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SEQUELAE OF COVID-19 AFTER HOSPITAL DISCHARGE: PROTOCOL FOR IMPLEMENTING A TELEPHONE SURVEY

SEQUELAS DE COVID-19 APÓS A ALTA HOSPITALAR: PROTOCOLO PARA IMPLEMENTAÇÃO DE INQUÉRITO POR TELEFONE

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Abstract

Objective: Given the limited evidence on the persistent effects of COVID-19, this article aims to present the research implementation protocol for monitoring the complications of COVID-19 infection in survivors of hospitalization in the city of Rio de Janeiro. Methodology: Prospective cohort study of adult patients after hospital discharge due to SARS-Cov-2 infection. Patients whose hospital discharge occurred between August 2021 and February 2022 were included. The study population was monitored over a period of 6 months. During this period, the interviews were carried out through a telephone survey with the application of a questionnaire, previously validated, and based on a literature review on instruments and scales for assessing post-COVID-19 clinical conditions. Results: The systematization of the protocol research is essential to promote the reproducibility of the implementation design in similar studies focused on sequelae related to COVID-19. The implementation of field work involved the following steps: (i) selection, recruitment and training of field interviewers (ii) pilot study, (iii) research implementation and cohort follow-up and (iv) monitoring of the quality of the study. Conclusion: The findings of this study are expected to expand the scientific evidence base on research protocols related to the effects of the disease in the Brazilian population, as well as assist in the management of long COVID, especially in clinical and community settings. This research has shown that continuous longitudinal follow-up is critical to better characterize the natural history and pathogenesis of the long-term health consequences of COVID-19.

Keywords: COVID-19; Long COVID; Sequelae; Telephone survey.

Resumo

Objetivo: Dadas as evidências limitadas sobre os efeitos persistentes de COVID-19, este artigo tem como objetivo apresentar o protocolo de implementação de pesquisa para monitoramento das complicações da infecção pelo COVID-19 em sobreviventes de internação na cidade do Rio de Janeiro. Metodologia: Estudo de coorte prospectivo de pacientes adultos após alta

hospitalar por infecção por SARS-Cov-2. Foram incluídos pacientes cuja alta hospitalar ocorreu entre agosto de 2021 e fevereiro de 2022. A população do estudo foi monitorada por um período de 6 meses. Nesse período, as entrevistas foram realizadas por meio de inquérito telefônico com aplicação de questionário, previamente validado, e baseado em revisão de literatura sobre instrumentos e escalas para avaliação de quadros clínicos pós-COVID-19. Resultados: A sistematização da pesquisa do protocolo é essencial para promover a reprodutibilidade do desenho de implementação em estudos semelhantes focados em sequelas relacionadas ao COVID-19. A implementação do trabalho de campo envolveu as seguintes etapas: (i) seleção, recrutamento e treinamento dos entrevistadores de campo (ii) estudo piloto, (iii) implementação da pesquisa e acompanhamento da coorte e (iv) monitoramento da qualidade do estudo. Conclusão: Espera-se que os achados deste estudo ampliem a base de evidências científicas sobre protocolos de pesquisa relacionados aos efeitos da doença na população brasileira, bem como auxiliem no manejo da COVID longa, principalmente em ambientes clínicos e comunitários. Esta pesquisa mostrou que o acompanhamento longitudinal contínuo é fundamental para melhor caracterizar a história natural e a patogênese das consequências de saúde a longo prazo de COVID-19.

Palavras-chave: COVID-19; COVID longa; Sequelas; Inquérito telefónico.

INTRODUCTION

More than two years after the global pandemic caused by SARSCoV-2, special attention has been paid to the ability of the disease to cause severe complications in a considerable proportion of post-hospitalization patients (LUND et al., 2021; AYOUBKHANI et al., 2021). Although in most cases symptoms disappear within two to four weeks after the initial medical condition, a growing body of evidence has been presenting long-term sequelae in about 20% of hospitalized individuals. (WHO, 2021; MIZRAHI et al., 2023 ; CROOK et al., 2021; DE MIRANDA et al., 2022).

The post-COVID-19 condition can display a wide variety of manifestations, the main ones, frequently reported by patients, being fatigue, anxiety, respiratory failure, acute respiratory distress syndrome (ARDS), delirium, propensity to develop blood clots, in addition to cardiac and neurological alterations (KUODI et al., 2022; ROSA et al., 2021). In a systematic review of 53 studies involving patients after hospital discharge, a worse quality of life was observed compared with healthy controls, even after adjustments for age and sex were made. Besides impacting on the health condition, due to physical, cognitive and mental disabilities associated with the

disease, complications generate an additional burden for healthcare services and social security, both already affected after the acute crisis of the pandemic (ROSA et al., 2021; MANNAN et al., 2021).

