BMJ Open

A pilot test for the reopening of nightclubs and other late-night venues during the COVID-19 pandemic: 'Reobrim Sitges'

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-058595
Article Type:	Original research
Date Submitted by the Author:	27-Oct-2021
Complete List of Authors:	Cunillera Puértolas, Oriol; IDIAP Jordi Gol, Unitat de Suport a la Recerca Costa de Ponent; Universitat Autònoma de Barcelona Contreras-Martos, Sara; IDIAP Jordi Gol, Unitat de Suport a la Recerca Costa de Ponent; Universitat Autònoma de Barcelona Marzo-Castillejo, Mercè; IDIAP Jordi Gol, Unitat de Suport a la Recerca Costa de Ponent; Universitat Autònoma de Barcelona López Gallegos, Darío; Institut Catala De La Salut, Servei d'Atenció Primària Alt Penedès-Garraf-Baix Llobregat Nord, Direcció d'Atenció Primària Costa de Ponent Acedo Anta, Mateo; Institut Català de la Salut, Secretaria Tècnica, Direcció d'Atenció Primària Costa de Ponent; Universitat de Barcelona Facultat de Medicina i Ciencies de la Salut, Escola d'Infermeria Almeda Ortega, Jesús; IDIAP Jordi Gol, Unitat de Suport a la Recerca Costa de Ponent; Universitat Autònoma de Barcelona Colom, Joan; Agència de Salut Pública de Catalunya, Sub-direcció General de Drogodependències Basora, Josep; IDIAP Jordi Gol, Institut Universitari d'Investigació en Atenció Primària Salvador-Gonzalez, Betlem; IDIAP Jordi Gol, Unitat de Suport a la Recerca Costa de Ponent; Universitat Autònoma de Barcelona
Keywords:	COVID-19, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Public health < INFECTIOUS DISEASES

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

A pilot test for the **reopening** of **nightclubs** and other late-night **venues during the COVID-19 pandemic: 'Reobrim Sitges'**

Oriol Cunillera Puértolas[1,2]

Sara Contreras-Martos[1,2,3]

Mercè Marzo- Castillejo[1,2,3]

Darío López Gallegos[4]

Mateo Acedo Anta[5,6]

Jesús Almeda Ortega[1,2,3]

Joan Colom Farran[7]

Josep Basora i Gallisà[8]

Betlem Salvador González[1,3]

1-Unitat de Suport a la Recerca Costa de Ponent, Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol), Cornellà de Llobregat, Spain

2-Universitat Autònoma de Barcelona, Bellaterra (Cerdanyola del Vallès), Spain.

3-Unitat de Suport a la Recerca, Direcció d'Atenció Primària Costa de Ponent, Institut Català de la Salut, L'Hospitalet de Llobregat, Spain

4-Servei d'Atenció Primària Alt Penedès-Garraf-Baix Llobregat Nord, Direcció d'Atenció Primària Costa de Ponent, Institut Català de la Salut, L'Hospitalet de Llobregat, Spain.

5-Secretaria Tècnica, Direcció d'Atenció Primària Costa de Ponent, Institut Català de la Salut, Cornellà de Llobregat, Spain.

6-Escola d'Infermeria, Facultat de Medicina i Ciències de la Salut, Universitat de Barcelona, Barcelona, Spain

7-Subdirecció General de Drogodependències. ASPCAT. Departament de Salut, Generalitat de Catalunya, Barcelona, Spain.

8-Institut Universitari d'Investigació en Atenció Primària (IDIAP Jordi Gol), Barcelona, Spain.

* *Corresponding author:* Betlem Salvador-González
C/ Bellaterra, 41, 1er pis 08940 Cornellà de Llobregat, Barcelona. bsalvador@ambitcp.catsalut.net

Word count: 3086 words

ABSTRACT

Background: The economic impact of governmental legal restrictions during COVID-19 pandemic requires evaluation of the balance between health and economy. This study aims to assess the health impact of reopening the local nightlife under controlled conditions.

Methods: Observational study with a paired control group (1:5 ratio), performed in a nightlife restricted area in Sitges on May 2021. Volunteers were selected through a convenience sampling. Participants, aged over 17, presented negative Ag-RDT test on the same afternoon, and not having a positive RT-PCR or Ag-RDT test and/or symptoms associated with COVID-19 in the last 7 days, not being close contact with someone infected in the last 10 days, or having had close contact with someone with a suspicion of COVID-19 in the last 48 hours was required to access the event. Mask was mandatory, drinking was allowed and no social distance was required. The main outcome was evidence of infection by SARS-CoV-2 at 14 days follow-up.

Results: Of the 391 participants no positive SARS-CoV-2 cases were detected at 14 days, resulting in an estimation of a cumulative incidence (95% confidence interval) of 0 (0, 943.45) /100,000 inhabitants. In the control group, 2 cases with RT-PCR test were identified, a cumulative incidence of 102.30 (12.39, 369.55) /100,000 inhabitants.

Conclusions: Attendance to night-clubs under controlled conditions and previous negative Ag-RDT did not show an increased transmissibility of SARS-CoV-2. Secure aperture of nightlife sector is possible under reduced capacity límits, controlled access by Ag-RDT, and environments where compliance of sanitary measures conditions are maintainable.

Strengths and limitations of this study

- No studies have focused on the reopening of the more common sources on nightlife under the COVID-19 pandemic: small clubs.
- This is an observational study with a convenience sampling, with a paired control group.
- Participants performed Ag-RDT tests the afternoon of the event's day. Ag-RDT follow-up tests 6 days after the intervention minimized unregistered infections in the exposed group
- Setting: 5 nightclubs with interior areas and exterior terraces, wearing masks was mandatory, drinking was allowed, and social distance was not required.

INTRODUCTION

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic had infected 186 million people and caused over 4 million deaths worldwide by July 12th 2021, with wide variability between countries and regions [1]. The SARS-CoV-2 transmission mostly occurs by direct contact or through droplets and aerosols from an infected person located within 2 meters range and exposition times over 15 minutes [2,3]. Indoor, poorly ventilated, crowded spaces [4] where people gather are hotspots for the transmission of virus [5].

The Coronavirus Disease 2019 (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 polymerase chain reaction (RT-PCR), which detects viral RNA, presenting good results in terms of reliability, sensibility 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 specialized professionals increases the total delivery times and costs [8]. In contrast, the lateral flow immunochromatographic rapid antigen diagnostic tests (Ag-RDT) for SARS-CoV-2 can detect viral proteins and provide results *in situ* within less than 30 minutes; despite its sensitivity is below WHO's recommendations, Ag-RDTs still offer the possibility of rapid, easy and inexpensive detection of SARS-CoV-2 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 sanitary and social crisis subsequent to the COVID-19 pandemic have forced many governments to deploy new social policies and legal restrictions, mostly focused on reducing the spreading of COVID-19. In Spain, restrictions to mobility and economic activity -with temporal closure of restaurants, hotels and nightlife activities - began with the first alarm state on March 2020 [11]. Currently, some restrictions on capacity limitations and opening hours still prevail. The balance between health and economy is still on study in the more flexible stage we are in: bars, restaurants, pubs, discotheques, and concert venues were still on the tightrope, claiming for secure measures allowing them to flounder.

The herd-immunity, mainly through massive vaccination, is the key goal to restore social and economic activities in this sector. In Catalunya, on May 5th 2021, a 30.5% of the population had received at least one dose, and a 13.6% had completed vaccination [12]. Due to age prioritisation, only 6.9% of 18-24 years old Catalans and 11% of aged 25-49 had some vaccination, thus constituting age ranges where legal measures were still prominent on controlling virus transmission.

Some studies have been carried out in Catalunya to assess the impact of losing legal restrictions on various types of social activities, including indoor gigs and dining passes in restaurants; although just two articles have been published up to date [13,14], press conferences have spread some results on three initiatives [15]. None of these studies detected any increased risk associated with the expositions.

The present study is another step in generating evidence on the safety reopening of social activities in Catalonia. We aimed to assess the impact of loosening alarm state restrictions in small clubs nightlife on SARS-CoV-2 infections at 14 days.

METHODS

This is an observational study with a paired control group, performed in a nightlife restricted area in Sitges (Barcelona, Spain) on May 20th 2021.
The volunteer attending the event were recruited by convenience sampling promoted -mainly through social networks- by participant entities (council, guild, locals) and registered through the official city council web. Inclusion and exclusion criteria for all exposition groups (formed by study volunteers and staff groups) are defined in table 1. Participants performed their Ag-RDT tests in scheduled intervals the afternoon of the event's day in Sitges. The Ag-RDT test was performed by trained health professionals following manufacture's instructions (AllTest, Ref. ICOV-502, Japan). Manufacturers' reported sensitivity and especificity were 96.4% and 99.9%, respectively.

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

Inclusion criteria	Exclusion criteria
1. Aged over 17	1. Declaring to have a positive RT-PCR or Ag-RDT test 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 [16,17]): *a) at least one of these: fever, persistent cough, shortness of breath, anosmia, ageusia* *b) at least two of the following: sore throat, a cold, fatigue, myalgia, headache, vomiting or diarrhea stomach ache*
3.Having an individual health card of the Catalan public healthcare system	
4. A negative Ag-RDT test the same afternoon (provided by the organization)	
	3. Having had close contact with someone infected in the last 10 days
	4. Having had close contact with someone with a suspicion of COVID-19 in the last 48 hours

The nightlife event was developed from 23:00 p.m. of May 20th to 3:00 a.m of May 21st, in a restricted street section, including 5 nightclubs with interior areas (capacity 42-98 people) and exterior terraces (capacity 15-35 people), with controlled registered access exclusively for participants. Mask was mandatory (quirurgical or FFP2). Drinking was allowed indoors and

outdoors. Social distance was not required. Hydroalcoholic gel and panels reminding COVID-19 safety standards and their participation in the study were distributed throughout all the area. A follow-up Ag-RDT test 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-EHR), by a pseudonymized paired extraction of individuals not attending the social event. Pairing was executed by exact age, sex, residence municipality, socioeconomic index, previous SARS-CoV-2 confirmed infection, and vaccination status (at least one dose administred), by a 1:5 ratio.

Sample size was conditioned on capacity limitations fixed on 75% of the locals' usual limits, resulting in 400 volunteers. Considering the 14 days cumulative incidence of COVID-19 occurring in the health district (Gerència Territorial Metropolitana Sud) on April 29th 2021 (210.46/100,000 inhabitants [https://dadescovid.cat/]), significant differences would be found observing a 14 days incidence in the intervention group of 1.38% (6 positive cases), with a level of significance of 0.05 and power of 0.8.

