



Early View

Research letter

Eight lessons from two-year use of the Post-COVID-19 Functional Status scale

Cindy M.M. de Jong, Y.N. Jenny Le, Gudula J.A.M. Boon, Stefano Barco, Frederikus A. Klok, Bob Siegerink

Please cite this article as: de Jong CMM, Le YNJ, Boon GJAM, *et al.* Eight lessons from two-year use of the Post-COVID-19 Functional Status scale. *Eur Respir J* 2023; in press (<https://doi.org/10.1183/13993003.00416-2023>).

This manuscript has recently been accepted for publication in the *European Respiratory Journal*. It is published here in its accepted form prior to copyediting and typesetting by our production team. After these production processes are complete and the authors have approved the resulting proofs, the article will move to the latest issue of the ERJ online.

Copyright ©The authors 2023. This version is distributed under the terms of the Creative Commons Attribution Non-Commercial Licence 4.0. For commercial reproduction rights and permissions contact permissions@ersnet.org

Eight lessons from two-year use of the Post-COVID-19 Functional Status scale

Cindy M.M. de Jong¹, Y.N. Jenny Le², Gudula J.A.M. Boon¹, Stefano Barco^{3,4}, Frederikus A. Klok¹, Bob Siegerink²

¹Department of Medicine - Thrombosis and Hemostasis, Leiden University Medical Center, Leiden, the Netherlands

²Department of Clinical Epidemiology, Leiden University Medical Center, Leiden, the Netherlands

³Department of Angiology, University Hospital Zurich, Zurich, Switzerland

⁴Center for Thrombosis and Hemostasis, University Hospital Mainz, Mainz, Germany

Corresponding author:

Bob Siegerink

Department of Clinical Epidemiology, Leiden University Medical Center, Leiden, the Netherlands

Address: Albinusdreef 2, 2333 ZA, Leiden, the Netherlands

E-mail address: b.siegerink@lumc.nl

Phone number: +31-715265634

Twitter: @BobSiegerink

ORCID ID:

CMM de Jong: 0000-0002-2310-5820

YNJ Le: 0000-0003-0729-4016

GJAM Boon: 0000-0003-4532-436X

S Barco: 0000-0002-2618-347X

FA Klok: 0000-0001-9961-0754

B Siegerink: 0000-0002-8454-9142

Text word count: 1194

Number of references: 15

Number of tables and/or figures: 1

Take home message

Based on the literature and users' experiences, lessons could be learned after two-year use of the Post-COVID-19 Functional Status (PCFS) scale, that could contribute to its optimal use. All in all, the PCFS scale provided added value during the pandemic.

Key words

COVID-19

Functional Status

Patient Reported Outcome Measure

Post-COVID-19 Functional Status scale

Research letter

The number of confirmed cases of coronavirus disease 2019 (COVID-19) worldwide exceeded 750 million as of February 2023[1], leaving an estimated 65 million individuals experiencing post-acute sequelae of COVID-19 or 'long COVID', or a modelled estimate of 6.2% of individuals experiencing long COVID symptoms three months after symptomatic SARS-CoV-2 infection.[2, 3] Early in the pandemic, we proposed the Post-COVID-19 Functional Status (PCFS) scale in the European Respiratory Journal, which resulted from a slight adaptation of the Post-Venous thromboembolism Functional Status (PVFS) scale developed in 2019.[4-6] The PCFS scale is designed to monitor functional recovery and identify patients with incomplete or poor recovery after COVID-19 in research and clinical practice.

Since the introduction of the PCFS scale, the uptake and incorporation in the COVID-19 research community have been well with an altmetrics score of 149 and 276 citations, and the scale is being recommended in guidelines, including the World Health Organization's guideline on clinical management of COVID-19.[7-12] To investigate the application of the PCFS scale in detail, we evaluated the available literature and distributed a survey to users of the scale. The PCFS scale and manual for the structured interview and patient-reported assessment, details of the literature searches and survey, and a full report on the findings can be found on our PCFS resource page (via <https://osf.io/qgpdv/>).[13, 14] In this research letter, we summarise the main findings.

Use

We have learned that the PCFS scale is adopted in numerous countries and settings. More than 25 translations are available. In addition to formal cross-cultural adaptation studies, several validation studies have been performed as part of translation processes that have varying quality due to limited resources and the pressing circumstances during the COVID-19 pandemic.