Longitudinal and ambidirectional cohort study of COVID-19 survivors who were discharged from the Hospital in Wuhan, China, showed that within 1 year after the acute infection, most hospital survivors had a good physical and functional recovery, but the health status was still lower than that of the control population. According to the authors, impairment of pulmonary diffusion and radiographic abnormalities were still common in critically ill patients at 12 months (HUANG et al., 2022). A study in Belgium found that older patients tend to have more severe symptoms, leading to a longer post-COVID-19 period (LORENT et al., 2022).

In Brazil, there are still few studies that have investigated sequelae resulting from post-hospitalization due to COVID-19, which best-known terms are “long-COVID-19”, “post-COVID-19”, “persistent symptoms of COVID-19”, “post-COVID-19 manifestations”, “post-acute COVID-19” and “post-COVID-19 syndrome” (DE MIRANDA et al., 2022; MANNAN et al., 2021). Given the limited evidence on the persistent effects of the disease, this article aims to contribute to the presentation of the implementation protocol of the research on monitoring the COVID-19 infection complications in survivors of hospitalization in the city of Rio de Janeiro.

METHODOLOGY

Study Design:

This is a prospective cohort study of adult patients hospitalized for SARS-Cov-2 in public and private hospitals located in the city of Rio de Janeiro, second largest city in Brazil with 6,320,446 inhabitants, between December 2021 and July 2022. Patients were recruited by a convenience sample, consecutively and not randomly, to compose three monitoring cohorts for a period of nine months (3, 6 and 9 months after hospital discharge) (Figure 1).

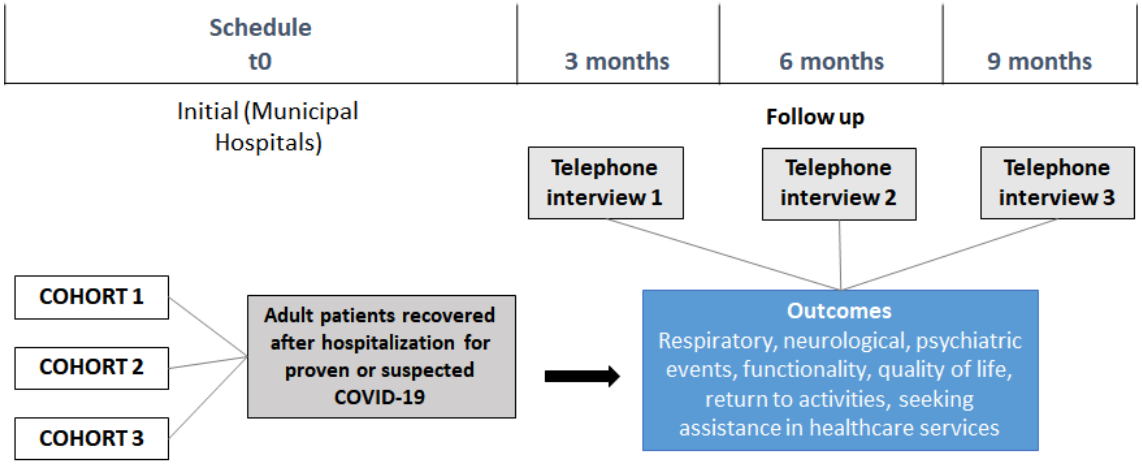

Figure 1 - Schedule of the research implementation on COVID-19 Sequelae in post-hospital discharge patients

Case definition:

For the definition of COVID-19 cases, the clinical-epidemiological criterion recommended by the Ministry of Health was considered. That is, the presence of an acute respiratory condition, characterized by fever or a feverish sensation (in the case of suspected COVID-19, fever may not be present), even if self-reported, accompanied by cough, sore throat, runny nose or breathing difficulty. For the elderly, fever may be absent. Specific criteria of aggravation were also incorporated, such as syncope, mental confusion, excessive sleepiness, irritability and lack of appetite (MS, 2019).

Source of information and eligibility criteria

Participants were identified from the Data Base of two important information systems of the Ministry of Health/DATASUS for COVID-19: SIVEP- Gripe (Influenza Epidemiological Surveillance Information System) and E-SUS VE (Epidemiological Surveillance – a system for registering notifications of suspected COVID-19 cases), which were made available by the State Department of Health of Rio de Janeiro. Adult patients with confirmed diagnosis of COVID-19, which hospital admission occurred in the city of Rio de Janeiro from August 2021 to February 2022, were included in this research.