Variables

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

All other variables were obtained from PC-EHR: age, sex, MEDEA socioeconomic deprivation index [18] (classifiying 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 AstraZenecae/Janssen-Johnson&Johnson).

This information was collected for all participants, which were cathegorized according to their role as Organizers, Security personnel, Club workers, or Volunteers.

Statistical analysis

All variables were described and compared by participant role groups. Median, interquartile range, mean and standard deviation 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 Chi-square tests and complete case analysis. As pairing was performed by the exact characteristics, no description will be 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 confidence intervals 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 with The Sitges Council the initial proposal. 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. There was an immediate return of results to the entities to allow their dissemination

Ethical considerations

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 Civil Protection Plan of Catalonia (PROCICAT). The study guarantees compliance with the new General Data Protection Regulation (GDPR)) EU 2016/679, the guidelines of the Principles of the Declaration of Hèlsinki and the Belmont Report.

Participants were informed about the project and signed a responsible statement and informed consent to participate and allowed the use of their pseudonymized data exclusively for this project. Informed consent was not required for participants in the control group as the information was pseudonymized.

The external entity 'Curasana' (www.curasana.org) was responsible for the logistic and performance of Ag-RDT tests. Results were sent to the Catalan Institute of Health (ICS); positive results were communicated and introduced to EHR for assistance purposes. The ICS and the IDIAPJGol were independently responsible for the data processing within the framework of this study.

RESULTS

No positive Ag-RDTs tests were detected at baseline. The final exposition group was composed of 391 participants (332 volunteers, 9 security staff, 32 bartenders/DJs, 18 organizers) that accessed the nightlife restricted area. Participants had a median/mean age of 37/37.5 years, 50% were between 23 and 50 years (Table 2). 55.7% were male, and there was an underrepresentation of extreme catalan socioeconomic ranges (specially the least deprived, with a 4.1% in front of the 28.6% in general population). About 9.0% had been previously infected by SARS-CoV-2, 10.7% had at least one vaccination dose, and 1.0% had been both vaccinated and infected.

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

Volunteers stayed in the local nightlife delimited area for a mean of 177 minutes (minimum-maximum: 59-210 minutes). 88% of participants attended the 6 days Ag-RDT, all of them with negative results.

No positive SARS-CoV-2 cases were detected at 14 days in the exposition group, (estimated cumulative incidence (95% confidence interval): 0 (0, 943.45) / 100,000 inhabitants) and 2 positive RT-PCR cases in the control group (cumulative incidence of 102.30 (12.39, 369.55) / 100,000 inhabitants).

Table 2. Sample characteristics and outcomes in the sample of participants in the 'Reobrim Sitges' study, Overall and by role groups.

	n	Missings	Global	Organizers (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
Sex : 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, 0.48]	-0.32 [-0.32, -0.14]	0.64 [0.48, 1.07]	-0.32 [-0.32, 0.64]	-0.32 [-0.32, 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	2020-11-02 [2020-08-17, 2021-01-08]	2021-01-13 [2020-11-04, 2021-01-17]	-	2021-01-19 [2021-01-02, 2021-02-05]	2020-10-15 [2020-08-12, 2021-01-03]	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-RTD 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	18	373						-
PCR			13 (72.22%)	-	2 (100.00%)	2 (100.00%)	9 (64.29%)	
TAR			5 (27.78%)	-	0 (0.00%)	0 (0.00%)	5 (35.71%)	
Test results at 14 days	18	373						-
Negative result			18 (100.00%)	-	2 (100.00%)	2 (100.00%)	14 (100.00%)	

DISCUSSION

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

Up to date, most of articles studying COVID-19 in mass-gathering events either reported retrospective analyses of SARS-CoV-2 transmission [19–21] or described mitigation plans and measures applied during mass-gathering events [22,23]. Only one controlled trial was published in Catalonia [13].

Revollo et al. [13] present a randomized controlled trial assessing the impact, in terms of SARS-CoV-2 infections, of attending a live gig in a medium-sized concert hall (capacity of 900 people) in Barcelona, on December 2020. 1047 individuals aged 18-59 years with a negative Ag-RDT on the same day, no comorbidities, and declaring not having a positive COVID-19 diagnose during the last 14 days were randomly assigned to the experimental group and attended the indoor event (at 50% of hall'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 with our study are: sample size, use of Ag-RDT as inclusion criteria, age ranges, freedom of movement with no social distance, and use of masks (although both FFP2 and quirurgical were allowed in our study). Both studies obtained similar results, despite in ours a) drinking was allowed in all the perimeter, and b) the event was developed in locals with indoor capacities below 100 people without indoor air quality control, and with bigger outdoor areas.

On March 2021 an observational study assessed the impact of attending to a live gig in a big concert hall in Barcelona: 4.584 attendees (below 30% of 17,000 persons hall's capacity) with negative Ag-RDT simultaneously enjoyed the experience in three isolated groups, with no social distancing, wearing FFP2 masks and independent drinking areas, resulting in a cumulative incidence at 14 days of 130.7 infections per 100,000 inhabitants. This, compared to the age-adjusted estimation of 295.5/100,000 observed in the city of Barcelona for the same period, supposed no significant impact due to the event [14], in line with our results.

As aforementioned, the press has published other experiences such as the "Obrir Girona" initiative [15], performed from April 23rd to May 22nd 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 distance), and a pop gig (1,000 attendees at 56% capacity, wearing masks -drinking allowed at exterior bar- with no social distance). "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 1,350, only 3 participants got a positive test between day 7 and 14 after the events [24]. Remarkably, the study inclusion criteria of participants relied not only on Ag-RDT screening, but 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 criterium.

Other projects have been developed in Netherlands and United Kingdom to examine how events can be reopened with reduced risk [25,26]. A pilot study in Liverpool explored the nightclubs reopening in semi-controlled settings [27]. Despite differences in the methodology, results were in line with ours; an exploratory modelling of transmission risks at nightclubs suggests that primary transmissions are reduced by 53% through testing on the day.

Informally, if these unpublished results are right, social activities in Catalonia under sanitary controlled access would have resulted in 9 people infected at 14 days out of 6739 participants up to date. However, press information has attributed to the three extraordinarily authorized festivals in Catalonia on July 2021 a risk of infection around 1.7 times higher than expected [28,29]; without a published official report, the press conference of the government public health agency pointed out 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 a considered safe environment, along with the apparition of more contagious SARS-CoV-2 variants, as possible causes for such bad results in comparison to pilot studies. This led to new limitations and highlighted the importance of vaccination and the cumulative protective effect of Ag-RDT tests and masks in these scenarios.

On july 29th, after few weeks of alarming negative evolution, specially in the 15-24 age range population, the Catalan government decided to suppress the reopening of nightlife social activities [30]. The opening of such activities had been done until then without any sanitary access control, exclusively with mandated use of masks. The dissonance between results of controlled studies and real life, apart from the higher transmissibility of the delta variant, highlights the importance of this access control and sanitary measures when reducing the spreading of the virus.

Despite Ag-RDT lacks in 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 test needs to be evaluated in every situation depending on the type of activitie and the epidemiological data at the time of the event, including rate of vaccination [31]. 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 [31]. In our study, as the two studies in Barcelona, the organization provided the tests the same day. This guarantees the temporal proximity to the event and the inalterability of results, but requires a logistic, sanitary and economic effort which could be assumable for large events but hardly for small clubs' nightlife. Moreover, performing tests does not exclude the necessity to follow other security measures, as the use of the mask [26]. 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 probable 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 enviroment, necessary to recover social and

economic activities, while to disencouraging uncontrolled nightlife “botellón” (street alcohol consumption) and ilegal private massive events.

During our study, the first cases of SARS-CoV-2 Delta variant had been detected in Spain; this variant seems to be around 60% more transmissible than the Alpha variant. Thus, Delta variant is spreading worldwide as the fittest and fastest variant and it is becoming dominant in many countries. Evidence in the UK shows that 75% of infections by Delta variant are occurring in people who are not vaccinated and about 4 to 57% in people who are fully vaccinated [32], thus affecting age ranges more prone to enjoy nightlife. More research is needed to ensure our results can be extrapolated to the Delta variant.

Some limitations are present in our study. The selection of volunteers was non-random, with the aim of including a profile of clients specific of each nightclub. To adjust for this selection bias, a control group matched by age, sex, and socioeconomic index, history of previous 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 we cannot control.

On the other hand, monitoring new infections through EHR may not have detected asymptomatic or mild symptomatic cases that were not consulted by health systems. This fact was minimized in the intervention group with the performance of the Ag-RDT follow-up test 6 days after the intervention, with an acceptable loss rate of 12%. Despite the lower sensitivity and specificity of the Ag-RDT test, this follow-up increased the likelihood of measuring the impact of the intervention on the onset of new infections, at risk of overestimating the negative impact of the intervention.

As a conclusion, in our study the attendance to nightclubs under controlled conditions and previous negative Ag-RDT did not show an increased transmissibility of SARS-CoV-2. These results, within the framework of health and safety, provide insight into the possibility of more secure apertures for event organizers.

ACKNOWLEDGMENTS

We would like to thank Carles Cortés, Eva Lacasta, David Alburquerque, Mercè Fernandez and the whole team of Ajuntament de Sitges (Sitges City Council) that made it possible, Damià Orts and the Associació d'Establiments d'Oci Nocturn de Sitges (Association of Nightlife Premises of Sitges) and Glòria Cabrera and the Federació Catalana de Locals d'Oci Nocturn (Catalan Federation of Nightclubs) for the counseling in the design of the study and dissemination, and Esther Sancho and the whole Curasana team.

DECLARATION OF INTERESTS

The authors declare no conflict of interest.

FUNDING

The Sitges Council funded the initiative (covering all test, organization and security costs), relying on the Catalan Public Health Agency to develop it. Award/Grant number is not applicable.

They did not intervene in the analysis, discussion or publications of results.

CONTRIBUTORS

OC: Study design, data analysis and manuscript elaboration. SC: Study design and manuscript elaboration. MM: Study design and manuscript elaboration. DL: Study design and manuscript elaboration. MA: Study design, data extraction and manuscript revision. JA: Study design and manuscript elaboration. JC: Conception, study design and manuscript revision. JB: Conception, study design and manuscript revision. BS: Conception, study design and manuscript elaboration. All authors have approved the final version of the manuscript.

REFERENCES

1 Johns Hopkins University. Center for Systems Science and Engineering (CSSE). Coronavirus COVID-19 (2019-nCoV). https://www.arcgis.com/apps/dashboards/bda7594740fd40299423467b48e9ecf6 (accessed 13 Aug 2021).

