contagious SARS-CoV-2 variants, were pointed out as possible causes for such poor results in comparison with pilot studies. This led to new limitations and highlighted the importance of vaccination and the cumulative protective effect of Ag-RDTs and masks in these scenarios.

Generalisability

On 29 July, after a few weeks of reporting a negative evolution, especially in the 15–24 age range population, the Catalan government decided to suppress the reopening of nightlife social activities.²⁹ Such activities had been opened until then without any sanitary access control,

exclusively with mandated use of masks. The dissonance between the results of controlled studies and real life, apart from the higher transmissibility of the Delta variant, highlights the importance of access control and sanitary measures when reducing the spread of the virus.

Despite Ag-RDT lacking high sensitivity,⁹ evidence supports its use, along with other measures, to ensure safe enough environments for mass gathering (nightlife) events; a low-cost, easy performance and quick-result test seems a good option for a wide range of social activities. Nonetheless, the use of Ag-RDT needs to be evaluated in every situation depending on the type of activity and the epidemiological data at the time of the event, including vaccination rate.³⁰ Each real situation needs to balance the benefits of having rapid Ag-RDT results for immediate and appropriate management and public health action against the harm of false negative results.³⁰ In this study, as in the two studies in Barcelona, the organisation provided the tests the same day. This guarantees the temporal proximity to the event and the inalterability of results, although logistic, sanitary and economic resources are required, which could be feasible for large events but not so much for nightlife in small clubs. Additionally, performing tests does not exclude the necessity to follow other safety measures, such as mask use.²⁴ Applications in line with the ‘Re-open EU’ or the one used in the ‘Obrir Girona’ study can be a useful tool for reporting low infection capacity probability from different sources.

The highly variable context/situation hinders the reproducibility of these types of studies. The extension of vaccination to all age ranges along with sanitary access control to nightlife activities should provide a safer nightlife environment, necessary to recover social and economic activities, while discouraging uncontrolled nightlife ‘botellón’ (street alcohol consumption) and illegal private mass events.

This study was performed when the first cases of SARS-CoV-2 Delta variant had been detected in Spain, the Delta variant being around 60% more transmissible than the predominant Alpha variant. Although the transmissibility context was determinant to allow ethical approval, the results presented must be carefully interpreted according to the low background infection rate at the time of the study. At that time, the pandemic was in a regression phase, with a cumulative incidence in Catalonia at 14 days of 210 cases per 100 000 inhabitants.¹² Further research is therefore needed to ensure the results can be extrapolated to the Delta and future variants and in the different severity and transmissibility scenarios. Delta variant spread worldwide as the fittest and fastest variant until then and it became dominant in many countries. Evidence in the UK showed that 75% of infections by Delta variant occurred in people who were not vaccinated and about 4%–57% in people who were fully vaccinated,³¹ thus affecting age ranges more disposed to enjoying nightlife.

Strengths and limitations

There are limitations in this study. The selection of volunteers was non-random (convenience sampling), with the aim of including a profile of clients specific to each nightclub. To adjust for this selection bias, a control group matched by age, gender, socioeconomic index, history of SARS-CoV-2 infection and SARS-CoV-2 vaccine status was sought. However, a residual bias cannot be ruled out as a result of other parameters that cannot be controlled.

Many limitations are inherent to how SARS-CoV-2 infection is measured, given the different criteria applied for intervention and control groups. At baseline, the intervention group received an Ag-RDT evaluation that was not applied in the control group, which was selected according to EHR without any additional prior check-up. Although sensitivity and specificity of the Ag-RDTs are far from perfect, there is a higher probability of underestimating the presence of SARS-CoV-2 infection in the control group (ie, having included asymptomatic or mild symptomatic cases not attended by health systems in the control group), which could reflect on a worse evolution of controls. Also, evidence of infections at 14 days was obtained for the volunteers and the control group through EHR, although the intervention group performed a follow-up Ag-RDT 6 days after the intervention (with an acceptable loss rate of 12%, as compared with similar studies in the UK earlier this year²⁶), which complemented EHR information. These follow-up tests increased the likelihood of measuring the impact of the intervention on the onset of new infections, reducing the underestimation of asymptomatic cases identified through EHR at follow-up only in the intervention group.

The highly fluctuating characteristics in transmissibility and severity of the different variants and phases during the pandemic hinder extrapolation of all studies' findings to the context in which they were developed. Therefore, aspects mentioned in the Generalisability section of the discussion are a major limitation for this study.

CONCLUSION

In conclusion, in this study, attendance to nightclubs under controlled conditions and with a requirement for negative Ag-RDT did not show an increased transmissibility of SARS-CoV-2 in a pandemic context of low infection rates. These results, within the framework of health and safety, provide insight into the possibility of safer openings for event organisers.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Ethics approval This study was approved by the Research Ethics Committee of the Institute for Primary Health Care Research Jordi Gol i Gurina (IDIAPJGol) and the Technical Committee of the Catalonia Civil Protection Plan (PROCCAT) (reference number 21/119-PCV). The study guarantees compliance with the new General Data Protection Regulation (GDPR) (EU 2016/679), the guidelines of the Principles of the Declaration of Helsinki and the Belmont Report. Participants were informed about the project and signed a statement of compliance and informed consent to participate and allow the use of their pseudonymised data exclusively for this project. Informed consent was not required for participants in the control group as the information was pseudonymised. The external entity 'Curasana' (www.curasana.org) was responsible for the logistics and for performing Ag-RDTs. The results were sent to the Catalan Institute of Health (ICS); positive results were communicated and entered into EHR for assistance purposes. The ICS and the IDIAPJGol were independently responsible for the data processing within the framework of this study.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. Due to ethical reasons stated by the Ethics Committee, data cannot be made available.

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