

**Study protocol - for registration in ClinicalTrials.gov**

**Effect of COVID-19 lockdown on alcohol and tobacco use in two Chilean universities:  
a difference-in-difference analysis**

**Sponsor:** Universidad de La Frontera

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# **Effect of COVID-19 lockdown on alcohol use in two Chilean universities: a difference-in-difference analysis**

## **Background**

The coronavirus disease 2019 (COVID-19) pandemic has led to substantial societal changes in most high and middle-income countries. This can translate to changes in the volume and patterns of alcohol use, with severe consequences for health and societal wellbeing [1].

The COVID-19 pandemic could potentially affect alcohol and tobacco use in several ways. First, governments have introduced policies to reduce viral transmission, including social distancing policies to restrict people's mobility and exposure to SARS-CoV-2. These have ranged from stay-at-home advice and remote-work guidance to statutory closures of schools and universities, bars and restaurants and restrictions for public gatherings [2, 3]. The most restrictive policies have included lockdowns (with various levels of stringency) and curfews. Such policies have disrupted routines and reshaped social interactions as well as acting as an acute stressful event, which could, in turn, affect alcohol and tobacco use [1, 4-6].

Second, the pandemic could directly impact alcohol and tobacco use through changes in affordability due to the negative economic consequences, reducing people's disposable income and consumption as a result [7]. A SARS-CoV-2 infection could also directly impact tobacco or alcohol use, as the majority of infected individuals have experienced fever, malaise or cough [8]. An estimated 10% of those who had COVID-19 persist with fatigue, dyspnoea, disturbance of smell or taste after 8-24 weeks, which could affect their alcohol use [9]. Persistent COVID-19 symptoms have been reported to be as high as 50% among those who were hospitalized due to COVID-19 [10].

Third, governments have adopted policies that directly influence alcohol and tobacco availability and affordability. Such policies include total ban of tobacco (South Africa)[11] or alcohol sales (e.g. South Africa, India, Thailand, Panama),[12-15] changes in opening hours (as in parts of Chile and Mexico) and even raised alcohol taxes in some States in India [16].

Lockdowns, especially those that include statutory restrictions for people's mobility, have likely the largest potential effect on alcohol and tobacco use. Previous studies reporting the effect of COVID-19 lockdowns on alcohol use have reported a mixed picture, with some studies reporting an increase in high-risk drinking (either volume or heavy episodic drinking),[17-21] volume of alcohol use [22] and frequency of alcohol use [23], while other

studies have reported reductions in alcohol use [24-26]. Mixed changes on tobacco use have also been reported, with a relatively equal proportion of respondents describing an increase or reduction in their use of tobacco [17, 20, 27-30]. Evidence comes primarily from countries in Europe, the United States, Australia, and New Zealand. One common limitation of these studies is that they compare a pre-pandemic with a pandemic period and are thus not able to disentangle the direct effects of the pandemic with those from lockdown and curfew policies.

In this study, we will advance prior knowledge by providing evidence from a country in Latin America, one of the worst-hit regions worldwide. Latin America accounts for 8.4% of the global population, but 20.3% of the total SARS-COV2 cases and 30.2% of the COVID-19 deaths to date [31]. In addition, we will exploit the variation in lockdown policies in two regions in Chile to disentangle the effects of the COVID-19 pandemic with those from a lockdown.

The aim of the study is to examine the effect of a regional lockdown on alcohol use in two university populations in the Araucanía and Coquimbo regions in Chile. We will use a difference-in-difference analysis to obtain causal estimates of these COVID-19 policies.

## **Methods**

### *Study design*

The study is a controlled before-and-after study of COVID-19 policies in two Chilean regions. We will report the results in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [32].