2 Jayaweera M, Perera H, Gunawardana B, *et al.* Transmission of COVID-19 virus by droplets and aerosols: A critical review on the unresolved dichotomy. *Environ Res* 2020;**188**:109819. doi:10.1016/J.ENVRES.2020.109819

3 Oran DP, Topol EJ. Prevalence of Asymptomatic SARS-CoV-2 Infection : A Narrative Review. *Ann Intern Med* 2020;**173**:362–7. doi:10.7326/M20-3012

4 Somsen GA, van Rijn C, Kooij S, *et al.* Small droplet aerosols in poorly ventilated spaces and SARS-CoV-2 transmission. *Lancet Respir Med* 2020;**8**:658. doi:10.1016/S2213-2600(20)30245-9

5 World Health Organization. Coronavirus disease (COVID-19). 2020.https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-covid-19 (accessed 13 Aug 2021).

6 Lauer S, Grantz K, Bi Q, *et al.* The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. *Ann Intern Med* 2020;**172**:577–82. doi:10.7326/M20-0504

7 Wang W, Xu Y, Gao R, *et al.* Detection of SARS-CoV-2 in Different Types of Clinical Specimens. *JAMA* 2020;**323**:1843. doi:10.1001/JAMA.2020.3786

8 Younes N, Al-Sadeq DW, Al-Jighefee H, *et al.* Challenges in Laboratory Diagnosis of the Novel Coronavirus SARS-CoV-2. *Viruses* 2020;**12**:582. doi:10.3390/v12060582

9 World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. 2020.https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays (accessed 13 Aug 2021).

10 Mina MJ, Peto TE, García-Fiñana M, *et al.* Clarifying the evidence on SARS-CoV-2 antigen rapid tests in public health responses to COVID-19. *Lancet* Published Online First: 17 February 2021. doi:10.1016/S0140-6736(21)00425-6

11 Ministerio de la Presidencia R con las C y MD. Real Decreto 463/2020, de 14 de marzo, por el que se declara el estado de alarma para la gestión de la situación de crisis sanitaria ocasionada por el COVID-19. 2020. https://www.boe.es/buscar/pdf/2020/BOE-A-2020-3692-consolidado.pdf (accessed 13 Aug 2021).

12 Departament de Salut. Generalitat de Catalunya. Dades COVID VACUNACIÓ. 2021.https://dadescovid.cat/vacunacio/ (accessed 13 Aug 2021).

13 Revollo B, Blanco I, Soler P, *et al.* Same-day SARS-CoV-2 antigen test screening in an indoor mass-gathering live music event: a randomised controlled trial. *Lancet* Published Online First: 2021. doi:10.1016/S1473-3099(21)00268-1

14 Llibre JM, Videla S, Clotet B, *et al.* Screening for SARS-CoV-2 Antigen Before a Live Indoor Music Concert: An Observational Study. *Ann Intern Med* Published Online First: 20 July 2021. doi:10.7326/M21-2278

15 Centre Blockchain de Catalunya. Obrir Girona – CBCat. 2021.https://obrirgirona.cat/ (accessed 13 Aug 2021).

16 Generalitat de Catalunya. Departament de Salut. Procediment d'actuació enfront de casos d'infecció pel nou coronavirus SARS-CoV-2 Sub-direcció General de Vigilància i Resposta a Emergències de Salut Pública. 2021. https://canalsalut.gencat.cat/web/.content/_A-Z/C/coronavirus-2019-ncov/material- (accessed 13 Aug 2021).
17 Gobierno de España. Ministerio de Sanidad. Estrategia de detección precoz, vigilancia y control de COVID-19 . 2021.
18 Domínguez-Berjón MF, Borrell C, Cano-Serral G, *et al.* [Constructing a deprivation index based on census data in large Spanish cities(the MEDEA project)]. *Gac Sanit* 2008;**22**:179–87. doi:10.1157/13123961
19 Mat NFC, Edinur HA, Razab MKAA, *et al.* A Single Mass Gathering Resulted in Massive Transmission of COVID-19 Infections in Malaysia with Further International Spread. *J Travel Med* 2020;**27**. doi:10.1093/JTM/TAAA059
20 Pavli A, Smeti P, Papadima K, *et al.* A cluster of COVID-19 in pilgrims to Israel. *J Travel Med* 2020;**27**:1–3. doi:10.1093/JTM/TAAA102
21 Shmuel K, Dalia M, Tair L, *et al.* Low pH Hypromellose (Taffix) nasal powder spray could reduce SARS-CoV-2 infection rate post mass-gathering event at a highly endemic community: an observational prospective open label user survey. *Expert Rev Anti Infect Ther* 2021;:1. doi:10.1080/14787210.2021.1908127
22 Limbachia J, Owens H, Matean M, *et al.* Organizing a Mass Gathering Amidst a Rising COVID-19 Public Health Crisis: Lessons Learned From a Chinese Public Health Forum in Vancouver, BC. *Cureus* Published Online First: 29 December 2020. doi:10.7759/cureus.12365
23 McCloskey B, Zumla A, Ippolito G, *et al.* Mass gathering events and reducing further global spread of COVID-19: a political and public health dilemma. *Lancet* 2020;**395**:1096. doi:10.1016/S0140-6736(20)30681-4
24 Agència Catalana de Notícies. Els impulsors d'Obrir Girona demanen ampliar el programa a tot Catalunya després de l'èxit de la prova - Diari de Girona. 2021.https://www.diaridegirona.cat/girona/2021/06/04/els-impulsors-dobrir-girona-demanen-52621652.html (accessed 13 Aug 2021).
25 Dutch government. Fieldlab Evenementen. 2020.https://fieldlabevenementen.nl/fieldlab-english/ (accessed 13 Aug 2021).
26 Gov.UK. Information on the Events Research Programme - GOV.UK. 2021.https://www.gov.uk/government/publications/information-on-the-events-research-programme (accessed 13 Aug 2021).
27 Department for Digital Culture Media and Sport - Gov.UK. Events Research Programme: Phase I findings - GOV.UK. 2021.https://www.gov.uk/government/publications/events-research-programme-phase-i-findings/events-research-programme-phase-i-findings (accessed 13 Aug 2021).
28 Mouzo J. Los festivales de música en Cataluña aumentaron la transmisión de la covid: más de 2.000 asistentes se infectaron. El País. 2021.https://elpais.com/espana/catalunya/2021-08-04/los-festivales-de-musica-en-cataluna-aumentaron-la-transmision-de-la-covid-mas-de-2000-asistentes-se-infectaron.html (accessed 13 Aug 2021).
29 Cabezas C. Roda de premsa sobre el seguiment del procés de vacunació de la COVID-19 a Catalunya.

2011;:31:55.https://www.youtube.com/watch?v=9MUfakIxVSA&t=1915s (accessed 13 Aug 2021).

30 Diari Oficial de la Generalitat de Catalunya. RESOLUCIÓ SLT/2498/2021. Barcelona: : Generalitat de Catalunya 2021. https://dogc.gencat.cat/ca/document-del-dogc/?documentId=907691 (accessed 13 Aug 2021).

31 Peeling RW, Olliaro PL, Boeras DI, *et al.* Scaling up COVID-19 rapid antigen tests: promises and challenges. *Lancet Infect Dis* Published Online First: 2021. doi:10.1016/S1473-3099(21)00048-7

32 Public Health England. SARS-CoV-2 variants of concern and variants under investigation in England. Technical Briefing 15. 2021.

Reporting checklist for cohort study.

Based on the STROBE cohort guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cohortreporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	3
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	#3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	#4	Present key elements of study design early in the paper	5
Setting	#5	Describe the setting, locations, and relevant dates, including periods	5-6

		of recruitment, exposure, follow-up, and data collection	
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up.	5-6
Eligibility criteria	#6b	For matched studies, give matching criteria and number of exposed and unexposed	6
Variables	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	6
Bias	#9	Describe any efforts to address potential sources of bias	6
Study size	#10	Explain how the study size was arrived at	6
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	6
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	
6			
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	6
Statistical methods	#12c	Explain how missing data were addressed	6
Statistical methods	#12d	If applicable, explain how loss to follow-up was addressed	NA
Statistical methods	#12e	Describe any sensitivity analyses	
NA			
Results			
Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible,	7

		included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	
Participants	#13b	Give reasons for non-participation at each stage	7
Participants	#13c	Consider use of a flow diagram	
NA			
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	7-8
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	
8			
Descriptive data	#14c	Summarise follow-up time (eg, average and total amount)	
7			
Outcome data	#15	Report numbers of outcome events or summary measures over time. Give information separately for exposed and unexposed groups if applicable.	
8			
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8
Main results	#16b	Report category boundaries when continuous variables were categorized	NA
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
7			
Other analyses	#17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA

Discussion

Key results	#18	Summarise key results with reference to study objectives	9
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	11
Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	11
Generalisability	#21	Discuss the generalisability (external validity) of the study results	10-11
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

This checklist was completed on 05. October 2021 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

BMJ Open

Black box study with a paired control group to evaluate the reopening of nightlife during COVID-19 pandemic: 'Reobrim Sitges'

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-058595.R1
Article Type:	Original research
Date Submitted by the Author:	29-Dec-2021
Complete List of Authors:	Cunillera Puértolas, Oriol; IDIAP Jordi Gol, Unitat de Suport a la Recerca Costa de Ponent; Universitat Autònoma de Barcelona Contreras-Martos, Sara; IDIAP Jordi Gol, Unitat de Suport a la Recerca Costa de Ponent; Universitat Autònoma de Barcelona Marzo-Castillejo, Mercè; IDIAP Jordi Gol, Unitat de Suport a la Recerca Costa de Ponent; Universitat Autònoma de Barcelona López Gallegos, Darío; Institut Catala De La Salut, Servei d'Atenció Primària Alt Penedès-Garraf-Baix Llobregat Nord, Direcció d'Atenció Primària Costa de Ponent Acedo Anta, Mateo; Institut Català de la Salut, Secretaria Tècnica, Direcció d'Atenció Primària Costa de Ponent; Universitat de Barcelona Facultat de Medicina i Ciencies de la Salut, Escola d'Infermeria Almeda Ortega, Jesús; IDIAP Jordi Gol, Unitat de Suport a la Recerca Costa de Ponent; Universitat Autònoma de Barcelona Colom, Joan; Agència de Salut Pública de Catalunya, Sub-direcció General de Drogodependències Basora, Josep; IDIAP Jordi Gol, Institut Universitari d'Investigació en Atenció Primària Salvador-Gonzalez, Betlem; IDIAP Jordi Gol, Unitat de Suport a la Recerca Costa de Ponent; Universitat Autònoma de Barcelona
Primary Subject Heading:	Infectious diseases
Secondary Subject Heading:	Epidemiology, Infectious diseases, Public health
Keywords:	COVID-19, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Public health < INFECTIOUS DISEASES

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Black box study with a paired control group to evaluate the reopening of nightlife during COVID-19 pandemic: 'Reobrim Sitges'

Oriol Cunillera Puértolas[1,2]

Sara Contreras-Martos[1,2,3]

Mercè Marzo- Castillejo[1,2,3]

Darío López Gallegos[4]

Mateo Acedo Anta[5,6]

Jesús Almeda Ortega[1,2,3]

Joan Colom Farran[7]

Josep Basora i Gallisà[8]

Betlem Salvador-González[1,3]

1-Unitat de Suport a la Recerca Costa de Ponent, Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol), Cornellà de Llobregat, Spain

2-Universitat Autònoma de Barcelona, Bellaterra (Cerdanyola del Vallès), Spain.

