Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Gac Sanit. (2022);36(1):70–73

Protocolo

Socio-economic and psychological impact of COVID-19 pandemic in a Spanish cohort BIOVAL-D-COVID-19 study protocol

Andrea Miranda-Mendizabal[a,*], Silvia Recoder[b], Ester Calbo Sebastian[c], Marc Casajuana Closas[d], David Leiva Ureña[e], Rumen Manolov[e], Nuria Matilla Santander[f], Carlos G. Forero[a,*], Pere Castellví[a]

[a] Department of Medicine, Universitat Internacional de Catalunya, Sant Cugat del Vallès, Barcelona, Spain
[b] Department of Basic Sciences, Universitat Internacional de Catalunya, Sant Cugat del Vallès, Barcelona, Spain
[c] Hospital Universitari Mútua Terrassa, Terrassa, Barcelona, Spain
[d] Institut Universitari de Investigació en Atenció Primaria Jordi Gol, Barcelona, Spain
[e] Departament of Psychology, Universitat de Barcelona, Barcelona, Spain
[f] Karolinska Instituten, Stockholm, Sweden

ARTICLE INFO

Article history:
Received 1 July 2021
Accepted 4 October 2021
Available online 20 October 2021

Keywords:
COVID-19 pandemic
Mental disorders
Suicide
Socioeconomic factors
Spain

ABSTRACT

Objective: SARS-CoV-2 outbreak has a negative psychological impact among general population. Data comparing mental health status before and during the outbreak is needed. The BIOVAL-D-COVID-19 study assess the socio-economic and psychological impact of the COVID-19 pandemic and lockdown in a representative sample of non-institutionalized Spanish adult population, and estimate the incidence of mental health disorders, including suicidal behaviours, and possible related factors.
Method: Observational longitudinal study including two online surveys: baseline survey (T0) performed during 2019 and follow-up survey (T1) conducted 12-month later. The latter included nine sections: socio-demographic, health status, mental health, employment conditions and status, material deprivation, use of healthcare services, intimate partner violence and resilience. Four of the nine sections are administered in T0 and T1 assessments. Longitudinal data analyses will estimate adjusted incidence rates of mental health disorders using Poisson regression models. Risk and protective factors will be analysed through multiple logistic regression models.

Impacto socioeconómico y psicológico de la pandemia de COVID-19 en una cohorte española protocolo del estudio BIOVAL-D-COVID-19

Palabras clave:
Pandemia COVID-19
Trastornos mentales
Suicidio
Factores socioeconómicos
España

RESUMEN

Objetivo: el estudio BIOVAL-D-COVID-19 evaluará el impacto socioeconómico y psicológico de la pandemia de COVID-19 y del confinamiento en una muestra representativa de población española adulta no institucionalizada, y estimará la incidencia de trastornos de salud mental, incluida la conducta suicida, y los posibles factores relacionados.
Métodos: estudio longitudinal que incluye dos encuestas *online:* la encuesta basal (T0) realizada durante 2019 y la encuesta de seguimiento (T1) realizada 12 meses después. Esta última tiene nueve secciones: variables sociodemográficas, estado de salud general, salud mental, condiciones laborales y estatus laboral, privación material, uso de servicios de salud, violencia de pareja y resiliencia. Cuatro de las nueve secciones se administran en ambas encuestas (T0 y T1). Se utilizarán modelos de regresión de Poisson para el análisis longitudinal de las tasas de incidencia ajustadas de trastornos de salud mental. Los factores de riesgo y de protección se analizarán mediante modelos de regresión logística múltiple.

Introduction

Political and health measures taken to curb the COVID-19 pandemic have affected many aspects of day-to-day life.[1] Their impact has been mostly studied among specific populations (e.g., healthcare workers, infected individuals and their families)[2–5] and, to a lesser extent, among general population[6–8] and patients with pre-existing conditions.[9,10]

Spanish data show that as consequences of the first wave of COVID-19 pandemic, general adult population mostly report depressive[11] and anxiety symptoms.[11,12] For individuals aged 60 years, depressive and avoidant coping styles are early psychological effects of the pandemic and lockdown.[13] Specifically, risk factors

* Corresponding authors at: Department of Medicine, Universitat Internacional de Catalunya, Sant Cugat del Vallès, Barcelona, Spain.
E-mail address: cgarciaf@uic.es (C.G. Forero).

