VIA MEDICA

ORIGINAL ARTICLE

Aldona Kubica[1], Piotr Michalski[1], Łukasz Pietrzykowski[1], Alicja Rzepka-Cholasińska[1], Agata Kosobucka-Ozdoba[1], Małgorzata Jasiewicz[2], Ewa Laskowska[2], Jacek Kryś[3], Małgorzata Ostrowska[2]

[1]Department of Cardiological Rehabilitation and Health Promotion, Collegium Medicum, Nicolaus Copernicus University, Bydgoszcz, Poland
[2]Department of Cardiology and Internal Medicine, Bydgoszcz, Poland
[3]Department of Health Economics, Bydgoszcz, Poland

Post-COVID-19 rehabilitation (PCR-SIRIO 8) study. A rationale and protocol of the study

Corresponding author:

Aldona Kubica, Department of Health Promotion, Collegium Medicum, Nicolaus Copernicus University, Bydgoszcz, Poland;
e-mail: akubica@cm.umk.pl

Medical Research Journal 2022; Volume 7, Number 4, 280–283
10.5603/MRJ.a2022.0046

ISSN 2451-2591
e-ISSN 2451-4101

ABSTRACT

A substantial proportion of the COVID-19 survivors require the physical and mental support due to the post COVID-19 syndrome. In response to this demand a comprehensive rehabilitation program tailored to the individual needs has been developed. The program is linked with a Post-COVID-19 Rehabilitation (PCR-SIRIO 8) study that aims to objectively evaluate the outcomes of the post-COVID-19 rehabilitation. The study was designed as a prospective, single-center, observational study involving patients suffering from post-COVID-19 syndrome. Patients meeting the inclusion criteria are invited for an initial visit including medical and physiotherapeutic examination. Rehabilitation program includes physical training, therapeutic education, and psychotherapeutic workshops. Individual psychotherapeutic, educational and medical visits are carried out additionally depending on the patient's needs. Closing visit evaluates individual effects of the rehabilitation program.

We believe that our observational study will provide knowledge necessary to optimize post-COVID-19 rehabilitation.

Key words: COVID-19, rehabilitation

Med Res J 2022; 7 (4): 280–283

Introduction

In late 2019 a highly pathogenic novel coronavirus of severe acute respiratory syndrome (SARS-CoV-2) emerged, causing a global pandemic of coronavirus disease-2019 (COVID-19). This new hitherto unknown disease, has had a huge devastating impact on the lives of individuals and entire societies [1–12]. There are three stages of the COVID-19:

— up to 4 weeks — acute phase;
— between 4–12 weeks — phase of persistent symptoms closely related to the clinical course of the SARS-CoV-2 infection;
— over 12-weeks — the chronic phase, often defined as the post COVID-19 syndrome — the symptoms that developed during the acute phase of infection take a chronic course with no other clinical justification for other accompanying diseases [13].

The last two phases are referred to post active phase of infection syndrome (post COVID-19 syndrome). It should be emphasized that the course of the acute phase of SARS-CoV-2 infection does not determine the course of the recovery period and the risk of the post COVID-19 syndrome [14]. While the symptoms that appear in the acute phase of the SARS-CoV-2 infection are relatively homogeneous, the clinical presentation of the post COVID-19 syndrome is diverse [13]. The most common symptoms include:

— respiratory symptoms: shortness of breath, cough, sputum production;
— cardiovascular symptoms: chest pain, arrhythmias, heart failure;
— general symptoms: chronic fatigue, fever, non-specific pain complaints (*e.g.* joint pain, muscle pain, headache), gastric disorders, nausea, cognitive disorders (mainly in the field of basic operational

functions, the so-called "brain fog"), memory and concentration disorders, sleep disorders (shallowing and fragmentation), symptoms of peripheral neuropathy, mental disorders (anxiety, depression) [13, 14].