3-Unitat de Suport a la Recerca, Direcció d'Atenció Primària Costa de Ponent, Institut Català de la Salut, L'Hospitalet de Llobregat, Spain

4-Servei d'Atenció Primària Alt Penedès-Garraf-Baix Llobregat Nord, Direcció d'Atenció Primària Costa de Ponent, Institut Català de la Salut, L'Hospitalet de Llobregat, Spain.

5-Secretaria Tècnica, Direcció d'Atenció Primària Costa de Ponent, Institut Català de la Salut, Cornellà de Llobregat, Spain.

6-Escola d'Infermeria, Facultat de Medicina i Ciències de la Salut, Universitat de Barcelona, Barcelona, Spain

7-Subdirecció General de Drogodependències. ASPCAT. Departament de Salut, Generalitat de Catalunya, Barcelona, Spain.

8-Institut Universitari d'Investigació en Atenció Primària (IDIAP Jordi Gol), Barcelona, Spain.

* *Corresponding author:* Betlem Salvador-González
C/ Bellaterra, 41, 1er pis 08940 Cornellà de Llobregat, Barcelona. bsalvador@ambitcp.catsalut.net

Word count: 3230 words

ABSTRACT

Background: The economic impact of governmental legal restrictions during COVID-19 pandemic requires evaluation of the balance between health and economy. This study aims to assess the health impact of reopening nightlife under controlled conditions.

Objectives: To assess the impact of loosening alarm state restrictions in small clubs nightlife on SARS-CoV-2 infections at 14 days.

Design: Black box study with a paired control group (1:5 ratio)

Setting: A nightlife restricted area in Sitges on 20st May 2021. 5 nightclubs with interior areas and exterior terraces. Wearing masks was mandatory, drinking was allowed, and social distance was not required.

Participants: Volunteers were selected through a convenience sampling. Participants, aged over 17, with negative Ag-RDT test on the same afternoon, and without a positive RT-PCR or Ag-RDT test and/or symptoms associated with COVID-19 in the last 7 days, not being close contact with someone infected in the last 10 days, or having had close contact with someone with a suspicion of COVID-19 in the last 48 hours was required to access the event.

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

Results: Of the 391 participants (median age 37 years; 44.3% women), no positive SARS-CoV-2 cases were detected at 14 days, resulting in an estimation of a cumulative incidence (95% confidence interval) of 0 (0, 943) /100,000 inhabitants. In the control group, 2 cases with RT-PCR test were identified, a cumulative incidence of 102.30 (12.4, 369) /100,000 inhabitants.

Conclusions: Attendance to nightlife under controlled conditions and previous negative Ag-RDT did not show an increased transmissibility of SARS-CoV-2. Secure aperture of nightlife sector is possible under reduced capacity límits, controlled access by Ag-RDT, and environments where compliance of sanitary measures conditions are maintainable.

Strengths and limitations of this study

- This is a black box study with a convenience sampling, with a paired control group.
- Participants performed Ag-RDT tests the afternoon of the event's day prior accessing the event
- Evidence of infection by SARS-CoV-2 at 14 days was obtained in the EHR
- Ag-RDT follow-up tests 6 days after the intervention minimized unregistered infections in the exposed group with only 12% loss.

INTRODUCTION

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic had infected 186 million people and caused over 4 million deaths worldwide by July 12th 2021, with wide variability between countries and regions [1]. The SARS-CoV-2 transmission mostly occurs by direct contact or through droplets and aerosols from an infected person located within 2 meters range and exposition times over 15 minutes [2,3]. Indoor, poorly ventilated, crowded spaces [4] where people gather are hotspots for the transmission of virus [5].

The Coronavirus Disease 2019 (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 polymerase chain reaction (RT-PCR), which detects viral RNA, presenting good results in terms of reliability, sensibility 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 specialized professionals increases the total delivery times and costs [8]. In contrast, the lateral flow immunochromatographic rapid antigen diagnostic tests (Ag-RDT) for SARS-CoV-2 can detect viral proteins and provide results *in situ* within less than 30 minutes. Despite its sensitivity is below WHO's recommendations, Ag-RDTs still offer the possibility of rapid, easy and inexpensive detection of SARS-CoV-2 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 sanitary and social crisis subsequent to the COVID-19 pandemic have forced many governments to deploy new social policies and legal restrictions, mostly focused on reducing the spreading of COVID-19. In Spain, restrictions to mobility and economic activity -with temporal closure of restaurants, hotels and nightlife activities - began with the first alarm state on March 2020 [11]. At the moment of writing this paper, September 2021, some restrictions on capacity limitations and opening hours still prevail. The balance between health and economy is still on study in the more flexible stage we are in: bars, restaurants, pubs, discotheques, and concert venues were still on the tightrope, claiming for secure measures allowing them to flounder.

The herd-immunity, mainly through massive vaccination, is the key goal to restore social and economic activities in this sector. In Catalunya, on May 5th 2021, a 30.5% of the population had received at least one dose, and a 13.6% had completed vaccination [12]. Due to age prioritisation, only 6.9% of 18-24 years old Catalans and 11% of aged 25-49 had some vaccination, thus constituting age ranges where legal measures were still prominent on controlling virus transmission.

Some studies have been carried out in Catalunya to assess the impact of losing legal restrictions on various types of social activities, including indoor gigs and dining passes in restaurants; although just two articles have been published up to date [13,14], press conferences have spread some results on three initiatives [15]. None of these studies detected any increased risk associated with the expositions.

The present study is another step in generating evidence on the safety reopening of social activities in Catalonia. We aimed to assess the impact of loosening alarm state restrictions in small clubs nightlife on SARS-CoV-2 infections at 14 days.

METHODS

This is a black box study with a paired control group, performed in a nightlife-restricted area in Sitges (Barcelona, Spain) on May 20th 2021.
The volunteer attending the event were recruited by convenience sampling promoted -mainly through social networks- by participant entities (council, guild, locals) and registered through the official city council web. Inclusion and exclusion criteria for all exposition groups (formed by study volunteers and staff groups) are defined in table 1. Participants performed their Ag-RDT tests in scheduled intervals the afternoon of the event's day in Sitges. The Ag-RDT test was performed by trained health professionals following manufacture's instructions (AllTest, Ref. ICOV-502, Japan). Manufacturers' reported sensitivity and especificity were 96.4% and 99.9%, respectively.

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

Inclusion criteria	Exclusion criteria
1. Aged over 17	1. Declaring to have a positive RT-PCR or Ag-RDT test 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 [16,17]): *a) at least one of these: fever, persistent cough, shortness of breath, anosmia, ageusia* *b) at least two of the following: sore throat, a cold, fatigue, myalgia, headache, vomiting or diarrhea stomach ache*
3.Having an individual health card of the Catalan public healthcare system	
4. A negative Ag-RDT test the same afternoon (provided by the organization)	
	3. Having had close contact with someone infected in the last 10 days
	4. Having had close contact with someone with a suspicion of COVID-19 in the last 48 hours

The nightlife event was developed from 23:00 p.m. of May 20th to 3:00 a.m of May 21st, in a restricted street section, including 5 nightclubs with interior areas (capacity 42-98 people) and exterior terraces (capacity 15-35 people), with controlled registered access exclusively for participants. Mask was mandatory (quirurgical or FFP2), except for drinking or smoking.

Drinking was allowed indoors and outdoors. Social distance was not required. Hydroalcoholic gel and panels reminding COVID-19 safety standards and their participation in the study were distributed throughout all the area. No special ventilation measures were required. A follow-up Ag-RDT test 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-EHR), by a pseudonymized paired extraction of individuals not attending the social event. Pairing was executed by exact age, sex, residence municipality, socioeconomic index, previous SARS-CoV-2 confirmed infection, and vaccination status (at least one dose administred), by a 1:5 ratio.

Sample size was conditioned on capacity limitations fixed on 75% of the locals' usual limits (according to and authorized by the Health Department within the context of this study), resulting in 400 volunteers. Considering the 14 days cumulative incidence of COVID-19 occurring in the health district (Gerència Territorial Metropolitana Sud) on April 29th 2021 (210/100,000 inhabitants [https://dadescovid.cat/]), significant differences would be found observing a 14 days incidence in the intervention group of 1.38% (6 positive cases), with a level of significance of 0.05 and power of 0.8.

Variables

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

All other variables were obtained from PC-EHR: age, sex, MEDEA socioeconomic deprivation index [18] (classifiying 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 AstraZenecae/Janssen-Johnson&Johnson).

This information was collected for all participants, which were cathegorized according to their role as Organizers, Security personnel, Club workers, or Volunteers.

Statistical analysis

All variables were described and compared by participant role groups. Median, interquartile range, mean and standard deviation 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 Chi-square tests and complete case analysis. As pairing was performed by the exact characteristics, no description will be 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 confidence intervals 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 with The Sitges Council the initial proposal. 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. There was an immediate return of results to the entities to allow their dissemination

Ethical considerations

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 Civil Protection Plan of Catalonia (PROCICAT). The study guarantees compliance with the new General Data Protection Regulation (GDPR)) EU 2016/679, the guidelines of the Principles of the Declaration of Hèlsinki and the Belmont Report.

Participants were informed about the project and signed a responsible statement and informed consent to participate and allowed the use of their pseudonymized data exclusively for this project. Informed consent was not required for participants in the control group as the information was pseudonymized.

The external entity 'Curasana' (www.curasana.org) was responsible for the logistic and performance of Ag-RDT tests. Results were sent to the Catalan Institute of Health (ICS); positive results were communicated and introduced to EHR for assistance purposes. The ICS and the IDIAPJGol were independently responsible for the data processing within the framework of this study.

RESULTS

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

Staff groups were significantly different from volunteers in terms of age (organizers were significantly older), sex (due to a 100% male security personnel) and socioeconomic status (55.5% -5- of security personnel came from most deprived areas). Although not significant, security personnel and bartenders/DJs had lower percentages of vaccination and previous infection. As control group was matched by exact characteristics, it presented the exact same distribution for all variables except for the outcomes.