We have also learned that the face validity, construct validity and concurrent validity of the PCFS scale are adequate, while some psychometric properties such as predictive validity remain to be studied. Several studies evaluated the validity of the PCFS scale, showing that the scale appears to

measure what it purports to measure, and correlates reasonably with other relevant outcome measures. Moreover, the inter-rater agreement of the structured interview was shown to be substantial, both at baseline and after six-month follow-up of COVID-19 survivors.[15]

Based on the literature and users' experiences, we have learned that the use of the PCFS scale as additional outcome measure is supported. For now, the scale is intended to be used in addition to other (patient-reported) instruments to evaluate the consequences of COVID-19 on functional status – not as a stand-alone instrument replacing other relevant outcome measures.

We have learned that the scale is considered to be useful. The survey was distributed to 100 users, of whom 54 completed the survey. The 54 participants rated their experience with use of the PCFS scale from 0 (disagree) to 10 (agree): median 8 was scored for 'easy for physicians to use and understand' and 'recommend the scale to other colleagues', and median 10 for 'easy for patients to use and understand' and 'useful as a tool in the SARS-CoV-2 pandemic'. In articles in which the authors stated an opinion on the PCFS scale, its use was recommended or the scale was considered useful. None of the articles described the scale as unusable or discouraged its use.

Methods

We have learned that reporting the full methodology when using the PCFS scale is crucial for optimal interpretation. Of the articles, study protocols and trial registrations in which the scale was used as an outcome measure (n=103), 64% did not specify how the scale was assessed. Describing the assessment method(s) (i.e. structured interview, questionnaire or flowchart), timing of assessment(s), and analysis methods ensures transparency and reproducibility. The majority of survey participants considered all three assessment methods 'important' or 'extremely important', with the questionnaire being the most favourable assessment method. Notably, 41% of the participants used the scale in clinical setting or for both clinical and scientific work. Since studies evaluating the psychometric properties used several assessment methods, we cannot provide a single recommendation on how to best assess the PCFS in clinical practice, but we do recommend to not mix methods for one

assessment. Assessment through the structured interview helps reducing subjectivity and allows for blinding, and is therefore recommended in research settings.

As standardization of measurement will allow for comparisons, the PCFS scale is intended to be assessed at specified time points (as described in the manual: 1. at discharge; 2. in the first weeks after discharge, e.g. four-week and eight-week post-discharge; 3. after six months). Of these, a three-month follow-up period was most commonly used to monitor recovery after COVID-19. Results of the survey underline this, as part of the participants applied the scale at 12 weeks after discharge. Assessment of the PCFS over time enables to evaluate the course of symptoms and functional status, and to identify patients with functional deterioration or insufficient recovery. Notably, only in about half of the 150 identified published articles, study protocols and trial registrations, the time window around assessment of the PCFS was reported. More importantly, a time window of several weeks was found in a considerable number of studies. **Based on this, we stress that standardized measurement and applying a time window of one assessment that is as tight as possible will optimise the use of the PCFS scale.** To evaluate functional status over time, assessment of a pre-COVID-19 scale grade could be considered, in particular in patients who have pre-existing functional disabilities, but more research is needed to recommend this practice.

Further, we have learned that the inclusion of scale grade 5 ('death') is not always taken into account. Grade 5 is part of the scale to allow all included patients to be assessed and not only focus on survivors, thus preventing selection bias. Remarkably, according to the 14 studies that reported the distribution of PCFS scale grades, grade 5 was almost absent which could be the result of incomplete assessment or reporting. Based on the survey in which participants were asked about the scale grade distribution they had encountered (roughly), grade 5 ('death') was reported at some time points, supporting the idea that a survivor bias is present in some PCFS studies.

Being an ordinal scale rather than a score or binary measure, the scale can be used to classify patients into categories leading to unequivocal interpretation, and at the same time, enables to assess patients within a broad range of functional limitations. Of the 72 published articles in which analyses

were performed, regression analysis was performed in nine studies: only two used ordinal logistic regression, while seven dichotomised the PCFS and used binary logistic regression thus reducing the score's usefulness. **Considering this, we strongly suggest to consciously consider the ordinality of the PCFS scale during statistical analysis.**

Based on the available literature and experiences of users, we have summarised the eight lessons that could be learned after the two-year use of the PCFS scale (**Table 1**). We acknowledge that many studies that evaluated the psychometric properties or used the scale as outcome measure have been performed under the pressing circumstances of the pandemic. To optimise the use of the scale, the lessons from its two-year use should be taken into account. Even so and ultimately, the PCFS scale has been shown to provide added value during the COVID-19 pandemic.

Conflicts of interest

SB reports institutional research grants from Concept Medical, Bard, Bentley, Boston Scientific, INARI, Sanofi, and Bayer; and personal fees from Concept Medical, Bayer, Boston Scientific, and INARI.