A substantial proportion of the COVID-19 survivors develop symptoms of the post COVID-19 syndrome during their convalescence [15]. In order to return to normal life, work and routine activities, post-COVID-19 convalescents need support both in the physical and mental spheres. In response to this demand, we have developed a comprehensive post-COVID-19 rehabilitation program tailored to the individual needs. The program is linked with a Post-COVID-19 Rehabilitation (PCR-SIRIO 8) study that aims to objectively evaluate the outcomes of the post-COVID-19 rehabilitation.

Material and methods

The study was designed as a prospective, single-center, observational study involving patients suffering from post-COVID-19 syndrome who undergo a dedicated multidisciplinary outpatient rehabilitation program in Dr. Antoni Jurasz University Hospital No.1 in Bydgoszcz, Collegium Medicum, Nicolaus Copernicus University, Poland. The study protocol was approved by the Ethics Committee of the Collegium Medicum, Nicolaus Copernicus University (approval number KB 414/2021). All patients in our post-COVID-19 rehabilitation program who give their informed consent are enrolled in the study.

The post-COVID-19 rehabilitation program is individualized depending on the respiratory and cardiovascular capacity and the profile of neuropsychiatric disorders assessed at the initial visit. We assume that such strategy allows to obtain optimal benefits. The aims of the program include:

— improvement of exercise capacity;
— improvement of respiratory efficiency and muscle strength;
— improvement of overall physical fitness;
— improvement of neurocognitive functions;
— mental health support;
— comprehensive health education.

The inclusion criteria to the post-COVID-19 rehabilitation program are based on the characteristics of the reported symptoms, their severity and the period that has elapsed since the COVID-19 diagnosis.

The inclusion criteria:

Up to 12 months after termination of diagnosis of the COVID-19 and any of the following:

— at least slight functional limitations diagnosed with the use of the Post-COVID-19 Functional Status (PCFS) scale (score > 1);
— decrease of muscle strength according to the Medical Research Council (MRC) scale for muscle strength > 1;
— severity of dyspnea according to the modified MRC (mMRC) dyspone scale > 2.

The exclusion criteria:

The severity of symptoms that prevent patients from functioning independently in the physical and/or mental sphere.

Protocol of the PCRP-SIRIO 8 study

The COVID-19 survivors meeting the inclusion criteria are invited for an initial visit including medical and physiotherapeutic examination to exclude contraindications to the rehabilitation program (Fig. 1). Patients who gave written informed consent are included in the study. Baseline study evaluation includes: body composition assessment, ergospirometry, assessment of patients' functioning (FCIS, Functioning in Chronic Disease Scale), quality of live evaluation (Heart QoL), assessment of adherence to dietary recommendations (ACDS Diet, Adherence in Chronic Diseases Scale Diet) and laboratory tests: complete blood count, glucose, sodium, potassium, creatinine, estimated glomerular filtration rate, C-reactive protein, N-terminal pro-brain natriuretic peptide, thyroid stimulating hormone) [16–24]. The following scales and tests are used in baseline physioterapeutic study assessment: muscle strength testing (MRC scale for muscle strength), assessment of the perceived exertion (Borg scale), fatigue assessment (MFIS, Modified Fatigue Impact Scale), dyspnea assessment (mMRC dyspnoe scale), respiratory pattern assessment, assessment of the exercise tolerance (6MWT, 6 Minute Walk Test; ISWT, Incremental Shuttle Walk Test; 30CST, 30 second Chair Stand Test), physical fitness assessment (SPPB test, Short Physical Performance Battery test). Therapeutic visits, including physical training and therapeutic education (topics: What is dyspnea and how can I deal with it?; How can I deal with Chronic Fatigue Syndrome?; Learning of physical activity planning; Dietary recommendations for patients after COVID-19; Self-assessment of the respiratory system; Smoking and the respiratory system; Inhalation learning; Learning of breathing exercises; Learning to cough effectively; Take care of your heart) take place three times a week, and psychotherapeutic workshops (topics: Anxiety disorders and depression — does it affect me?; How can I cope with stress?; Memory and attention exercises) are performed once a week for 6 weeks. Moreover, individual psychotherapy, education and medical visits are carried out additionally depending on the patient's needs [25–34]. Closing visit evaluates individual effects of the rehabilitation program applying body composition assessment, ergospirometry, FCIS, ACDS Diet and Heart QoL, muscle strength testing, Borg scale, MFIS, mMRC dyspnoe scale, 6MWT, ISWT, 30CST, SPPB test (Fig. 1).