Volunteers stayed in the local nightlife delimited area for a mean of 177 minutes (minimum-maximum: 59-210 minutes). 373 (88%) participants attended the 6 days Ag-RDT, all of them with negative results.

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

Table 2. Sample characteristics and outcomes in the sample of participants in the 'Reobrim Sitges' study, Overall and by role groups.

	n	Missings	Global	Organizers (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
Sex : 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, 0.48]	-0.32 [-0.32, -0.14]	0.64 [0.48, 1.07]	-0.32 [-0.32, 0.64]	-0.32 [-0.32, 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	2020-11-02 [2020-08-17, 2021-01-08]	2021-01-13 [2020-11-04, 2021-01-17]	-	2021-01-19 [2021-01-02, 2021-02-05]	2020-10-15 [2020-08-12, 2021-01-03]	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-RTD 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	18	373						-
PCR			13 (72.22%)	-	2 (100.00%)	2 (100.00%)	9 (64.29%)	
TAR			5 (27.78%)	-	0 (0.00%)	0 (0.00%)	5 (35.71%)	
Test results at 14 days	18	373						-
Negative result			18 (100.00%)	-	2 (100.00%)	2 (100.00%)	14 (100.00%)	

DISCUSSION

Key results

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

Comparison with previous studies

Up to date, most of articles studying COVID-19 in mass-gathering events either reported retrospective analyses of SARS-CoV-2 transmission [19–21] or described mitigation plans and measures applied during mass-gathering events [22,23]. Only one controlled trial was published in Catalonia [13].

Revollo et al. [13] present a randomized controlled trial assessing the impact, in terms of SARS-CoV-2 infections, of attending a live gig in a medium-sized concert hall (capacity of 900 people) in Barcelona, on December 2020. 1047 individuals aged 18-59 years with a negative Ag-RDT on the same day, no comorbidities, and declaring not having a positive COVID-19 diagnose during the last 14 days were randomly assigned to the experimental group and attended the indoor event (at 50% of hall'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 with our study are: sample size, use of Ag-RDT as inclusion criteria, age ranges, freedom of movement with no social distance, and use of masks (although both FFP2 and quirurgical were allowed in our study). Both studies obtained similar results, despite in ours a) drinking was allowed in the entire perimeter, and b) the event was developed in locals with indoor capacities below 100 people without indoor air quality control, and with bigger outdoor areas.

On March 2021, an observational study assessed the impact of attending to a live gig in a big concert hall in Barcelona: 4.584 attendees (below 30% of 17,000 persons hall's capacity) with negative Ag-RDT simultaneously enjoyed the experience in three isolated groups. No social distancing and wearing FFP2 masks were required, and independent drinking areas were habilitated. It resulted in a cumulative incidence at 14 days of 131infections per 100,000 inhabitants. This, compared to the age-adjusted estimation of 296/100,000 observed in the city of Barcelona for the same period, supposed no significant impact due to the event [14], in line with our results.

As aforementioned, the press has published other experiences such as the "Obrir Girona" initiative [15], performed from April 23rd to May 22nd 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 distance), and a pop gig (1,000 attendees at 56% capacity, wearing masks -drinking allowed at exterior bar- with no social distance). "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 1,350, only 3 participants got a positive test between day 7 and 14 after the events [24]. Remarkably, the study inclusion criteria of participants relied on not only Ag-RDT screening, but 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 criterium.

Other projects have been developed in Netherlands and United Kingdom to examine how events can be reopened with reduced risk [25,26]. Fitzgerald et al [27] explored the management of COVID-19 restrictions to operate safely in licensed premises. Physical distancing, which was not required in the present study, was one of the more challenging. A pilot study in Liverpool explored the nightclubs reopening in semi-controlled settings [28]. Despite differences in the methodology, results were in line with ours; an exploratory modelling of transmission risks at nightclubs suggests that primary transmissions are reduced by 53% through testing on the day.

Informally, if these unpublished results were right, social activities in Catalonia under sanitary controlled access would have resulted in 9 people infected at 14 days out of 6739 participants up to date. However, press information has attributed to the three extraordinarily authorized festivals in Catalonia on July 2021 a risk of infection around 1.7 times higher than expected [29,30]. Without a published official 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 a considered safe environment, along with the apparition of more contagious SARS-CoV-2 variants, were pointed out as possible causes for such bad results in comparison to pilot studies. This led to new limitations and highlighted the importance of vaccination and the cumulative protective effect of Ag-RDT tests and masks in these scenarios.

GeneralisabilityOn July 29th, after few weeks of alarming negative evolution, especially in the 15-24 age range population, the Catalan government decided to suppress the reopening of nightlife social activities [31]. The opening of such activities had been done until then without any sanitary access control, exclusively with mandated use of masks. The dissonance between results of controlled studies and real life, apart from the higher transmissibility of the delta variant, highlights the importance of this access control and sanitary measures when reducing the spreading of the virus.

Despite Ag-RDT lacks in 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 test needs to be evaluated in every situation depending on the type of activity and the epidemiological data at the time of the event, including rate of vaccination [32]. 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 [32]. In our study, as the two studies in Barcelona, the organization provided the tests the same day. This guarantees the temporal proximity to the event and the inalterability of results, but requires a logistic, sanitary and economic effort, which could be assumable for large events but hardly for small clubs' nightlife. Moreover, performing tests does not exclude the necessity to follow other security measures, as the use of the mask [26]. 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 probable 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 enviroment, necessary to recover social and economic activities, while to disencouraging uncontrolled nightlife "botellón" (street alcohol consumption) and ilegal private massive events.

During our study, the first cases of SARS-CoV-2 Delta variant had been detected in Spain; this variant seems to be around 60% more transmissible than the Alpha variant. Thus, Delta variant is spreading worldwide as the fittest and fastest variant and it is becoming dominant in many countries. Evidence in the UK shows that 75% of infections by Delta variant are occurring in people who are not vaccinated and about 4 to 57% in people who are fully vaccinated [33], thus affecting age ranges more prone to enjoy nightlife. Moreover, incidence rates were in regression [12]. More research is needed to ensure our results can be extrapolated to the Delta and future variants, and in the different scenarios of transmissibility.

Strengths and limitations

Some limitations are present in our study. The selection of volunteers was non-random (convenience sampling), with the aim of including a profile of clients specific of each nightclub. To adjust for this selection bias, a control group matched by age, sex, and socioeconomic index, history of previous 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 we cannot control.

On the other hand, both the volunteers and the control group evidence of infections at 14 days was obtained through EHR, and we may not have detected asymptomatic or mild symptomatic cases that were not consulted by health systems. This fact was minimized in the intervention group with the performance of the Ag-RDT follow-up test 6 days after the intervention, with an acceptable loss rate of 12% (as compared to similar studies in the UK earlier this year [28]). Despite the lower sensitivity and specificity of the Ag-RDT test, this follow-up increased the likelihood of measuring the impact of the intervention on the onset of new infections, at risk of overestimating the negative impact of the intervention. However, not presenting baseline tests could lead to another bias in the contrary direction; we expect that those crossed biases would minimize overall bias

Interpretation

As a conclusion, in our study the attendance to nightclubs under controlled conditions and previous negative Ag-RDT did not show an increased transmissibility of SARS-CoV-2. These results, within the framework of health and safety, provide insight into the possibility of more secure apertures for event organizers.

ACKNOWLEDGMENTS

We would like to thank Carles Cortés, Eva Lacasta, David Alburquerque, Mercè Fernandez and the whole team of Ajuntament de Sitges (Sitges City Council) that made it possible, Damià Orts and the Associació d'Establiments d'Oci Nocturn de Sitges (Association of Nightlife Premises of Sitges) and Glòria Cabrera and the Federació Catalana de Locals d'Oci Nocturn (Catalan Federation of Nightclubs) for the counseling in the design of the study and dissemination, and Esther Sancho and the whole Curasana team.

DECLARATION OF INTERESTS

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Due to ethical reasons stated by the Ethics Comitee, data can not be made available.

FUNDING

The Sitges Council funded the initiative (covering all test, organization and security costs), relying on the Catalan Public Health Agency to develop it. Award/Grant number is not applicable.

They did not intervene in the analysis, discussion or publications of results.

CONTRIBUTORS

OC: Study design, data analysis and manuscript elaboration. SC: Study design and manuscript elaboration. MM: Study design and manuscript elaboration. DL: Study design and manuscript elaboration. MA: Study design, data extraction and manuscript revision. JA: Study design and manuscript elaboration. JC: Conception, study design and manuscript revision. JB: Conception, study design and manuscript revision. BS: Conception, study design and manuscript elaboration. All authors have approved the final version of the manuscript.

REFERENCES

1 Johns Hopkins University. Center for Systems Science and Engineering (CSSE). Coronavirus COVID-19 (2019-nCoV). https://www.arcgis.com/apps/dashboards/bda7594740fd40299423467b48e9ecf6 (accessed 13 Aug 2021).

2 Jayaweera M, Perera H, Gunawardana B, *et al.* Transmission of COVID-19 virus by droplets and aerosols: A critical review on the unresolved dichotomy. *Environ Res* 2020;**188**:109819. doi:10.1016/J.ENVRES.2020.109819

3 Oran DP, Topol EJ. Prevalence of Asymptomatic SARS-CoV-2 Infection : A Narrative Review. *Ann Intern Med* 2020;**173**:362–7. doi:10.7326/M20-3012

4 Somsen GA, van Rijn C, Kooij S, *et al.* Small droplet aerosols in poorly ventilated spaces and SARS-CoV-2 transmission. *Lancet Respir Med* 2020;**8**:658. doi:10.1016/S2213-2600(20)30245-9

5 World Health Organization. Coronavirus disease (COVID-19). 2020.https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-covid-19 (accessed 13 Aug 2021).

6 Lauer S, Grantz K, Bi Q, *et al.* The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. *Ann Intern Med* 2020;**172**:577–82. doi:10.7326/M20-0504

7 Wang W, Xu Y, Gao R, *et al.* Detection of SARS-CoV-2 in Different Types of Clinical Specimens. *JAMA* 2020;**323**:1843. doi:10.1001/JAMA.2020.3786

8 Younes N, Al-Sadeq DW, Al-Jighefee H, *et al.* Challenges in Laboratory Diagnosis of the Novel Coronavirus SARS-CoV-2. *Viruses* 2020;**12**:582. doi:10.3390/v12060582

9 World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. 2020.https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays (accessed 13 Aug 2021).