FAK reports grants or contracts from Bayer, BMS, BSCI, MSD, Leo Pharma, Actelion, VarmX, The Netherlands Organisation for Health Research and Development, the Dutch Thrombosis Association, The Dutch Heart Foundation and the Horizon Europe Program, all unrelated to this work and paid to his institution.

BS, CMMdJ, YNJL and GJAMB report no conflicts of interest related to this work.

Table 1: The eight lessons that could be learned after the two-year use of the Post-COVID-19 Functional Status scale.

1	The PCFS scale is adopted in numerous countries and settings
2	Face validity, construct validity and concurrent validity are adequate, while some psychometric properties such as predictive validity remain to be studied
3	Use of the PCFS scale as additional outcome measure -in addition to other relevant measures- is supported by the community
4	The scale is considered to be useful, based on the literature and a survey among users
5	Reporting the full methodology when using the PCFS scale is crucial for optimal interpretation
6	Standardized measurement and applying a tight time window around one assessment will optimise its interpretability
7	Inclusion of scale grade 5 ('death') is not always taken into account which could lead to bias
8	The ordinality of the PCFS scale should be considered during statistical analysis in order to use the PCFS scale to its full potential

PCFS: Post-COVID-19 Functional Status.

References

1. World Health Organization. WHO Coronavirus (COVID-19) Dashboard. 2023 [cited 03-01-2023]; Available from: <https://covid19.who.int/>
2. Davis HE, McCorkell L, Vogel JM, et al. Long COVID: major findings, mechanisms and recommendations. *Nat Rev Microbiol* 2023: 1-14.
3. Wulf Hanson S, Abbafati C, Aerts JG, et al. Estimated Global Proportions of Individuals With Persistent Fatigue, Cognitive, and Respiratory Symptom Clusters Following Symptomatic COVID-19 in 2020 and 2021. *Jama* 2022: 328(16): 1604-1615.
4. Klok FA, Boon GJAM, Barco S, et al. The Post-COVID-19 Functional Status scale: a tool to measure functional status over time after COVID-19. *Eur Respir J* 2020: 56(1).
5. Klok FA, Barco S, Siegerink B. Measuring functional limitations after venous thromboembolism: A call to action. *Thromb Res* 2019: 178: 59-62.
6. Boon GJAM, Barco S, Bertolotti L, et al. Measuring functional limitations after venous thromboembolism: Optimization of the Post-VTE Functional Status (PVFS) Scale. *Thromb Res* 2020: 190: 45-51.
7. Sociedades Científicas y Colegios Profesionales del área de rehabilitación. Consenso Interdisciplinario de Rehabilitación para Personas Adultas Post COVID-19. Recomendaciones para la práctica clínica., August 2020.
8. Rabaday S, Altenberger J, Brose M, et al. [Guideline S1: Long COVID: Diagnostics and treatment strategies]. *Wien Klin Wochenschr* 2021: 133(Suppl 7): 237-278.
9. Koczulla AR, Ankermann T, Behrends U, et al. [S1 Guideline Post-COVID/Long-COVID]. *Pneumologie* 2021: 75(11): 869-900.
10. Servei Català de la Salut. Guia clínica per a l'atenció de les persones amb símptomes persistents de COVID-19., March 2021.
11. Swaminathan N, Jiandani M, Surendran PJ, et al. Beyond COVID-19: Evidence-Based Consensus Statement on the Role of Physiotherapy in Pulmonary Rehabilitation in the Indian Context. *J Assoc Physicians India* 2020: 68(12): 82-89.
12. World Health Organization. Clinical management of COVID-19: living guideline, 15 September 2022. Geneva. (WHO/2019-nCoV/Clinical/2022.2). License: CC BY-NC-SA 3.0 IGO., 2022.
13. Siegerink B, Boon GJAM, Barco S, et al. Open Science Framework (OSF). The Post-COVID-19 Functional Status (PCFS) Scale: a tool to measure functional status over time after COVID-19. 03-01-2023 [cited 03-01-2023]; Available from: <https://osf.io/qgpdv/>
14. Siegerink B, Klok FA, Le YNJ. Use of the PCFS two years after its introduction - a literature review and survey amongst users. Date created: 2022-07-12. Last Updated: 2023-01-05. [cited; Available from: <https://osf.io/h5equ/>
15. Du HW, Fang SF, Wu SR, et al. Six-month follow-up of functional status in discharged patients with coronavirus disease 2019. *BMC Infect Dis* 2021: 21(1): 1271.