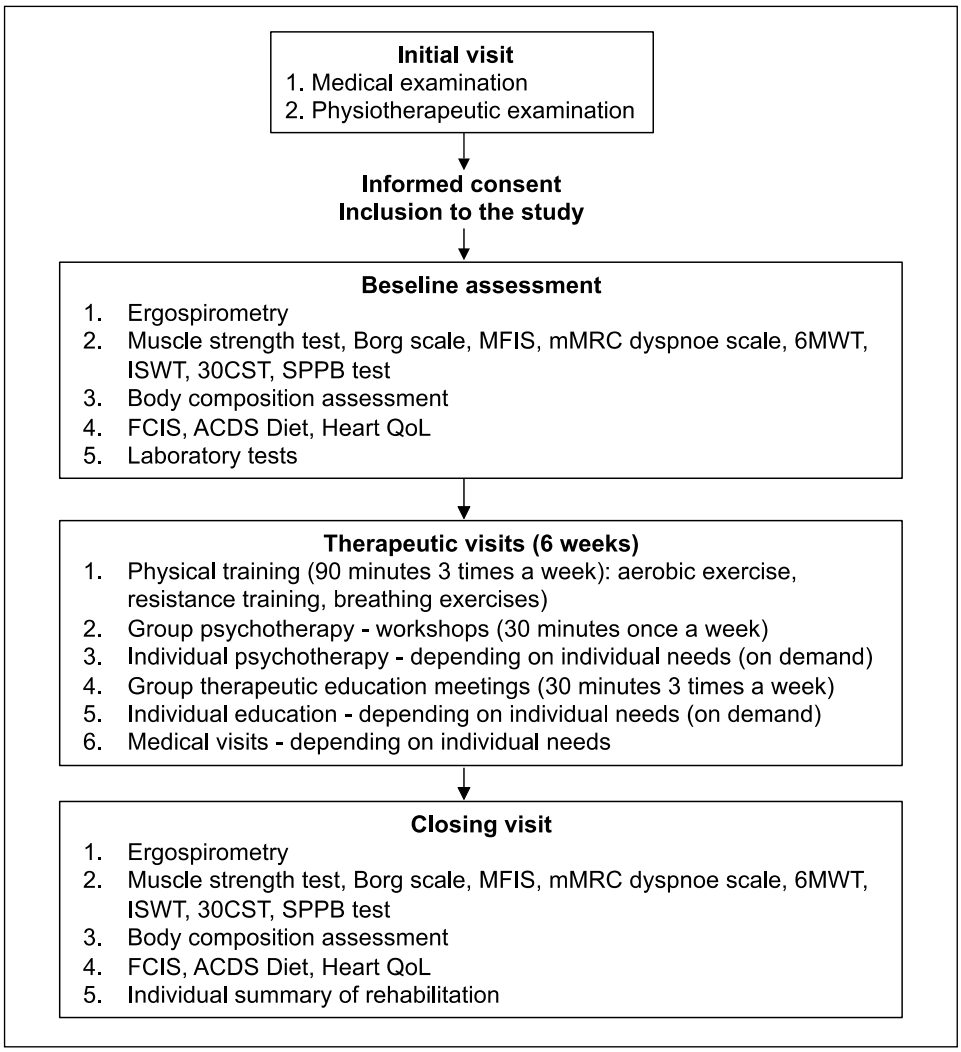

Figure 1. The PCR-SIRIO 8 study flow chart

Discussion

According to the Stanford Hall consensus statement for post-COVID-19 rehabilitation in UK up to 50% of hospitalized patients with COVID-19 may require ongoing care with the goal of improving long-term outcomes [35]. The British Society of Rehabilitation Medicine has developed a position statement that includes the rehabilitation care pathways and coordinated networks that will be required following the COVID-19 pandemic [36]. Following recommendations contained in both documents we developed a patient-centred and tailored to individual patient's needs rehabilitation program. Taking into account physical, cognitive and psychological issues related to the post-COVID-19 syndrome a holistic approach to managing these issues was planned [15]. In line with our previous experience education of patients is a key part in our rehabilitation programs [20, 27, 28]. Unfortunately, there is sparse evidence on results of rehabilitation in post-COVID-19 patients, therefore we applied objective measures to evaluate results of our rehabilitation program. We believe that our observational study will provide knowledge necessary to optimize post-COVID-19 rehabilitation.

References

1. Paciorek P, Romaniuk M, Husejko J, et al. Impact of COVID-19 pandemic on emergency medical service response to emergency calls — a retrospective analysis of data from Emergency Medical Service station in Bydgoszcz. Medical Research Journal. 2022; 7(3): 190–196, doi: 10.5603/mrj.a2022.0033.
2. Nadolny K, Ładny JR, Zyśko D, et al. Interventions of emergency medical teams in Poland during the SARS-CoV-2 pandemic. Kardiol Pol. 2021; 79(1): 72–75, doi: 10.33963/KP.15632, indexed in Pubmed: 33021351.
3. Ratajczak J, Szczerbiński S, Kubica A. Occurrence and Temporal Variability of Out-of-Hospital Cardiac Arrest during COVID-19 Pandemic in Comparison to the Pre-Pandemic Period in Poland-Observational Analysis of OSCAR-POL Registry. J Clin Med. 2022; 11(14): 4143, doi: 10.3390/jcm11144143, indexed in Pubmed: 35887907.

4. Szczerbiński S, Ratajczak J, Jasiewicz M, et al. Observational analysiS of out-of-hospital Cardiac Arrest occurRence and temporal variability patterns in subpopulation of southern POLand from 2006 to 2018: OSCAR-POL registry. Cardiol J. 2021 [Epub ahead of print], doi: 10.5603/CJ.a2021.0060, indexed in Pubmed: 34312830.
5. Kubica J, Podhajski P, Magielski P, et al. IMPACT of PCSK9 inhibition on clinical outcome in patients during the inflammatory stage of the SARS-COV-2 infection: Rationale and protocol of the IMPACT-SIRIO 5 study. Cardiol J. 2022; 29(1): 140–147, doi: 10.5603/CJ.a2021.0148, indexed in Pubmed: 34787891.
6. Szczerbinski S, Ratajczak J, Lach P, et al. Epidemiology and chronobiology of out-of-hospital cardiac arrest in a subpopulation of southern Poland: A two-year observation. Cardiol J. 2020; 27(1): 16–24, doi: 10.5603/CJ.a2018.0025, indexed in Pubmed: 29611174.
7. Bielski K, Szarpak A, Jaguszewski MJ, et al. The influence of COVID-19 on out-hospital cardiac arrest survival outcomes: an updated systematic review and meta-analysis. J Clin Med. 2021; 10(23): 5573, doi: 10.3390/jcm10235573, indexed in Pubmed: 34884289.
8. Nadolny K, Szczerbiński S, Ładny J, et al. Out-of-hospital cardiac arrest and COVID-19 pandemic. Medical Research Journal. 2021; 6(2): 83–85, doi: 10.5603/mrj.2021.0029.
9. Kubica J, Ostrowska M, Stolarek W, et al. Impact of COVID-19 pandemic on acute heart failure admissions and mortality: a multicentre study (COV-HF-SIRIO 6 study). ESC Heart Fail. 2022; 9(1): 721–728, doi: 10.1002/ehf2.13680, indexed in Pubmed: 34786869.
10. Ostrowska M, Kasprzak M, Stolarek W, et al. Longer hospitalizations and higher in-hospital mortality for acute heart failure during the COVID-19 pandemic in larger vs. smaller cardiology departments: subanalysis of the COV-HF-SIRIO 6 multicenter study. Rev Cardiovasc Med. 2022; 23(9): 292, doi: 10.31083/j.rcm2309292.
11. Lackowski P, Piasecki M, Kasprzak M, et al. COVID-19 pandemic year in the cardiology department. Medical Research Journal. 2021; 6(1): 40–46, doi: 10.5603/mrj.a2021.0009.
12. Granström J, Lantz P, Lidin M, et al. Perceptions of delay when afflicted by an acute myocardial infarction during the first wave of the COVID-19 pandemic. Eur J Cardiovasc Nurs. 2022 [Epub ahead of print], doi: 10.1093/eurjcn/zvac021, indexed in Pubmed: 35672906.
13. Akbarialiabad H, Taghrir MH, Abdollahi A, et al. Long COVID, a comprehensive systematic scoping review. Infection. 2021; 49(6): 1163–1186, doi: 10.1007/s15010-021-01666-x, indexed in Pubmed: 34319569.
14. Friedman KJ, Murovska M, Pheby DFH, et al. Our evolving understanding of ME/CFS. Medicina (Kaunas). 2021; 57(3): 200, doi: 10.3390/medicina57030200, indexed in Pubmed: 33652622.
15. Kubica A, Michalski P, Kasprzak M, et al. Functioning of patients with post-COVID syndrome — preliminary data. Medical Research Journal. 2021; 6(3): 224–229, doi: 10.5603/mrj.a2021.0044.
16. Kubica A. Self-reported questionnaires for a comprehensive assessment of patients after acute coronary syndrome. Medical Research Journal. 2019; 4(2): 106–109, doi: 10.5603/mrj.a2019.0021.
17. Michalski P, Kasprzak M, Kosobucka A, et al. Sociodemographic and clinical determinants of the functioning of patients with coronary artery disease. Medical Research Journal. 2021; 6(1): 21–27, doi: 10.5603/mrj.a2021.0003.
18. Buszko K, Pietrzykowski Ł, Michalski P, et al. Validation of the Functioning in Chronic Illness Scale (FCIS). Medical Research Journal. 2018; 3(2): 63–69, doi: 10.5603/mrj.2018.0011.
19. Kubica A, Kosobucka A, Michalski P, et al. Self-reported questionnaires for assessment adherence to treatment in patients with cardiovascular diseases. Medical Research Journal. 2017; 2(4): 115–122, doi: 10.5603/mrj.2017.0015.
20. Kubica A, Adamski P, Bączkowska A, et al. The rationale for Multilevel Educational and Motivational Intervention in Patients after Myocardial Infarction (MEDMOTION) project is to support multicentre randomized clinical trial Evaluating Safety and Efficacy of Two Ticagrelor-based De-escalation Antiplatelet Strategies in Acute Coronary Syndrome (ELECTRA – SIRIO 2). Medical Research Journal. 2020; 5(4): 244–249, doi: 10.5603/mrj.a2020.0043.
21. Kubica A, Kosobucka A, Fabiszak T, et al. Assessment of adherence to medication in patients after myocardial infarction treated with percutaneous coronary intervention. Is there a place for newself-reported questionnaires? Curr Med Res Opin. 2019; 35(2): 341–349, doi: 10.1080/03007995.2018.1510385, indexed in Pubmed: 30091642.
22. Kosobucka A, Michalski P, Pietrzykowski Ł, et al. Adherence to treatment assessed with the Adherence in Chronic Diseases Scale in patients after myocardial infarction. Patient Prefer Adherence. 2018; 12: 333–340, doi: 10.2147/PPA.S150435, indexed in Pubmed: 29551891.
23. Kubica A, Obońska K, Fabiszak T, et al. Adherence to antiplatelet treatment with P2Y12 receptor inhibitors. Is there anything we can do to improve it? A systematic review of randomized trials. Curr Med Res Opin. 2016; 32(8): 1441–1451, doi: 10.1080/03007995.2016.1182901, indexed in Pubmed: 27112628.
24. Kubica A, Obońska K, Kasprzak M, et al. Prediction of high risk of non-adherence to antiplatelet treatment. Kardiol Pol. 2016; 74(1): 61–67, doi: 10.5603/KP.a2015.0117, indexed in Pubmed: 26101025.
25. Pietrzykowski Ł, Michalski P, Kosobucka A, et al. Knowledge about health and disease in obese patients after myocardial infarction. An observational study. Medical Research Journal. 2018; 2(4): 135–140, doi: 10.5603/mrj.2017.0018.
26. Michalski P, Kosobucka A, Pietrzykowski Ł, et al. Effectiveness of therapeutic education in patients with myocardial infarction. Medical Research Journal. 2017; 2(3): 89–96, doi: 10.5603/mrj.2017.0011.
27. Kubica A, Bączkowska A. Uzasadnienie interwencji motywacyjnych jako kluczowego elementu projektu wielopoziomowej edukacji i motywacji u pacjentów z zawałem serca (MEDMOTION). Folia Cardiologica. 2020; 15(1): 6–10, doi: 10.5603/fc.2020.0003.
28. Kubica A, Gruchała M, Jaguszewski M, et al. Adherence to treatment — a pivotal issue in long-term treatment of patients with cardiovascular diseases. An expert standpoint. Medical Research Journal. 2018; 2(4): 123–127, doi: 10.5603/mrj.2017.0016.
29. Michalski P, Kasprzak M, Siedlaczek M, et al. The impact of knowledge and effectiveness of educational intervention on readiness for hospital discharge and adherence to therapeutic recommendations in patients with acute coronary syndrome. Medical Research Journal. 2020; 5(2): 72–78, doi: 10.5603/mrj.a2020.0023.
30. Pietrzykowski Ł, Kasprzak M, Michalski P, et al. The influence of patient expectations on adherence to treatment regimen after myocardial infarction. Patient Educ Couns. 2022; 105(2): 426–431, doi: 10.1016/j.pec.2021.05.030, indexed in Pubmed: 34059362.
31. Pietrzykowski Ł, Kasprzak M, Michalski P, et al. Therapy Discontinuation after Myocardial Infarction. J Clin Med. 2020; 9(12): 4109, doi: 10.3390/jcm9124109, indexed in Pubmed: 33352811.
32. Pietrzykowski Ł, Michalski P, Kosobucka A, et al. Medication adherence and its determinants in patients after myocardial infarction. Sci Rep. 2020; 10(1): 12028, doi: 10.1038/s41598-020-68915-1, indexed in Pubmed: 32694522.
33. Kubica A, Kasprzak M, Obońska K, et al. Discrepancies in assessment of adherence to antiplatelet treatment after myocardial infarction. Pharmacology. 2015; 95(1-2): 50–58, doi: 10.1159/000371392, indexed in Pubmed: 25592409.
34. Kubica A, Kasprzak M, Siller-Matula J, et al. Time-related changes in determinants of antiplatelet effect of clopidogrel in patients after myocardial infarction. Eur J Pharmacol. 2014; 742: 47–54, doi: 10.1016/j.ejphar.2014.08.009, indexed in Pubmed: 25199965.
35. Barker-Davies RM, O'Sullivan O, Senaratne KP, et al. The Stanford Hall consensus statement for post-COVID-19 rehabilitation. Br J Sports Med. 2020; 54(16): 949–959, doi: 10.1136/bjsports-2020-102596, indexed in Pubmed: 32475821.
36. Phillips M, Turner-Stokes L, Wade D et al. Rehabilitation in the wake of Covid-19 - A phoenix from the ashes. https://www.bsrm.org.uk/downloads/covid-19bsrmissue1-published-27-4-2020.pdf (16.09.2022).