10 Mina MJ, Peto TE, García-Fiñana M, *et al.* Clarifying the evidence on SARS-CoV-2 antigen rapid tests in public health responses to COVID-19. *Lancet* Published Online First: 17 February 2021. doi:10.1016/S0140-6736(21)00425-6

11 Ministerio de la Presidencia R con las C y MD. Real Decreto 463/2020, de 14 de marzo, por el que se declara el estado de alarma para la gestión de la situación de crisis sanitaria ocasionada por el COVID-19. 2020. https://www.boe.es/buscar/pdf/2020/BOE-A-2020-3692-consolidado.pdf (accessed 13 Aug 2021).

12 Departament de Salut. Generalitat de Catalunya. Dades COVID . 2021.https://dadescovid.cat (accessed 13 Aug 2021).

13 Revollo B, Blanco I, Soler P, *et al.* Same-day SARS-CoV-2 antigen test screening in an indoor mass-gathering live music event: a randomised controlled trial. *Lancet* Published Online First: 2021. doi:10.1016/S1473-3099(21)00268-1

14 Llibre JM, Videla S, Clotet B, *et al.* Screening for SARS-CoV-2 Antigen Before a Live Indoor Music Concert: An Observational Study. *Ann Intern Med* Published Online First: 20 July 2021. doi:10.7326/M21-2278

15 Centre Blockchain de Catalunya. Obrir Girona – CBCat. 2021.https://obrirgirona.cat/ (accessed 13 Aug 2021).

16 Generalitat de Catalunya. Departament de Salut. Procediment d'actuació enfront de casos d'infecció pel nou coronavirus SARS-CoV-2 Sub-direcció General de Vigilància i Resposta a Emergències de Salut Pública. 2021. https://canalsalut.gencat.cat/web/.content/_A-Z/C/coronavirus-2019-ncov/material- (accessed 13 Aug 2021).
17 Gobierno de España. Ministerio de Sanidad. Estrategia de detección precoz, vigilancia y control de COVID-19. 2021.
18 Domínguez-Berjón MF, Borrell C, Cano-Serral G, *et al.* [Constructing a deprivation index based on census data in large Spanish cities (the MEDEA project)]. *Gac Sanit* 2008;**22**:179–87. doi:10.1157/13123961
19 Mat NFC, Edinur HA, Razab MKAA, *et al.* A Single Mass Gathering Resulted in Massive Transmission of COVID-19 Infections in Malaysia with Further International Spread. *J Travel Med* 2020;**27**. doi:10.1093/JTM/TAAA059
20 Pavli A, Smeti P, Papadima K, *et al.* A cluster of COVID-19 in pilgrims to Israel. *J Travel Med* 2020;**27**:1–3. doi:10.1093/JTM/TAAA102
21 Shmuel K, Dalia M, Tair L, *et al.* Low pH Hypromellose (Taffix) nasal powder spray could reduce SARS-CoV-2 infection rate post mass-gathering event at a highly endemic community: an observational prospective open label user survey. *Expert Rev Anti Infect Ther* 2021; 1. doi:10.1080/14787210.2021.1908127
22 Limbachia J, Owens H, Matean M, *et al.* Organizing a Mass Gathering Amidst a Rising COVID-19 Public Health Crisis: Lessons Learned From a Chinese Public Health Forum in Vancouver, BC. *Cureus* Published Online First: 29 December 2020. doi:10.7759/cureus.12365
23 McCloskey B, Zumla A, Ippolito G, *et al.* Mass gathering events and reducing further global spread of COVID-19: a political and public health dilemma. *Lancet* 2020;**395**:1096. doi:10.1016/S0140-6736(20)30681-4
24 Agència Catalana de Notícies. Els impulsors d'Obrir Girona demanen ampliar el programa a tot Catalunya després de l'èxit de la prova - Diari de Girona. 2021.https://www.diaridegirona.cat/girona/2021/06/04/els-impulsors-dobrir-girona-demanen-52621652.html (accessed 13 Aug 2021).
25 Dutch government. Fieldlab Evenementen. 2020.https://fieldlabevenementen.nl/fieldlab-english/ (accessed 13 Aug 2021).
26 Gov.UK. Information on the Events Research Programme - GOV.UK. 2021.https://www.gov.uk/government/publications/information-on-the-events-research-programme (accessed 13 Aug 2021).
27 Fitzgerald N, Uny I, Brown A, *et al*. Managing COVID-19 Transmission Risks in Bars: An Interview and Observation Study. *J Stud Alcohol Drugs*, 2021; **82:** 42-54. doi: 10.15288/jsad.2021.82.42
28 Department for Digital Culture Media and Sport - Gov.UK. Events Research Programme: Phase I findings - GOV.UK. 2021.https://www.gov.uk/government/publications/events-research-programme-phase-i-findings/events-research-programme-phase-i-findings (accessed 13 Aug 2021).
29 Mouzo J. Los festivales de música en Cataluña aumentaron la transmisión de la covid: más de 2.000 asistentes se infectaron. El País. 2021.https://elpais.com/espana/catalunya/2021-08-04/los-festivales-de-musica-en-cataluna-aumentaron-la-transmision-de-la-covid-mas-de-2000-asistentes-se-infectaron.html (accessed 13 Aug 2021).

30 Cabezas C. Roda de premsa sobre el seguiment del procés de vacunació de la COVID-19 a Catalunya. 2011;:31:55.https://www.youtube.com/watch?v=9MUfakIxVSA&t=1915s (accessed 13 Aug 2021).
31 Diari Oficial de la Generalitat de Catalunya. RESOLUCIÓ SLT/2498/2021. Barcelona: Generalitat de Catalunya 2021. https://dogc.gencat.cat/ca/document-del-dogc/?documentId=907691 (accessed 13 Aug 2021).
32 Peeling RW, Olliaro PL, Boeras DI, *et al.* Scaling up COVID-19 rapid antigen tests: promises and challenges. *Lancet Infect Dis* Published Online First: 2021. doi:10.1016/S1473-3099(21)00048-7
33 Public Health England. SARS-CoV-2 variants of concern and variants under investigation in England. Technical Briefing 15. 2021.

Reporting checklist for cohort study.

Based on the STROBE cohort guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cohortreporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	3
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	#3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	#4	Present key elements of study design early in the paper	5
Setting	#5	Describe the setting, locations, and relevant dates, including periods	5-6

		of recruitment, exposure, follow-up, and data collection	
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up.	5-6
Eligibility criteria	#6b	For matched studies, give matching criteria and number of exposed and unexposed	6
Variables	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	6
Bias	#9	Describe any efforts to address potential sources of bias	6
Study size	#10	Explain how the study size was arrived at	6
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	6
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	
6			
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	6
Statistical methods	#12c	Explain how missing data were addressed	6
Statistical methods	#12d	If applicable, explain how loss to follow-up was addressed	NA
Statistical methods	#12e	Describe any sensitivity analyses	
NA			
Results			
Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible,	7

		included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	
Participants	#13b	Give reasons for non-participation at each stage	7
Participants	#13c	Consider use of a flow diagram	
NA			
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	7-8
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	
8			
Descriptive data	#14c	Summarise follow-up time (eg, average and total amount)	
7			
Outcome data	#15	Report numbers of outcome events or summary measures over time. Give information separately for exposed and unexposed groups if applicable.	
8			
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8
Main results	#16b	Report category boundaries when continuous variables were categorized	NA
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
7			
Other analyses	#17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA

Discussion

Key results	#18	Summarise key results with reference to study objectives	9
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	11
Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	11
Generalisability	#21	Discuss the generalisability (external validity) of the study results	10-11
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

This checklist was completed on 05. October 2021 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

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)

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-058595.R2
Article Type:	Original research
Date Submitted by the Author:	24-Mar-2022
Complete List of Authors:	Cunillera Puértolas, Oriol; IDIAP Jordi Gol, Unitat de Suport a la Recerca Costa de Ponent; Universitat Autònoma de Barcelona Contreras-Martos, Sara; IDIAP Jordi Gol, Unitat de Suport a la Recerca Costa de Ponent; Universitat Autònoma de Barcelona Marzo-Castillejo, Mercè; IDIAP Jordi Gol, Unitat de Suport a la Recerca Costa de Ponent; Universitat Autònoma de Barcelona López Gallegos, Darío; Institut Catala De La Salut, Servei d'Atenció Primària Alt Penedès-Garraf-Baix Llobregat Nord, Direcció d'Atenció Primària Costa de Ponent Acedo Anta, Mateo; Institut Català de la Salut, Secretaria Tècnica, Direcció d'Atenció Primària Costa de Ponent; Universitat de Barcelona Facultat de Medicina i Ciencies de la Salut, Escola d'Infermeria Almeda Ortega, Jesús; IDIAP Jordi Gol, Unitat de Suport a la Recerca Costa de Ponent; Universitat Autònoma de Barcelona Colom, Joan; Agència de Salut Pública de Catalunya, Sub-direcció General de Drogodependències Basora, Josep; IDIAP Jordi Gol, Institut Universitari d'Investigació en Atenció Primària Salvador-Gonzalez, Betlem; IDIAP Jordi Gol, Unitat de Suport a la Recerca Costa de Ponent; Universitat Autònoma de Barcelona
Primary Subject Heading:	Infectious diseases
Secondary Subject Heading:	Epidemiology, Infectious diseases, Public health
Keywords:	COVID-19, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Public health < INFECTIOUS DISEASES

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

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

Oriol Cunillera Puértolas[1,2]

Sara Contreras-Martos[1,2,3]

Mercè Marzo- Castillejo[1,2,3]

Darío López Gallegos[4]

Mateo Acedo Anta[5,6]

Jesús Almeda Ortega[1,2,3]

Joan Colom Farran[7]

Josep Basora i Gallisà[8]

Betlem Salvador-González[1,3]

1-Unitat de Suport a la Recerca Costa de Ponent, Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol), Cornellà de Llobregat, Spain

2-Universitat Autònoma de Barcelona, Bellaterra (Cerdanyola del Vallès), Spain.

3-Unitat de Suport a la Recerca, Direcció d'Atenció Primària Costa de Ponent, Institut Català de la Salut, L'Hospitalet de Llobregat, Spain

4-Servei d'Atenció Primària Alt Penedès-Garraf-Baix Llobregat Nord, Direcció d'Atenció Primària Costa de Ponent, Institut Català de la Salut, L'Hospitalet de Llobregat, Spain.

5-Secretaria Tècnica, Direcció d'Atenció Primària Costa de Ponent, Institut Català de la Salut, Cornellà de Llobregat, Spain.

6-Escola d'Infermeria, Facultat de Medicina i Ciències de la Salut, Universitat de Barcelona, Barcelona, Spain

7-Subdirecció General de Drogodependències. ASPCAT. Departament de Salut, Generalitat de Catalunya, Barcelona, Spain.