### *Participants*

The study population are university communities from two regions in Chile (Coquimbo, northern Chile, and Araucanía, southern Chile). These university communities include undergraduate and postgraduate students, full-time and part-time academics, leadership positions, administrative staff and service personnel. Eligibility criteria include (1) those with study rights either at the undergraduate and postgraduate levels by July 27, 2020; or (2) workers with a full-time or part-time contract with the University, including academics and assistant personnel, (3) with an email registered in the Human Resource Office of each university.

### *Intervention*

We will examine the effect of lockdown in the context of the COVID-19 pandemic. During the study period, the Chilean Ministry of Health established a five-step process for social distancing measures. These ranged from full lockdown (step 1) to almost no restrictions (step 5). Even under full lockdown, citizens were able to obtain permits for essential activities (e.g., buying food or going to the doctor). These permits had a maximum of two per week and were obtained in a virtual station of the Chilean Police Force (Carabineros de Chile). Table S1 describes the five phases in detail. Table S2 describes the different types of permits people were allowed to use. It must be noted that, due to the COVID-19 pandemic, the Chilean government issued a night curfew with a total prohibition to leave home between 22.00 and 05.00 for the whole country from March 22, 2020, to date. Table 1 includes the specific policies implemented in both regions at the time of each data collection period.

### *Comparator*

The comparator is the absence of lockdown at a given time. During most of the study period, the whole country had in place restrictions for public gatherings, school closures and advice for remote work. Both universities instructed remote work from March 16, 2020, which continued during the whole study period.

### *Covariates*

We will adjust for covariates that are not influenced by the intervention but correlate with the outcome to increase the statistical power. These covariates include sex, age, educational level, living arrangements, existing medical conditions, and type of relationship with the university (i.e., student, academic or service personnel). We will categorise education into four categories: complete secondary education, incomplete undergraduate education, complete undergraduate education, and postgraduate education degree. We will categorise living arrangements into living alone or not. Existing medical conditions will be categorised into a dichotomous variable on whether the participants reported any of the following: high blood pressure; diabetes; cardiac problems (cardiac insufficiency, myocardial infarction, or others; respiratory conditions (asthma, respiratory insufficiency; depression; anxiety; other mental health problem; cancer (any malignancy including leukaemia or lymphoma; and fibromyalgia). We will categorise the type of relationship into three categories: student, service or administration personnel, and academic or leadership position.

### *Outcomes*

We will examine three primary outcomes: weekly grams of alcohol use, heavy episodic drinking (HED) and number of cigarettes smoked per day. Weekly grams of alcohol use were measured at baseline with a question of how many drinks of beer (in portions of 330 cc), wine and similar (chicha and pipeño, two types of unfiltered wines, in portions of 140 cc) and spirits (pisco, rum, whisky, tequila, vodka, gin or other strong liquors) in a typical week. We asked the same questions for a pre-pandemic period and a during-the-pandemic period. The follow-up at waves 2 to 6 included a similar question but for each day of the week (“how many drinks did you have each day of the week”).

We will convert the number of drinks into grams by multiplying the volume of each beverage by the density of alcohol (0.789). We will consider a standard drink of 15.8 grams based on the results of the Chilean National Health Survey 2009-2011, which had a standardized protocol to assess standard drinks in Chile. This data is available for all waves. Waves 0, 1, 5 and 6 include separate questions for beer, wine, and spirits.

We will measure HED with a question on how often the respondent drank 5 or more drinks on a single occasion (considering a 1-month period). The options were never, once, twice, 3 to 5 times, 6 to 9 times and 10 or more. We will convert this information into a continuous variable. We will convert the options 3-5 and 6-9 times to their arithmetic midpoint (4 and 7.5, respectively). We will convert the 10 or more option into the lower boundary (i.e., 10). This data is available for waves 0, 1, 4, 5 and 6.

We will measure the number of daily cigarettes smoked per day with a question on how many cigarettes has the participant smoked on average during the past week. We will convert this information into a continuous variable. This data is available for all waves.