The eligibility criteria were: (1) being 18 years old or older and (2) having been hospitalized for SARSCoV-2 infection proven by clinical condition or laboratory

diagnosis according to criteria established by the Ministry of Health (MOH). Exclusion criteria adopted included: (1) death during hospitalization, (2) absence of telephone number, (3) absence of a guardian for patients with communication difficulties (aphasia, cognitive deficit, severe hearing loss, non-Portuguese speakers), (4) presence of psychotic disorder, dementia or hospital readmission attributed to underlying diseases; (5) refusal or withdrawal of participation. Children and adolescents were not included because they had other patterns of complications, including multisystem inflammatory syndrome.

Outcomes and associated factors

The primary outcome, the central variable to answer the research question of this study, is the prevalence of complications (symptoms that extend after the acute infection). It was decided to use the term Long COVID to describe the presence of symptoms, inherently continuous or recurrent and decreasing, that persist for weeks or months after the initial diagnosis of SARS-CoV-2 infection (DE MIRANDA et al., 2022; MANNAN et al., 2021). The criterion adopted was that proposed by the National Institute for Health and Care Excellence (NICE), in England, where Long COVID can be divided into two stages: acute post-COVID-19 phase, where symptoms extend beyond 3 weeks, but less than 12 weeks, and chronic COVID phase, where symptoms appear beyond 12 weeks (LORENT et al., 2022). A set of variables will be added as potential factors associated with eligible outcomes in this research: demographic characteristics (age and sex), health condition (comorbidities, physical functional status before hospitalization and previous use of medications), clinical characteristics of the disease and, at last, the need for ICU admission, use of ventilatory support and the need for neuromuscular blockers.

Data collection instrument

The questionnaire for data collection was based on a literature review on instruments and scales to assess post-COVID-19 clinical conditions. Based on consultation with specialists in the areas of infectiology, pneumology and neurology, validated international scales were selected and used in similar research. The instrument contained a total of 70 questions and considered the following dimensions: a) general information; b) physical condition; c) respiratory or

cardiopulmonary symptoms; d) neurological, neuropsychiatric symptoms and psychological disorders; e) functional condition; f) reference units used for medical care and/or rehabilitation after hospital discharge (MS, 2019; NALBANDIAN et al., 2021; AYOUBKHANI et al., 2021; CHIPPA et al., 2022; KATAL et al., 2021; FREDERIKUS et al., 2020).

The scales included in the question blocks were those validated for the Brazilian population, a process by which equivalence between the original and final questionnaires is obtained based on the peculiarities of the target audience (ZHAO et al., 2020; WHO, 2020). In cases where the scales were not in the public domain, the authors were formally requested to authorize their use, including the process of translation and re-translation (English-Portuguese). The final validation process of the instrument took place through a panel of specialists involving the areas of infectiology, pneumology and neurology.

1. The Modified Medical Research Council (mMRC) scale for assessing dyspnea (0-4 scale) (MAHLER; WELLS, 1988). An mMRC score of 0-1 was considered mild, 2; moderate, 3 or 4 to indicate severe or very severe dyspnea, respectively.
2. The Eastern Cooperative Oncology Group Performance Status (PS-ECOG) Rating Scale assesses how the disease affects the patient's daily living skills, with a score ranging from zero to five points (SOK et al., 2019). The cutoff point equal to or greater than 3 was considered to be a patient with limited ability to carry out their daily activities.
3. Modified Borg scale (MBS) mainly used to evaluate the perception of dyspnea by individuals in a situation of physical exercise. A vertical scale quantified from 0 to 10, where 0 represents no symptoms and 10 represents maximum symptoms.
4. Six-Item Cognitive Screener used to assess cognitive performance (FERREIRA et al., 1998; GALE et al., 2017). It consists of six questions; three for memory (task: remembering the name of 3 items) and three for orientation (year, month and day of the week). A rating of 0-2 was considered no cognitive impairment and 3-6; suggestive of cognitive impairment.
5. The Patient Health Questionnaire (PHQ-9) Scale to evaluate patient health for Anxiety and Depression (KROENKE et al., 2009), used in a simplified version (PHQ-2). This screening instrument has 2 questions focused on symptoms of depression, with a score ranging from 0 to 3. A classification of 0-1 was considered no depressive

disorder and 2-6; suggestive of a depressive disorder.

6. The Generalized Anxiety Disorder (GAD-7) Scale to assess anxiety-related disorders, in its shortest version (GAD-2), uses only the first two questions, which represent the main symptoms of any anxiety disorder (SAPRA et al., 2020). A classification of 0-1 was considered no anxiety disorder and 2-6; suggestive of anxiety disorder.

7. The Primary Care of Post Traumatic Stress Disorder (PC-PTSD-5) Scale for screening post-traumatic stress disorder (PTS) was adapted with five questions (PRINS et al., 2016). The respondent is instructed to answer yes/no about how this trauma has affected them in the last month and can score from 0 to 5, assigning one point for a “yes” answer. A rating of 0-2 was considered no PTS disorder and 3-5; suggestive of PTS.

8. *WHO* disability assessment schedule (WHODAS 2.0) to measure disability caused by health conditions, validated in Brazil in 2016 (SALOMÃO, 2016). It evaluates the domains of cognition, mobility, self-care, interpersonal relationships, life activities and participation. The short version containing 12 questions was used. Based on a Brazilian study in the elderly population (FERRER et al., 2019), the score was from 0 to 4 in each question and the global score was 0-1: no disability; 2-5: mild disability; 6-11: moderate disability and >=12: severe disability.

9. Work Productivity and Activity Impairment: General Health (WPAI-GH) to assess loss of productivity at (paid or unpaid) work caused by health problems. Five questions are used to measure time lost from work (absenteeism), loss of productivity at work (presenteeism) and loss of general productivity in activities of daily living. Calculations are based on specific formulas, estimated from the number of hours and a score from 0 to 10 that resembles the Likert scale.

Data analysis

Frequencies and percentages of the results obtained in the study and their 95% confidence intervals will be calculated. Adjusted results will be presented using central tendency and dispersion measures, along with the mean or median difference as a measure of effect size.

The analysis of post-COVID-19 sequelae will be discussed as a prevalence ratio, using clinically relevant cutoffs. The established statistical significance level will

be 0.05 for all comparisons. As this is an exploratory study, the association between independent variables and outcomes will be evaluated using generalized estimation equations, and the analyses will be conducted using the R program (*R Development Core Team*).

RESULTS

Research implementation

This step corresponded to the operationalization of the research implementation process and involved: (i) selection and training of field interviewers (ii) pilot study (iii) research implementation: dissemination of the project and cohort follow-up and (iv) monitoring the quality of the study.

(i) The selection process of the field interviewers occurred through a public call, in partnership with the Coordination of the Professional Master's Degree in Family Health (PROFSAÚDE), linked to the Vice-Presidency of Education and Research of the Oswaldo Cruz Foundation. The team of interviewers was made up of healthcare professionals, familiar with the field of public health and who have previous experience in field research. The training was carried out through weekly online meetings, using virtual platforms, a space that later became the communication channel to guarantee the quality monitoring of the field work. The context of the research, its objectives and methodological design were addressed. For a better understanding of the questions, the “Manual for Conducting Telephone Interviews” was previously sent, for individual reading, as well as the data collection instrument. The objective was to discuss each item of the instrument and point out potential difficulties in its application during the virtual meeting. The questions that mentioned technical terms caused the need for semantic analysis, inviting the interviewee to indicate how they understood the content of the questionnaire items. Previously, each interviewer carried out a telephone collection with a volunteer, having similar characteristics to the study population (individual recovered after hospitalization for COVID-19), to clarify additional doubts. This phase also had the guidance of specialists (neurologist, infectiologist and pneumologist) for the applying of the questionnaire scales, which expanded the understanding of the instrument and helped in conducting the pilot test.

(ii) The pilot stage of the research aimed to obtain feedback on the clarity, objectivity and completeness of the collection instrument for its subsequent readjustment and improvement. A pre-test of the instrument was carried out with a group of patients recovered from COVID-19, from a hospital unit outside the prospective cohort, and who met the criteria established in the methodology. A spreadsheet was created with 22 eligible patients who were initially contacted by recruiters, undergraduate healthcare students, to disseminate the research and identify acceptance to participate in the interview to be held on a previously established day and time. The interviews, planned to last around 20 minutes, were recorded for further feedback directed to the interviewers on the necessary adjustments in the application of the questionnaire with the study participants. The pilot helped defining the interviewee's understanding of the questions, the interviewer's degree of difficulty in applying the scales in the real context of field work, as well as measuring the interview time. It was also a strategic phase for complementing the training of the interviewers in the field.

(iii) The cohort follow-up was established through a follow-up schedule, with the participants' agreement and according to their availability, so that contact could be made at 3, 6 and 9 months after hospital discharge, corresponding to the 1st, 2nd and 3rd study cohorts respectively (Figure 2). Each interviewer received a list of potential participants, randomly assigned, and the follow-up took place through voice or video call, at the participant's discretion, lasting 20 to 30 minutes. In order to guarantee the safety of the study participants, each interview was initiated by assuring that no information about passwords, card numbers or other data that would compromise the safety of the participants would be requested. The telephone interviews were recorded to verify consistency in data collection and the files were stored anonymously as to comply with the security standards according to the General Data Protection Law (LGPD). In compliance with the Guidelines for Conducting Research and Activities of CEPs during the Pandemic caused by the SARS-CoV-2 Coronavirus (COVID-19) (SEI/MS 0014765796, Brasília May 9, 2020), the Free and Informed Consent Form (FICF) was read and the participant's consent was recorded over the phone. Additionally, a copy of the document was sent via email to the participant. For those with communication difficulties and/or who needed support from a family member or caregiver, an FICF was drawn up for the guardian,

which was also read and the consent was recorded, when the participants agreed to it. They were classified as “lost to follow-up” after five unsuccessful contact attempts, at different times, and on several days within the window period (±15 days of the period of each wave of interviews). The interview records were coded in a structured database to allow further analysis of the information.

Figure 2 - Recruitment and cohort follow up flowchart of the post-COVID-19 recovered patients

(iv) Monitoring the quality of the study - To ensure the reliability and validity of responses, quality control monitoring was applied throughout the process. The following aspects were considered:

1. Telephone interviews were randomly recorded and audited to verify consistency in data collection. Audio files were stored anonymously on a server that will comply with the same security standards used for electronic clinical record data. Access to these files, which is restricted to the study team, will require user identification and password.
2. Data were entered into standardized data collection forms and stored using an electronic data capture system, and files exported in digital media for later verification and backup.
3. A data cleaning routine was applied in cases of inconsistency detection or missing data. This information also provided feedback regarding re-training needs.
4. Finally, the delivery of collected materials was periodically checked, which included the database, interview recordings and backup.

DISCUSSION

Given that the management of COVID-19 complications remains a challenge for healthcare professionals, this paper contributes to the importance of systematizing, through a research implementation protocol, the stages of detection of post-hospitalization disease sequelae, via telephone survey. Caring about the standardization of conduct, from the participant selection and recruitment to conducting the interviews, along with quality monitoring, are essential to ensure the reproducibility of the implementation design in similar research focused on the study of Long-COVID. By adding different scales of analysis, the protocol can be used in patients with different impairments, being relevant given that the post-COVID-19 syndrome can have numerous distinct sequelae (TSAGKARIS et al., 2022).

Given that the protocols must consider the comorbidities that may affect the clinical evolution of infected patients, it is suggested a multidisciplinary approach, bringing together different medical specialties and other areas of health both in protocol training and in the analysis of evidence (APÓSTOLO et al., 2018). The pre-scheduling of potential respondents served to increase the efficiency of the study

management, maximizing the adherence of the interviewees. Then, the telephone collection allowed the interviews to be carried out in a short period of time, optimizing the research implementation, especially in the context of a post-epidemic outbreak. It is expected that these research results can expand the scientific knowledge base on the effects of the disease in the Brazilian population, as well as help in the handling of Long COVID, mainly in clinical and community settings.

The strengths of the research are the inclusion of a significant sample of survivors who were hospitalized for COVID-19 in the city of Rio de Janeiro and the possibility of developing patient-centered evaluation of results. The potential limitations are not including a control arm in the study design that could explain the effects over time of analysis, losses to follow-up and the difficulty of participants to respond effectively to the telephone survey.

The results signal that continuous longitudinal follow-up is critical to better characterize the natural history and pathogenesis of the long-term health consequences of COVID-19.

ETHICS AND DISSEMINATION

The research was approved by the Research Ethics Committee of the Municipal Health Department of Rio de Janeiro, of CAAE 49766021.0.0000.5279. Terms of Free and Informed Consent (FICF) collected from participants or their families and/or caregivers, after consenting in the first telephone contact, will be filed, kept confidential and accessed restrictedly only by researchers. For the dissemination of the results, in addition to the statistical analysis plan, those will be sent for publication in peer-reviewed journals regardless of the results achieved.

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