8-Institut Universitari d'Investigació en Atenció Primària (IDIAP Jordi Gol), Barcelona, Spain.

* *Corresponding author:* Betlem Salvador-González
C/ Bellaterra, 41, 1er pis 08940 Cornellà de Llobregat, Barcelona
bsalvador@ambitcp.catsalut.net

Word count: 3375 words

ABSTRACT

Objectives: To assess the impact of the relaxing of 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 May 20, 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 Ag-RDT test on the same afternoon, without a positive RT-PCR or Ag-RDT test 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 knowlingly 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 days 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, 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, 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, controlled access by Ag-RDT and environments where compliance with sanitary measures are maintainable.

Strengths and limitations of this study

- Reobrim Sitges was a matched cohort study with convenience sampling and with a paired control group.
- Participants underwent Ag-RDT tests 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.
- Ag-RDT follow-up tests six 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), limits the generalisability of these findings.

INTRODUCTION

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic had infected 186 million people and caused over 4 million deaths worldwide by July 12, 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 two meters range and with exposure times of over 15 minutes [2,3]. Indoor, poorly ventilated, and crowded spaces [4] where people gather are hotspots for transmission of virus [5].

The Coronavirus Disease 2019 (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 polymerase chain reaction (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-RDT) for SARS-CoV-2 can detect viral proteins and provide results *in situ* within 30 minutes. 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 crisis 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 allowing 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 May 5, 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 18-24 years old Catalonian people and 11% aged 25-49 had some vaccination, thus constituting age ranges where legal measures were still prominent on 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 the relaxing of 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 May 20, 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-RDT tests in scheduled intervals the afternoon of the event day in Sitges. The Ag-RDT test 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.

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	1. Declaring to have had a positive RT-PCR or Ag-RDT test in the last seven days
2. Living in Sitges area and Barcelona	2. Presenting symptoms associated with COVID-19 in the last seven days (according to Catalan Health Department protocols [16,17]): *a) at least one of these: fever, persistent cough, shortness of breath, anosmia, ageusia* *b) at least two of the following: sore throat, a cold, fatigue, myalgia, headache, vomiting or diarrhoea stomach ache*
3.Having a personal card from the Catalan public healthcare system	
4. A negative Ag-RDT test the same afternoon (provided by the organisation).	
	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.

The nightlife event took place from 23:00 on May 20 to 03:00 on May 21, 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 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 test on day six after the event was performed on participants.

The control group was obtained through secondary data from the primary care electronic health records (PC-EHR), 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 days cumulative incidence of COVID-19 occurring in the health district (Gerència Territorial Metropolitana Sud) on April 29, 2021 (210/100,000 inhabitants [12]), 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 flowchart 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 days follow-up. As a secondary outcome, the number of positive Ag-RDTs performed in-person at six 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 days follow-up and for the control group only from PC-EHR.

All other variables were obtained from PC-EHR: age, gender, MEDEA socioeconomic deprivation index [18] (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 AstraZenecae/Janssen-Johnson&Johnson).

This information was collected for all participants, which 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, interquartile range, mean and standard deviation 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 Chi-square 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 confidence intervals 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.

Ethical considerations

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 (PROCICAT). 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 allowed 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-RDT tests. 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.

RESULTS

No positive Ag-RDTs tests 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). 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 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% -5- 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 minutes (minimum-maximum: 59-210 minutes). 373 (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% confidence interval): 0 (0, 943) / 100,000 inhabitants) and 2 positive RT-PCR cases in the control group (cumulative incidence of 102 (12.4, 369) / 100,000 inhabitants).

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, 0.48]	-0.32 [-0.32, -0.14]	0.64 [0.48, 1.07]	-0.32 [-0.32, 0.64]	-0.32 [-0.32, 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	2020-11-02 [2020-08-17, 2021-01-08]	2021-01-13 [2020-11-04, 2021-01-17]	-	2021-01-19 [2021-01-02, 2021-02-05]	2020-10-15 [2020-08-12, 2021-01-03]	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						-
PCR			13 (72.22%)	-	2 (100.00%)	2 (100.00%)	9 (64.29%)	
TAR			5 (27.78%)	-	0 (0.00%)	0 (0.00%)	5 (35.71%)	
Test results at 14 days: n (%)	18	373						-
Negative result			18 (100.00%)	-	2 (100.00%)	2 (100.00%)	14 (100.00%)	

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 [19–21] or described mitigation plans and measures applied during mass-gathering events [22,23]. 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-size concert hall (capacity for 900 people) in Barcelona, in December 2020. 1047 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, eight 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 criteria, 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: 4,584 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, wearing FFP2 masks was 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 to the age-adjusted estimation of 296/100,000 observed 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 April 23 to May 22, 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 (1,000 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 six months, had overcome COVID-19 in the last three months, or had a negative Ag-RDT in the last 36 hours. Of the 1,350 3 participants, only three had a positive test between day 7 and 14 after the events [24]. 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 United Kingdom to examine how events can be reopened with reduced risk [25,26]. Fitzgerald et al [27] 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 semi-controlled settings [28]. 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 6,739 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 [29,30]. 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 apparearance of more contagious SARS-CoV-2 variants, were pointed out as possible causes for such poor results in comparison to pilot studies. This led to new limitations and highlighted the importance of vaccination and the cumulative protective effect of Ag-RDT tests and masks in these scenarios.

Generalisability

On July 29, 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 [31]. 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 test 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 [32]. 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 [32]. 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 [26]. 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 dis-encouraging 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 to 57% in people who were fully vaccinated [33], 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, and socioeconomic index, history of previous 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 control 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-RDT tests are far from perfect, there is a higher probability of underestimating the presence of SARS-CoV-2 infection in the control group (i.e. 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 an Ag-RDT follow-up test six days after the intervention (with an acceptable loss rate of 12%, as compared to similar studies in the UK earlier this year [28]), 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 organizers.

ACKNOWLEDGMENTS

We would like to thank Carles Cortés, Eva Lacasta, David Alburquerque, Mercè Fernandez and the whole team of Ajuntament de Sitges (Sitges City Council) who made it possible, Damià Orts and the Associació d'Establiments d'Oci Nocturn de Sitges (Association of Nightlife Premises of Sitges) and Glòria Cabrera and the Federació Catalana de Locals d'Oci Nocturn (Catalan Federation of Nightclubs) for the advice on designing of the study and dissemination, and Esther Sancho and the whole Curasana team.

CONTRIBUTORS

OC: Study design, data analysis and manuscript drafting. SC: Study design and manuscript draft. MM: Study design and manuscript draft. DL: Study design and manuscript draft. MA: Study design, data extraction and manuscript revision. JA: Study design and manuscript draft. JC: Conception, study design and manuscript revision. JB: Conception, study design and manuscript revision. BS: Conception, study design and manuscript drafting. All authors have approved the final version of the manuscript.

COMPETING INTERESTS

The authors declare no conflicts of interest.

FUNDING

The Sitges Council funded the initiative (covering all test, organisation and security costs), relying on the Catalan Public Health Agency for its development (award/grant number not applicable). The funder was not involved in the analysis, discussion or publication of results.

DATA AVAILABILITY STATEMENT

Due to ethical reasons determined by the ethics committee, data can not be made available.

REFERENCES

1 Johns Hopkins University. Center for Systems Science and Engineering (CSSE). Coronavirus COVID-19 (2019-nCoV). https://www.arcgis.com/apps/dashboards/bda7594740fd40299423467b48e9ecf6 (accessed 13 Aug 2021).

2 Jayaweera M, Perera H, Gunawardana B, *et al.* Transmission of COVID-19 virus by droplets and aerosols: A critical review on the unresolved dichotomy. *Environ Res* 2020;**188**:109819. doi:10.1016/J.ENVRES.2020.109819

3 Oran DP, Topol EJ. Prevalence of Asymptomatic SARS-CoV-2 Infection : A Narrative Review. *Ann Intern Med* 2020;**173**:362–7. doi:10.7326/M20-3012

4 Somsen GA, van Rijn C, Kooij S, *et al.* Small droplet aerosols in poorly ventilated spaces and SARS-CoV-2 transmission. *Lancet Respir Med* 2020;**8**:658. doi:10.1016/S2213-2600(20)30245-9

5 World Health Organization. Coronavirus disease (COVID-19). 2020.https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-covid-19 (accessed 13 Aug 2021).

6 Lauer S, Grantz K, Bi Q, *et al.* The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. *Ann Intern Med* 2020;**172**:577–82. doi:10.7326/M20-0504

7 Wang W, Xu Y, Gao R, *et al.* Detection of SARS-CoV-2 in Different Types of Clinical Specimens. *JAMA* 2020;**323**:1843. doi:10.1001/JAMA.2020.3786

8 Younes N, Al-Sadeq DW, Al-Jighefee H, *et al.* Challenges in Laboratory Diagnosis of the Novel Coronavirus SARS-CoV-2. *Viruses* 2020;**12**:582. doi:10.3390/v12060582

9 World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. 2020.https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays (accessed 13 Aug 2021).

10 Mina MJ, Peto TE, García-Fiñana M, *et al.* Clarifying the evidence on SARS-CoV-2 antigen rapid tests in public health responses to COVID-19. *Lancet* Published Online First: 17 February 2021. doi:10.1016/S0140-6736(21)00425-6

11 Ministerio de la Presidencia R con las C y MD. Real Decreto 463/2020, de 14 de marzo, por el que se declara el estado de alarma para la gestión de la situación de crisis sanitaria ocasionada por el COVID-19. 2020. https://www.boe.es/buscar/pdf/2020/BOE-A-2020-3692-consolidado.pdf (accessed 13 Aug 2021).