### *Procedures*

We collected the data using an online survey sent by email to all eligible participants. Data were collected from July 27 to August 13 (wave 0 and 1), August 15 to August 25 (wave 2), September 7 to September 22 (wave 3), October 5 to October 16 (wave 4), November 9 to November 20 (wave 5), December 9 to December 21 (wave 6) and April 5 to April 23 (wave 7). In all waves, we used an online survey tool (QuestionPro) which creates a database automatically. We did not allow participants to leave questions blank, but participants could stop answering at any moment. We used the following protocol to remind participants to answer the questionnaire: After sending the survey, we sent a reminder every three days: twice via email, then to those who had provided a mobile phone number, we sent the survey

two more times via text messaging. No incentive was provided in exchange for their participation in any of the study waves. The first round of data collection included questions regarding the period before the COVID-19 pandemic (wave 0) and during the pandemic (wave 1).

#### *Sample size calculation*

Prior to the beginning of the study, we calculated a sample size of 1046 participants to detect a small effect size (0.2), with a statistical power of 0.95, alpha of 0.05 and a factor of 2 to take into account the impact of attrition.

#### *Ethical approval*

The Scientific Ethics Committee from the Universidad de la Frontera and Universidad Católica del Norte approved the study in accordance with Law 20.120 (2006). We obtained electronic written consent from all participants.

#### *Statistical analysis*

We will exploit the variation in lockdown policies in the two regions to measure the effect of lockdown on alcohol use. For this purpose, we will use a difference-in-difference (DiD) design to compare the effect of lockdown in multiple treatment periods. DiD is a quasi-experimental approach that allows using longitudinal data to obtain causal effects in the absence of randomization [33]. DiD is a well-established method in public health research and was first used by John Snow in his seminal study on the transmission of cholera in 1855 [34].

The canonical DiD consists of two time periods and two groups. One computes the difference in the mean outcomes of the treatment and control group after the treatment and subtract the difference that existed before treatment had any effect [35].

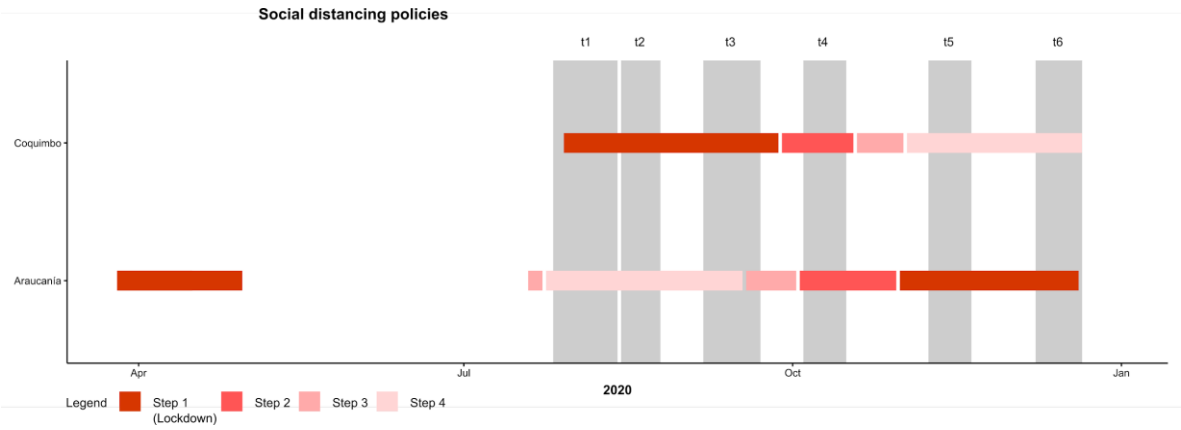
$$\delta_{DD} = (Y_{posttreat} - Y_{pretreat}) - (Y_{postcontrol} - Y_{precontrol})$$

The key identifying assumption is that, in the absence of treatment, the average outcomes would have followed parallel paths over time [33].

As depicted in Figure 1, our case is more complex, as there are multiple time periods (seven in total) and two groups that are both treated and not-treated in different time periods. For  $\tau$  periods and a particular time period denoted by  $t$  where  $t=1, \dots, \tau$ ,  $t_0$  represents the baseline measurement captured retrospectively at  $t_1$ . In time periods  $t_1$ ,  $t_2$  and  $t_3$ , the Coquimbo group

is exposed to lockdown while the Araucanía group is exposed to less restrictive social distancing policies. At  $t_4$  both groups are exposed to step 2 social distancing policies and at  $t_5$  and  $t_6$ ; this situation reverses, and Araucanía is exposed to lockdown and Coquimbo moves to less restrictive social policies. Treatment intensity  $D$  has values ranging from 5 (step 1) to 1 (step 5) (see Table S2 for details).

**Figure 1.** Social distancing policies in Coquimbo and Araucanía for the study period



In this setting, we will use a generalized difference-in-difference that allows for multiple treatment periods and several treatment intensities [36, 37]. The regression of a DiD model can be expressed in more general terms as

$$(1) \quad Y_{ist} = \alpha + \delta_{DD}TREAT_{st} + \theta X_{ist} + \beta_i + \gamma_t + e_{ist}$$

where  $Y_{ist}$  is the outcome for an individual  $s$  at time  $t$  and  $i$  is the region (Coquimbo or Araucanía),  $\delta_{DD}$  is the coefficient of interest of a treatment intensity variable,  $X_{ist}$  is a vector of control variables (e.g. age, sex),  $\beta_i$  is a region fixed effect, and  $\gamma_t$  is a set of time fixed effects. The identifying assumption, in this case, relies on a common trend assumption that both treatment groups would develop equally over time under at least one of the treatments. It assumes effect homogeneity conditional on observables  $X_{ist}$ .

An alternative to adjustment by control variables would be to use propensity score matching (PSM). Recent analyses Daw and Hartfield (2018) suggest that using PSM could increase bias due to regression to the mean when treatment assignment occurs at the population level. In this context, the difference between treatment groups is stable and unmatched analysis is unbiased. Matching on the preperiod level introduces regression to the mean bias [38]. For this reason, we chose to adjust for control variables and not to use PSM.

There is an ongoing debate about DiD when groups of units receive treatment at different times or different treatment intensities.[39, 40] Researchers are concerned this fixed effect regression provides greater weights to treatments with similar before and after treatment periods and uses treated units as controls.[39] This is unlikely to affect our study, as it has only two treated groups and thus no variation in treatment timing. Nonetheless, we will use the Callaway-Sant'Anna method (CS method) in sensitivity analyses. The method was built to handle staggered treatment adoption designs.[40] To accommodate this, we will divide the analysis into two sections ( $t_0$  versus  $t_1, t_2$  and  $t_3$ ) and ( $t_0$  versus  $t_5$  and  $t_6$ ).

The estimation will be done using linear mixed effects models. These models take into account the correlated nature of the data (repeated measures of the same individuals) and provide mathematically equivalent estimates than fixed effects linear regression. However, an additional advantage of linear mixed effects models is that they allow to vary the number of observations within each participant, handling missing data more efficiently than other analytical approaches [41].

#### *Statistical Software*

We will use R (current version 3.6.3) for all analyses. We will use the *lme4* function to run the DiD model and the *did* package for the Callaway-Sant'Anna method.



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## Supplementary Appendix

**Table S1.** Components of the step-by-step mobility restrictions for the COVID-19 pandemic in Chile during the study period

Phase	Curfew (22.00-05.00)	Lockdown	Schools	Restaurants and bars	Gyms	Public gatherings	Cinemas, theatres and similar	Closed spaces	Local mobility	Mobility permits	Older adults
Step 1	Yes	Yes	Remote education for preschool, elementary and higher schools	Closed, only take away allowed	Closed	Forbidden	Closed	Customer service restricted to no more than 1 person per 10 square meters	Passenger cruises forbidden. All buses must have a list of passengers for travelling times longer than 2 hours. Forbids travel to second residence. <sup>1</sup>	Allowed	Lockdown for residents in elderly care. Closure of day centers for older adults and meetings of "Clubes de Adultos Mayores"
Step 2	Yes	Yes, only Saturdays, Sundays and bank holidays	Remote education for preschool, elementary and higher schools	Open at 25% of their maximum capacity, maximum time two hours, only in open spaces	Sports activities for maximum 10 people in open spaces. Gyms closed	Public events allowed for a maximum of 10 people in a closed space and 20 people in an open space.	Closed	Customer service restricted to no more than 1 person per 10 square meters	Passenger cruises forbidden. All buses must have a list of passengers for travelling times longer than 2 hours. Forbids travel to second residence. <sup>1</sup>	Allowed	Lockdown for residents in elderly care. Closure of day centers for older adults and meetings of "Clubes de Adultos Mayores"

Step 3	Yes	No	Allowed after permission from Regional Secretary of Education	Open at 25% of their maximum capacity, maximum time two hours, only in open spaces	Sports activities for maximum 25 people in open spaces and 5 people in closed spaces, including gyms	"Oficios, ritos, seminarios and ceremonias" allowed for a maximum of 25 people in a closed space and 50 people in an open space.	Closed	Customer service restricted to no more than 1 person per 10 square meters	Allows travel to second place of residence	Allowed	Lockdown for residents in elderly care. Closure of day centers for older adults and meetings of "Clubes de Adultos Mayores"
Step 4	Yes	No	Allowed after permission from Regional Secretary of Education	Open at 50% of their maximum capacity	Sports activities for maximum 50 people in open spaces and 10 people in closed spaces, including gyms	"Oficios, ritos, seminarios and ceremonias" allowed for a maximum of 50 people in a closed space and 100 people in an open space.	Open at 50% of maximum capacity	Customer service restricted to no more than 1 person per 5 square meters	Allows travel to second place of residence	Allowed	Lockdown for residents in elderly care. Closure of day centers for older adults and meetings of "Clubes de Adultos Mayores"
Step 5	Yes	No	Allowed after permission from Regional Secretary of Education	Open at 75% of maximum capacity	Sports activities for maximum 100 people in open spaces and 20 people in closed spaces, including gyms	"Oficios, ritos, seminarios and ceremonias" allowed for a maximum of 100 people in a closed space and 200 people in an open space.	Open at 75% of maximum capacity	Customer service restricted to no more than 1 person per 5 square meters	Allows travel to second place of residence	Allowed	Visits to elderly care centers are allowed. Day centers for older adults open

1. Except people older than 65 years old and with chronic conditions. They are allowed to move but must remain in quarantine.  
Data based on Resolución Exenta 591 from the Chilean Ministry of Health, July 23, 2020

**Table S2.** Mobility permits during step 1 (lockdown) in Chile during the study period

Permit	Duration
Appointment in a health care centre	3 hours
Shopping for essential goods (food, medications, etc)	3 hours
Going out for a person with autistic spectrum disorder or any other cognitive disability	2 hours, no weekly limit
Walking dogs and other pets, two blocks around the place of residence	30 minutes
Payment of household expenses or collecting pensions or State subsidies	3 hours
Attending funerals of direct relatives	5 hours <sup>1</sup>
Collecting textbooks, school food or technological devices for school purposes	5 hours
Attending a court appointment	No limit
Take food or other essential products to older adults	2 hours
Take food or other essential products to prison inmates	3 hours
Transport children or adolescents between parents or caretakers' residences	2 hours
Visits to people with disabilities that are hospitalized	3 hours
Weddings or civil unions, including a maximum of 5 companions	4 hours
Donate blood	4 hours
Taking care of older adults and people with disabilities	No limit
Other important and urgent matters authorized in person by the Chilean Police Force	Depend

1. If the funeral is in the same region, 24 hours if it's in a different region than the one of residence