https://doi.org/10.1016/j.gaceta.2021.10.003

increasing worse mental health outcomes, are: being female,[11–16] having or have had a mental disorder,[12,13,16] have been exposed to COVID-19[15,16] and having had symptoms associated with the virus[12,16] or a close relative infected.[12] However, these studies have mostly used retrospective cross-sectional design[11–17] and included samples from specific geographical regions.[13,14]

An earlier published article, using data from a longitudinal population-based Spanish cohort just after the first wave of COVID-19 pandemic, shows that the prevalence of depression and suicidal ideation have not significantly increased.[18] However, COVID-19 pandemic and lockdown consequences on the Spanish general population over the time are yet to be fully appraised. The end of the pandemic may translate into social and economic consequences, probably widening or revealing inequalities in Spanish society, as it has occurred in some other countries.[1,7]

Therefore, direct comparisons of before, during and after the pandemic are needed. Such comparison would serve for identifying groups and risk factors where evidence-driven strategies might reduce consequences of the pandemic.

This study objectives are to assess the socio-economic and psychological impact of the SARS-CoV-2 outbreak and lockdown due to the COVID-19 pandemic in population-based cohort from the Spanish adult population, before and during the pandemic. The prospective pre-post pandemic design will increase knowledge about causal links between personal, familiar, and socioeconomic variables and COVID-19 outcomes. Results will have the potential to inform and improve preventive strategies implemented in similar situations.

Method

Study design

Observational longitudinal study through an online survey on Spanish residents will be carried out. The baseline survey (T0) was acquired as part of the BIOVAL-D project (Exp: PI16/00165) during October-November 2019 for assessing mental health prior to SARS-CoV-2 outbreak. The follow-up survey (T1) will be conducted after 12-months, using the same questionnaire with additional domains to identify risk and resilient factors associated to mental disorders and suicide behaviours after SARS-CoV-2 outbreak and lockdown, and to evaluate economic costs individually and at familiar level. The survey has an average duration of 30 minutes. Participants will have a unique personal link to fulfil the survey guaranteeing that it could be fully completed only once. However, links could be used to access the survey at different times until completeness is achieve.

Study sample

Baseline participants for the BIOVAL-D study come from a Spanish national population sample (≥18 years old) representative in terms of geographical areas, sex, age and income level, recruited during 2019 from an online secure panel data vendor including a final sample of 2005 individuals. The panel does not exclude any household and its members from the possibility of being recruited. Participants are randomly selected from an extensive list of mobile and landline phones, as well as personal interviews, ensuring the panel representativeness. The study left open the possibility to recontact the participants for future studies. For the follow-up survey all the 2005 participants will be recontacted by the panel provider. Participants will receive an informative email on the study objectives and characteristics, including a link to the informed consent. Upon consent, participants will receive a signed copy, asking for permission for subsequent contacts for study reasons. Response rates of 60% are expected. Participation is encouraged through an incentives system based on accumulative points and exchange. Points can be exchanged for physical (e.g., electronics and technology, children's toys, pet products, sports and leisure, etc.) and digital gifts (e.g., app, books, music, etc.) or donations to NGOs. All participants who answer 100% of the survey will accumulate the same number of points.

For assuring representativeness of the follow-up, in case it is needed because of low response rate, a subsample, from the same panel and who was not contacted at baseline, will be invited to participate at follow-up to complete sample size for comparison. For matching, selection will be made based on the socio-demographic characteristics (sex, age, geographic area, income level) of those individuals who will be replaced.

Sample size

Sample size is estimated based on the incidence data between T0 and T1, assuming an annual baseline depression incidence of 2% and COVID-19 exposure affecting 10% of the population, increasing incidence up to 10%. Based on these assumptions, with a statistical power of 0.80 at a 0.05 nominal significance level and considering a 40% loss-to-follow up cases, total sample size at follow-up has been estimated in 1200 people. Depression incidence has been selected for this purpose because it is expected to be especially high in the pandemic context being a good proxy variable for mental health effects. Furthermore, it has been done to be consistent with the criteria used in the baseline study it ensuring comparability.

Data gathering platform

Data will be managed using the "Dimensions" platform, a secure data web software for developing and running online surveys using panels. Links to the survey will be sent individually and encrypted, and associated with an identification code unconnected to personal information. The link will be active for a limited period of time.

Survey and dimensions assessed

The T1 follow-up survey is composed by 9 sections, detailed below. It was developed on purpose by the research team. Socio-demographic, health status, and mental health (except post-traumatic stress disorder), are administered at T0 and T1.

1) Socio-demographics

Age, gender, time residing at current address, marital status, coexistence with a partner and educational level.

2) Health status

Self-perceived physical and mental health; smoking status and World Health Organization Disability Assessment Schedule (12-items). The scale has been validated for the Spanish population.[19]

3) COVID-19 exposures

Items about COVID-19 exposure were developed *ad-hoc* for this study. Having been tested or diagnosed for COVID-19, COVID-19 symptoms and treatment, days at hospital including intensive care unit days, COVID-19-related stress with reasons (e.g., family finances, social isolation, worry about getting infected). Also, information on friends and relatives infected and/or death by COVID-19 will be gathered.

4) Mental Health

Depression: Spanish version of the Composite International Diagnostic Interview version 3.0 will be used,[20] including screening items for panic disorder (2-items), bipolar disorder (2-items) and general anxiety disorder (3-items); major depression episode

diagnostic section including 37-items (depression and anhedonia, 6-items; weight, 5-items; insomnia, 5- items; retardation and agitation, 4-items; fatigue, 2-items; worthlessness and guilt, 5-items; concentration, 4-items; suicide, 6-items). For study purposes, new item will ask the participants the trimester when they experienced each symptom. Finally, 2-items about being on treatment due to depression symptoms will be asked. Good clinical diagnostic agreement was reported for the CIDI instrument with face-to-face[21] and online assessments[22] among the Spanish population.

Anxiety: General Anxiety Disorder-7, 4-point Likert Scale with scores ranging from 0 to 21 will be used. The Spanish version has shown good reliability and validity evidence, and cut-off point for diagnoses has been established.[23]

Post-traumatic stress disorder (PTSD): Spanish version of the PCL-5 will be used (20-items)[24] for assessing PTSD directly related to being infected of COVID-19 or death of a close one due this condition.

5) Employment conditions and employment status

Poor employment conditions after the first lockdown due to COVID-19 pandemic (e.g., precarious employment) measured using the Employment Precarity Index (EPI) (https://precariousworkresearch.org/).[25,26] EPI score ranges between 0 and 30. The EPI will be applied on individuals who declare to be working or studying at the time of the survey, or to have lost their jobs permanently or temporarily during the three months before the survey. Changes in the employment status after the lockdown period, such as having become temporary or permanently unemployed, will be also asked. We will also ask whether individuals have attended work having COVID-19 compatible symptoms, their main occupation and whether they have been able to telework.

6) Material deprivation

Material deprivation will be assessed through household income, proportion of household income used for paying the rent or mortgage, and whether individuals are able to go on vacations one week per year, eat meat or fish (or the equivalent for other diets) at least two days per week, pay an unforeseen expense, and maintain a suitable temperature at home.

7) Use of healthcare services

Number of visits to primary care or to any medical specialist, days of hospitalization, days in intensive care unit, temporary employment regulation, and sick leave. Also, expenditures in sanitary products in euros. The cost of all items will be calculated using the tax list published in the Oblikue Database (http://esalud.oblikue.com/).

8) Resilience

Spanish version of the 10-items Connor-Davidson Resilience Scale.[27]

9) Intimate partner violence

Short-form version of the Composite Abuse Scale[28,29] to measure self-reported intimate partner violence since the beginning of lockdown. Participants will be asked whether they had, or still have, a partner since the beginning of lockdown, and if they have felt fear of that partner during it.

Statistical analysis plan

Statistical analyses will involve different methods depending on the use of cross-sectional or longitudinal data. Cross-sectional data will allow to estimate the prevalence and means of socio-demographic characteristics, risk and protective factors and socio-economic and mental health outcomes associated. Prevalence ratios for the association of risk and protective factors using bivariate associations (Chi-squared) and multiple models, using Poisson regression models with log-binomial link and robust standard errors. Coefficients and their 95% confidence intervals will be calculated. Sampling weights according to gender, age, geographic area and income levels will be applied to restore sample representativeness, and to calculate results stratified by gender and age groups. Longitudinal data analyses will be conducted by determining the sample fraction with no mental health problems at T0 with positive mental outcomes at T1. Crude incidence rates by 1000 person-years will be estimated. Adjusted incidence rates will be computed using Poisson regression models using a log-link function. Linear regression models using baseline values as predictors will be used for continuous T1 outcomes to estimate change between T0 and T1 by means. Time-to-event data will be analysed using Cox regression models. Selection bias due to non-random losses to follow-up will be corrected using inverse probability-of-censoring weights.[30]

Ethics and dissemination

Baseline study was approved by the Ethical Committee of the IMIM-Parc de Salut Mar (2014/5717/I) and the Ethical Committee of the Universitat Internacional de Catalunya (PIC-178-19). The latter also approved the follow-up study (MED-2020-02).

Before entering the study, participants will read and sign an informed consent. The data will be gathered in a completely anonymous way, with no possibility to match the data with participant's identity. In cases where mental health problems or intimate partner violence would be detected, participants will receive an automatic message, only visible to them upon survey completion, advising to contact health or social services that provides adequate information and assistance. All participants will receive a general message with recommendations and assistance contacts. A final report with the major results will be presented to the Observatori Social La Caixa as a requirement for granted projects. Study findings will be disseminated through different publications.

Editor in charge

Azucena Santillán-García.

Authorship contributions

A. Miranda-Mendizabal and S. Recoder drafted the first version of the manuscript. P. Castellví and C. G. Forero conceived, designed and supervised the overall study. E. Calbo Sebastián, M. Casajuana Closas, D. Leiva Ureña, R. Manolov and N. Matilla Santander participated in the writing of the manuscript, provided important intellectual content and gave their final approval of the version submitted for publication.

Funding

This work is funded by ISCIII-FEDER (PI16/00165) and Observatori Social La Caixa call to support research survey projects to assess the social impact of COVID-19 pandemic (Call LL20-2).

Conflicts of interests

None.

References

1. Pierce M, Hope H, Ford T, et al. Mental health before and during the COVID-19 pandemic: a longitudinal probability sample survey of the UK population. Lancet Psychiatry. 2020;7:883–92.
2. Gardner PJ, Moallef P. Psychological impact on SARS survivors: critical review of the English language literature. Can Psychol Can. 2020;56:123–35.
3. James PB, Wardle J, Steel A, et al. Post-Ebola psychosocial experiences and coping mechanisms among Ebola survivors: a systematic review. Trop Med Int Heal. 2019;24:671–91.
4. Ricci-Cabello I, Meneses-Echavez JF, Serrano-Ripoll MJ, et al. Impact of viral epidemic outbreaks on mental health of healthcare workers: a rapid systematic review and meta-analysis. J Affect Disord. 2020;277:347–57.
5. Wu P, Fang Y, Guan Z, et al. The psychological impact of the SARS epidemic on hospital employees in China: exposure, risk perception, and altruistic acceptance of risk. Can J Psychiatry. 2009;54:302–11.
6. Wang C, Pan R, Wan X, et al. Immediate psychological responses and associated factors during the initial stage of the 2019 coronavirus disease (COVID-19) epidemic among the general population in China. Int J Environ Res Public Health. 2020;17:1729.
7. Sønderskov KM, Dinesen PT, Santini ZI, et al. The depressive state of Denmark during the COVID-19 pandemic. Acta Neuropsychiatr. 2020;32:226–8.
8. Dawel A, Shou Y, Smithson M, et al. The effect of COVID-19 on mental health and wellbeing in a representative sample of Australian adults. Front Psychiatry. 2020;11:579985.
9. Fernández-Aranda F, Casas M, Claes L, et al. COVID-19 and implications for eating disorders. Eur Eat Disord Rev. 2020;28:239–45.
10. Zhou J, Liu L, Xue P, et al. Mental health response to the COVID-19 outbreak in China. Am J Psychiatry. 2020;177:574–5.
11. Rodríguez-Rey R, Garrido-Hernansaiz H, Collado S. Psychological impact and associated factors during the initial stage of the Coronavirus (COVID-19) pandemic among the general population in Spain. Front Psychol. 2020;11:1540.
12. González-Sanguino C, Ausín B, Castellanos MA, et al. Mental health consequences during the initial stage of the 2020 coronavirus pandemic (COVID-19) in Spain. Brain Behav Immun. 2020;87:172–6.
13. Bobes-Bascarán T, Sáiz PA, Velasco A, et al. Early psychological correlates associated with COVID-19 in a Spanish older adult sample. Am J Geriatr Psychiatry. 2020;28:1287–98.
14. Luceño-Moreno L, Talavera-Velasco B, García-Albuerne Y, et al. Symptoms of posttraumatic stress, anxiety, depression, levels of resilience and burnout in Spanish health personnel during the COVID-19 pandemic. Int J Environ Res Public Health. 2020;17:5514.
15. Dosil Santamaría M, Ozamiz-Etxebarri N, Redondo Rodríguez I, et al. Impacto psicológico de la COVID-19 en una muestra de profesionales sanitarios españoles. Rev Psiquiatr Salud Ment. 2021;14:106–12.
16. Alonso J, Vilagut G, Mortier P, et al. Mental health impact of COVID-19 pandemic on Spanish healthcare workers: a large cross-sectional survey. Rev Psiquiatr Salud Ment (Engl Ed). 2021;14:90–105.
17. García-Fernández L, Romero-Ferreiro V, López-Roldán P, et al. Mental health impact of COVID-19 pandemic on Spanish healthcare workers. Psychol Med. 2020;3:49–51.
18. Ayuso-Mateos JL, Morillo D, Haro JM, et al. Changes in depression and suicidal ideation under severe lockdown restrictions during the first wave of the COVID-19 pandemic in Spain: a longitudinal study in the general population. Epidemiol Psychiatr Sci. 2021;30:e49.
19. Vázquez-Barquero JL, Vázquez Bourgón E, Herrera Castanedo S, et al. [Spanish version of the new World Health Organization Disability Assessment Schedule II (WHO-DAS-II): initial phase of development and pilot study Cantabria Disability Work Group]. Actas Esp Psiquiatr. 2000;28:77–87.
20. Kessler RC, Üstün BB. The World Mental Health (WMH) Survey Initiative version of the World Health Organization (WHO) Composite International Diagnostic Interview (CIDI). Int J Methods Psychiatr Res. 2004;13:93–117.
21. Haro JM, Arbabzadeh-Bouchez S, Brugha TS, et al. Concordance of the Composite International Diagnostic Interview Version 3.0 (CIDI 3.0) with standardized clinical assessments in the WHO World Mental Health Surveys. Int J Methods Psychiatr Res. 2006;15:167–80.
22. Ballester L, Alayo I, Vilagut G, et al. Accuracy of online survey assessment of mental disorders and suicidal thoughts and behaviors in Spanish university students Results of the WHO World Mental Health-International College Student initiative. PLoS One. 2019;14:e0221529.
23. García-Campayo J, Zamorano E, Ruiz MA, et al. Cultural adaptation into Spanish of the generalized anxiety disorder-7 (GAD-7) scale as a screening tool. Health Qual Life Outcomes. 2010;8:8.
24. Orlando M, Marshall GN. Differential item functioning in a Spanish translation of the PTSD checklist: detection and evaluation of impact. Psychol Assess. 2002;14:50–9.
25. Bodin T, Çağlayan Ç, Garde AH, et al. Precarious employment in occupational health — an omega-net working group position paper. Scand J Work Environ Health. 2020;46:321–9.
26. Kreshpaj B, Orellana C, Burström B, et al. What is precarious employment? A systematic review of definitions and operationalizations from quantitative and qualitative studies. Scand J Work Environ Health. 2020;46:235–47.
27. Notario-Pacheco B, Solera-Martínez M, Serrano-Parra MD, et al. Reliability and validity of the Spanish version of the 10-item Connor-Davidson Resilience Scale (10-item CD-RISC) in young adults. Health Qual Life Outcomes. 2011;9:63.
28. Ford-Gilboe M, Wathen CN, Varcoe C, et al. Development of a brief measure of intimate partner violence experiences: the Composite Abuse Scale (Revised)-Short Form (CASR-SF). BMJ Open. 2016;6:e012824.
29. Hegarty K, Sheehan M, Schonfeld C. A multidimensional definition of partner abuse. J Fam Violence. 1999;14:399–415.
30. Howe CJ, Cole SR, Lau B, et al. Selection bias due to loss to follow up in cohort studies. Epidemiology. 2016;27:91–7.