12 Departament de Salut. Generalitat de Catalunya. Dades COVID . 2021.https://dadescovid.cat (accessed 13 Aug 2021).

13 Revollo B, Blanco I, Soler P, *et al.* Same-day SARS-CoV-2 antigen test screening in an indoor mass-gathering live music event: a randomised controlled trial. *Lancet* Published Online First: 2021. doi:10.1016/S1473-3099(21)00268-1

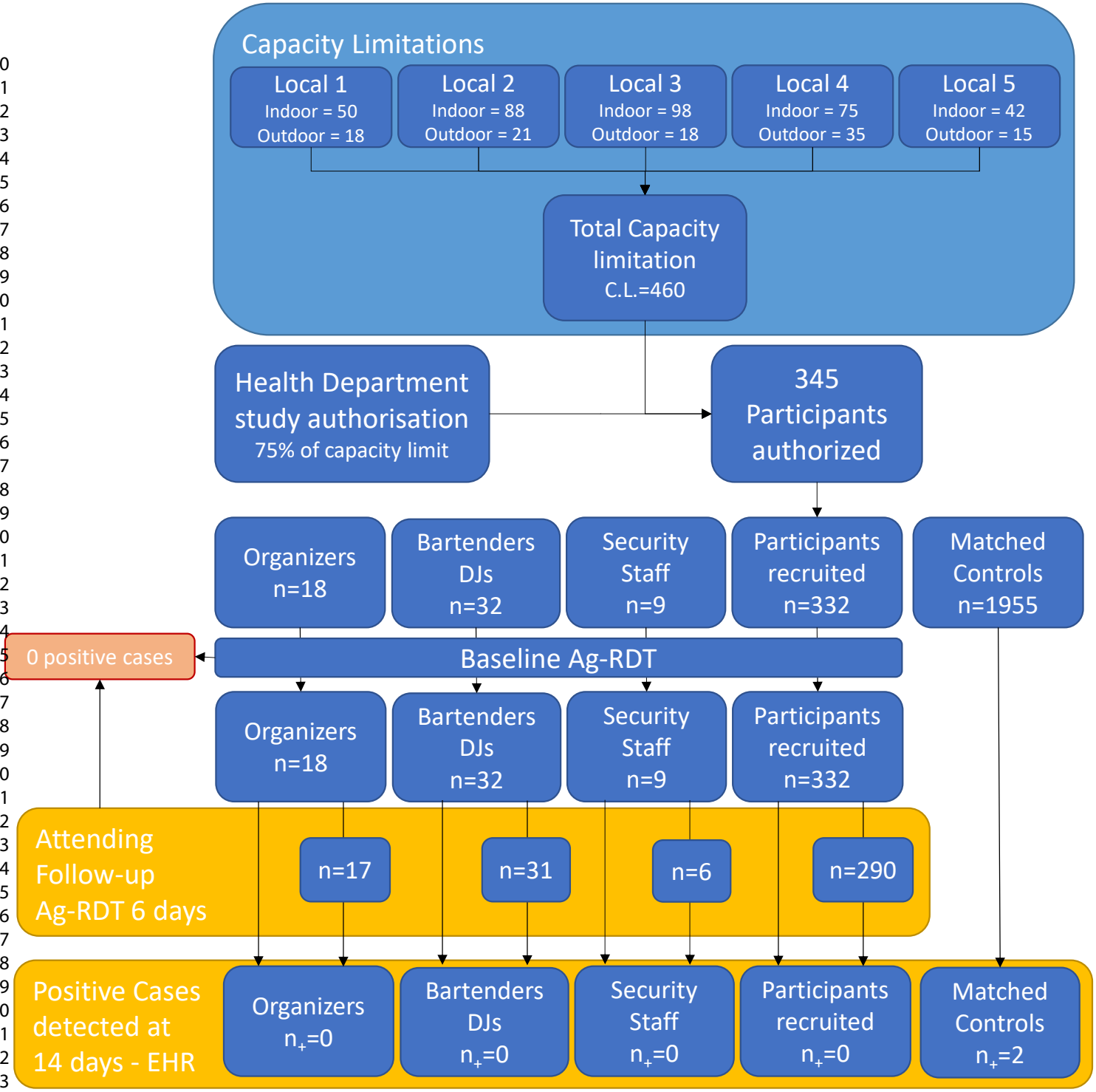
14 Llibre JM, Videla S, Clotet B, *et al.* Screening for SARS-CoV-2 Antigen Before a Live Indoor Music Concert: An Observational Study. *Ann Intern Med* Published Online First: 20 July 2021. doi:10.7326/M21-2278

15 Centre Blockchain de Catalunya. Obrir Girona – CBCat. 2021.https://obrirgirona.cat/ (accessed 13 Aug 2021).

16 Generalitat de Catalunya. Departament de Salut. Procediment d'actuació enfront de casos d'infecció pel nou coronavirus SARS-CoV-2 Sub-direcció General de Vigilància i Resposta a Emergències de Salut Pública. 2021. https://canalsalut.gencat.cat/web/.content/_A-Z/C/coronavirus-2019-ncov/material- (accessed 13 Aug 2021).
17 Gobierno de España. Ministerio de Sanidad. Estrategia de detección precoz, vigilancia y control de COVID-19. 2021.
18 Domínguez-Berjón MF, Borrell C, Cano-Serral G, *et al.* [Constructing a deprivation index based on census data in large Spanish cities (the MEDEA project)]. *Gac Sanit* 2008;**22**:179–87. doi:10.1157/13123961
19 Mat NFC, Edinur HA, Razab MKAA, *et al.* A Single Mass Gathering Resulted in Massive Transmission of COVID-19 Infections in Malaysia with Further International Spread. *J Travel Med* 2020;**27**. doi:10.1093/JTM/TAAA059
20 Pavli A, Smeti P, Papadima K, *et al.* A cluster of COVID-19 in pilgrims to Israel. *J Travel Med* 2020;**27**:1–3. doi:10.1093/JTM/TAAA102
21 Shmuel K, Dalia M, Tair L, *et al.* Low pH Hypromellose (Taffix) nasal powder spray could reduce SARS-CoV-2 infection rate post mass-gathering event at a highly endemic community: an observational prospective open label user survey. *Expert Rev Anti Infect Ther* 2021; 1. doi:10.1080/14787210.2021.1908127
22 Limbachia J, Owens H, Matean M, *et al.* Organizing a Mass Gathering Amidst a Rising COVID-19 Public Health Crisis: Lessons Learned From a Chinese Public Health Forum in Vancouver, BC. *Cureus* Published Online First: 29 December 2020. doi:10.7759/cureus.12365
23 McCloskey B, Zumla A, Ippolito G, *et al.* Mass gathering events and reducing further global spread of COVID-19: a political and public health dilemma. *Lancet* 2020;**395**:1096. doi:10.1016/S0140-6736(20)30681-4
24 Agència Catalana de Notícies. Els impulsors d'Obrir Girona demanen ampliar el programa a tot Catalunya després de l'èxit de la prova - Diari de Girona. 2021.https://www.diaridegirona.cat/girona/2021/06/04/els-impulsors-dobrir-girona-demanen-52621652.html (accessed 13 Aug 2021).
25 Dutch government. Fieldlab Evenementen. 2020.https://fieldlabevenementen.nl/fieldlab-english/ (accessed 13 Aug 2021).
26 Gov.UK. Information on the Events Research Programme - GOV.UK. 2021.https://www.gov.uk/government/publications/information-on-the-events-research-programme (accessed 13 Aug 2021).
27 Fitzgerald N, Uny I, Brown A, *et al*. Managing COVID-19 Transmission Risks in Bars: An Interview and Observation Study. *J Stud Alcohol Drugs*, 2021; **82:** 42-54. doi: 10.15288/jsad.2021.82.42
28 Department for Digital Culture Media and Sport - Gov.UK. Events Research Programme: Phase I findings - GOV.UK. 2021.https://www.gov.uk/government/publications/events-research-programme-phase-i-findings/events-research-programme-phase-i-findings (accessed 13 Aug 2021).
29 Mouzo J. Los festivales de música en Cataluña aumentaron la transmisión de la covid: más de 2.000 asistentes se infectaron. El País. 2021.https://elpais.com/espana/catalunya/2021-08-04/los-festivales-de-musica-en-cataluna-aumentaron-la-transmision-de-la-covid-mas-de-2000-asistentes-se-infectaron.html (accessed 13 Aug 2021).

30 Cabezas C. Roda de premsa sobre el seguiment del procés de vacunació de la COVID-19 a Catalunya. 2011;:31:55.https://www.youtube.com/watch?v=9MUfakIxVSA&t=1915s (accessed 13 Aug 2021).
31 Diari Oficial de la Generalitat de Catalunya. RESOLUCIÓ SLT/2498/2021. Barcelona: Generalitat de Catalunya 2021. https://dogc.gencat.cat/ca/document-del-dogc/?documentId=907691 (accessed 13 Aug 2021).
32 Peeling RW, Olliaro PL, Boeras DI, *et al.* Scaling up COVID-19 rapid antigen tests: promises and challenges. *Lancet Infect Dis* Published Online First: 2021. doi:10.1016/S1473-3099(21)00048-7
33 Public Health England. SARS-CoV-2 variants of concern and variants under investigation in England. Technical Briefing 15. 2021.

Figure 1: Participant flowchart


Capacity Limitations
Local 1
Indoor = 50
Outdoor = 18
Local 2
Indoor = 88
Outdoor = 21
Local 3
Indoor = 98
Outdoor = 18
Local 4
Indoor = 75
Outdoor = 35
Local 5
Indoor = 42
Outdoor = 15
Total Capacity limitation
C.L.=460
Health Department study authorisation
75% of capacity limit
345 Participants authorized
Organizers n=18
Bartenders DJs n=32
Security Staff n=9
Participants recruited n=332
Matched Controls n=1955
0 positive cases
Baseline Ag-RDT
Organizers n=18
Bartenders DJs n=32
Security Staff n=9
Participants recruited n=332
Attending Follow-up Ag-RDT 6 days
n=17
n=31
n=6
n=290
Positive Cases detected at 14 days - EHR
Organizers n+=0
Bartenders DJs n+=0
Security Staff n+=0
Participants recruited n+=0
Matched Controls n+=2

Reporting checklist for cohort study.

Based on the STROBE cohort guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cohortreporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	3
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	#3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	#4	Present key elements of study design early in the paper	5
Setting	#5	Describe the setting, locations, and relevant dates, including periods	5-6

		of recruitment, exposure, follow-up, and data collection	
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up.	5-6
Eligibility criteria	#6b	For matched studies, give matching criteria and number of exposed and unexposed	6
Variables	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	6
Bias	#9	Describe any efforts to address potential sources of bias	6
Study size	#10	Explain how the study size was arrived at	6
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	6
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	
6			
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	6
Statistical methods	#12c	Explain how missing data were addressed	6
Statistical methods	#12d	If applicable, explain how loss to follow-up was addressed	NA
Statistical methods	#12e	Describe any sensitivity analyses	
NA			
Results			
Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible,	7

		included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	
Participants	#13b	Give reasons for non-participation at each stage	7
Participants	#13c	Consider use of a flow diagram	
NA			
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	7-8
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	
8			
Descriptive data	#14c	Summarise follow-up time (eg, average and total amount)	
7			
Outcome data	#15	Report numbers of outcome events or summary measures over time. Give information separately for exposed and unexposed groups if applicable.	
8			
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8
Main results	#16b	Report category boundaries when continuous variables were categorized	NA
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
7			
Other analyses	#17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA

Discussion

Key results	#18	Summarise key results with reference to study objectives	9
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	11
Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	11
Generalisability	#21	Discuss the generalisability (external validity) of the study results	10-11
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

This checklist was completed on 05. October 2021 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai