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Original Article

Self-medication and off-label prescribing in post COVID-19 syndrome: Baseline data of a randomized acupressure and qigong trial

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ABSTRACT

Background: Post COVID-19 syndrome (PCS), characterized by persistent fatigue and multi-systemic symptoms following SARS-CoV-2 infection, emerged as a clinical challenge with limited treatment options and high patient burden. This paper presents the medication history and clinical baseline characteristics of PCS patients recruited in a randomized controlled trial (RCT).
Methods: Patients who reported PCS symptoms of ≥12 weeks after SARS-CoV-2 infection and who met defined fatigue criteria were included in this study. At baseline we assessed among others demographic data, symptom burden, medication history including off-label drug use, dietary supplements, and complementary self-help strategies.
Results: Altogether 235 adult PCS-patients were recruited between June 2022 and June 2023. The study population (mean age 42.1 years, 85.1 % female) reported a mean PCS duration of 56.4 weeks, with 74 % on sick leave. Patients frequently used off-label medications (e.g. antihistamines 9.4 %), supplements (vitamin D 53.6 %, minerals 50.2 %), and herbal medicine products (32.3 %). Most PCS patients had prior experience with complementary medicine. Correlations between fatigue and depressive symptoms (PHQ-9) were modest but notable. No strong associations were found between fatigue and age, sex, PCS duration, or vaccination status.
Conclusion: PCS-patients suffered from long-term complaints that led to a long period of sick leave and resorted to diverse, largely unproven therapeutic strategies amid clinical uncertainty. This baseline analysis highlights the unmet needs of PCS patients. Understanding these baseline patterns is essential for optimizing care pathways and patient-centered management strategies in PCS.
Trial registration: Clinicaltrial.gov (NCT05289154).

1. Introduction

The post COVID-19 syndrome (PCS), as defined by the WHO (12 weeks persistency)[1] was affecting >10 % of SARS-CoV-2 infected, leading to a high number of patients incapable to work, do household chores or take part in social activities, creating an enormous socio-economic impact.[2–4]

There are many similarities with Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) which develops as post-infectious residuum, and a subset of patients fulfils the Canadian Consensus criteria for ME/CFS.[5]

New, untested treatments are disseminated in patient self-help groups on Facebook or other social media and the internet and a variety of off-line therapies are prescribed by physicians.[6,7]

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Documenting early self-medication patterns and off-label prescriptions provides critical insight into real-world therapeutic behavior in the face of clinical uncertainty, and highlights gaps between patient needs and evidence-based care. Understanding the spectrum of self-initiated and physician-guided treatments in the early stages of PCS helps identify potentially beneficial or harmful practices.

We conducted a randomized clinical trial with the primary aim of evaluating the therapeutic effect and safety of acupressure and Qigong in patients with PCS. The aim of this article is to present the baseline characteristics of patients included in the randomized clinical trial and their medication history including use of prescribed drugs for the PCS, the off-label therapies, as well as dietary supplements, complementary medicine or over the counter medications together with the baseline clinical condition of the participants of the ACUQiG trial.

2. Methods

The study center was at the outpatient clinic for complementary and integrative medicine at the Institute of Social Medicine, Epidemiology, and Health Economics, Charité – Universitätsmedizin Berlin, Germany. Patients were recruited and examined here and additionally from across Germany via telemedicine. The trial was registered at Clinicaltrial.gov (NCT05289154) and was approved by the local ethics board (A2/073/22).

2.1. Study design

The ACUQiG trial recruited PCS patients for an open, assessor-blind, two-arm, randomized controlled, single center trial with a mixed methods approach to evaluate the effects of 8 weeks of acupressure plus Qigong on parameters of fatigue compared to a waitlist (Supplement 1).

The cohort analyzed and presented in this paper was taken from the ACUQiG trial and represents its baseline cohort before entering any intervention.

2.2. Participants

Included were n = 235 patients suffering from chronic fatigue following a SARS-CoV-2 infection, which had occurred at least 12 weeks before trial participation. They had to be aged 18–60 years, of any sex and gender and exhibit at least 3 of the following 7 symptoms at the time of inclusion: sleep disturbance, headache, joint pain/muscle pain, anxiety/depression, memory/concentration impairment, post-exertional malaise (PEM), or dysosmia/anosmia. Fatigue had to be modest to severe, assessed with validated scores: physical capacity was required to be max. 60 mm on a Visual Analogue Scale (VAS, 0–100 mm, with 0 indicating no force at all and 100 indicating best physical capacity), and the Physical Function subscale of the health-related quality-of-life questionnaire Short Form-36 (SF-36-PFS) had to be max. 65 points (low values reflecting worse physical function).

The exclusion criteria were: fatigue present prior to SARS-CoV-2 infection; the presence of severe PEM; other underlying diseases that could lead to symptoms of chronic fatigue, ongoing opioid therapy; chronic use of recreational drugs; starting or stopping psychotherapy during study participation; pregnancy or breastfeeding in female participants; ongoing participation in another clinical intervention trial; ongoing retirement or disability pension procedures. Details regarding the design and the interventions of the RCT will be presented separately.

2.3. Outcome measures

Socio demographic characteristics, including age, sex, and medical history; the date of the index infection and status of COVID-19 vaccination at point of infection and at study inclusion; history of hospitalization due to acute infection; clinical symptoms of PCS; actual work status; prior experience with complementary and integrative medicine (CIM); ongoing medications, off label therapies, and supplements. Severity of the fatigue was assessed with the SF-36-PFS (higher indicating better physical health). Physical capacity (VAS of 100 mm, higher indicates better physical health), Chalder Fatigue Questionnaire (lower values indicate better physical and mental health), severity of PEM (DSQ-PEM, lower indicates less malaise); sleep quality (Pittsburg Sleep Quality Index: PSQI, lower indicates better sleep quality); health-related quality of life (EQ-5D-5 L, higher indicates better quality of life); depression (Patient Health Questionnaire 9: PHQ-9, lower indicates less depressive symptoms) and severity of headache (VAS, lower indicates less pain).

Physical examinations were conducted. In a subset of patients: handgrip strength with a hydraulic dynamometer (Saehan SH5001) to quantify the exhaustibility of muscular effort[8]; pulmonary function using the spirometer Vitalograph copd-6 (Vitalograph GmbH, Rellinger Straße 64a, 20,257 Hamburg, Germany), providing the values of the forced expiratory volume within 1 and 6 s (FEV1 and FEV6) and the Tiffeneau-Index (FEV1/FEV6)[5]; orthostasis with repetitive measurements of blood pressure and heart rate sitting and standing[9]; concentration and attention test (Test d2-R) for the evaluation of cognitive fatigue.[10,11]

2.4. Sample size

The sample size for this baseline cohort analysis is based on the sample size estimation of the RCT. The estimate was based on an expected MCID between the treatment groups in the SF-36-PFS of 10 points, and a standard deviation of 23 points.[12] With a sample size of 85 patients per treatment group, a two-sided t-test with significance level of 5 % has a power of 80 %. To compensate for an expected dropout rate of approximately 15 %, 100 patients per study arm were planned. As a later amendment to the study protocol, it was decided to include up to 50 more patients, to be able to better form subgroups for subgroup-analysis, leading to 235 recruited patients in total.

2.5. Statistical analysis

Descriptive analysis included absolute and relative frequencies (percentages), mean values, standard deviation (SD), median, range and interquartile range (IQR) for all variables.

Aside from the descriptive analysis of the demographic data collected at baseline, the details of routine care, supplements and complementary medicine treatments used by the study population for PCS prior to their study enrollment were analyzed descriptively.

The analysis was done descriptively with means and standard deviations of the full analysis set (FAS) for the following questionnaires: VAS physical Capacity, SF-36-PFS, Chalder Fatigue Scale, VAS headache, DSQ-PEM, EQ-5D-5 L, PHQ-9, and PSQI.

Additionally, to assess the correlation between the SF-36-PFS and age, duration of PCS, severity of PCS symptomology and PHQ-9 score, we calculated in a post-hoc analysis the Pearson correlation coefficient. We additionally compare SF-36-PFS score by sex (male vs female), menopause status (yes vs no, for female only), use of supplements (ever users vs never users), and depressive symptomology (PHQ-9 score $\geq$10 vs <10) descriptively. We also provided the difference in baseline values of Chalder Fatigue Scale and SF-36-PFS between those who received the full COVID-19 vaccination (2 vaccinations shots +14 days) before vs no full COVID-19 vaccination before COVID-19 index infection.

The data was analyzed using SPSS (IBM SPSS Statistics for Windows, Version 25, Armonk, NY: IBM Corp).

3. Results

In total, 792 patients were screened for eligibility between June 2022 to July 2023, and 235 patients who fulfilled the inclusion criteria were randomized and completed the baseline assessment (Supplement 2). The mean age was 42.1 years, SD 10.3, 85.1 % were female, 99.1 % Caucasian, and 66.8 % had a university degree (Table 1).

The fatigue scores showed the prevalence of moderate to severe fatigue (see Table 2). The study population had a low rate of comorbidities

Table 1
Baseline characteristics (n = 235).

Demographics	n (%)
Age (years), mean ± standard deviation	42.1 ± 10.3
Female	200 (85.1 %)
Male	33 (14.0 %)
Divers	2 (0.9 %)
Menopause (women only)	56 (28.0 %)
Caucasian	233 (99,1 %)
University degree	157 (66.8 %)
Employment	
Full-time or part-time	47 (20.0 %)
Currently on sick leave due to post COVID-19 syndrome	174 (74.0 %)
Other (student, retirement, unemployed)	14 (6.0 %)
Comorbidities	
Asthma	21 (8.9 %)
Hypertension	16 (6.8 %)
Depressive or anxiety disorder	15 (6.4 %)
Obesity	5 (2.1 %)
Hypercholesterolemia	4 (1.7 %)
Immunosuppression	1 (0.4 %)
Rheumatic diseases	1 (0.4 %)
Chronic obstructive pulmonary disease	1 (0.4 %)
Diabetes	0 (0.0 %)
Smoking	25 (10.6 %)
Use of cannabis: occasional	4 (1.7 %)
Other drugs: occasional	1 (0.4 %)

Table 2
SARS-CoV2-Index infection, symptoms of PCS and status of vaccination at baseline (n = 235).

Index infection and status of vaccination	n (%)
Time to index infection in weeks, mean ± SD	56.4 ± 34.2
Number of vaccinations (plus 14 days*) before index infection leading to PCS	
0	71 (30.2 %)
1	6 (2.6 %)
2	39 (16.6 %)
3	111 (47.2 %)
4	8 (3.4 %)
Parameters of fatigue, mean ± SD	
SF-36-PFS (range 0–100)[1]	42.8 ± 16.8
Chalder Fatigue Scale (range 0–33)[2]	25.5 ± 4.3
Physical capacity (VAS, range 0–100)[3]	34.9 ± 12.4
PEM ≥ 14 h recovery time, n (%)	155 (66.0 %)
PHQ-9 (range 0–27)[4]	11.0 ± 4.1
PSQI (0–21)[5]	10.1 ± 3.7
EQ-5D-5 L-Index (range 0–1)[6]	0.6 ± 0.2
EQ-5D-5 L VAS (range 0–100)	36.2 ± 15.1
Additional Symptoms besides fatigue, mean ± SD	7.5 ± 1.6
Intolerance to physical activity	230 (97.9 %)
Fluctuation of symptoms	225 (95.7 %)
Memory / concentration impairment	219 (93.2 %)
Joint / muscle pain	200 (85.1 %)
Sleep disturbance	183 (77.9 %)
Headache	172 (73.2 %)
Post-exertional malaise	155 (66.0 %)
Dyspnea	155 (68.0 %)
Vertigo	128 (54.5 %)
Anxiety / depressiveness	110 (46.8 %)
Spontaneous sweating	86 (36.6 %)
Dysosmia / anosmia	53 (22.6 %)
Postural tachykardia syndrome (orthostasis)+	6 (4.6 %)

PCS: Post-COVID-syndrome. PEM: post-exertional malaise.

* We calculated plus 14 d, in order to be able to assume achieved immune reaction.

[1] SF-36-PFS: Short-Form-36 quality of life-physical function subscale: higher values indicate less fatigue (the norm being >75 in this age group).

[2] Chalder Fatigue Scale: lower values indicate less fatigue.

[3] VAS100mm (visual analogue scale)-physical capacity: higher indicates more capacity.

[4] PHQ-9-Patient Health Questionnaire: lower less depressive symptoms.

[5] PSQI-Pittsburgh Sleep Inventory Quality Index: lower indicates better sleep quality.

[6] EQ-5D-5L-Index (European Quality of Life 5 Dimensions): higher indicates better quality of life, EQ-5D-5L-VAS: higher indicates better quality of life.

+ of a subgroup of 77 patients with physical.

and was thus at low risk of COVID-19 mortality. On average, the index infection was reported at a mean of 56.4 weeks (SD 34.2) prior to study enrolment, while 74 % of the study participants were on sick leave due to PCS at baseline. Dynamometry for handgrip strength showed a recovery in the normal range for healthy adults; the Tiffenau- index of the spirometry measurements did not indicate an obstructive pathology underlying to the frequently reported symptom of dyspnea; the results of the d2 attention test revealed a concentration performance falls within the expected normal range for most adult populations, 18 % of participants had tachycardia after 10 min of standing and 6 % fulfilled the criteria of postural tachycardia syndrome.

Among study participants, most were taking prescription drugs or dietary supplements for PCS. Among prescription drugs, sleep medication, antidepressants, and off-label antihistamines were most frequently used (Fig. 1). Far more patients were taking supplements, most frequently vitamins B, C or folic acid, vitamin D and minerals or trace elements or phytotherapy. Of the 235 study participants, 192 (81.7 %) reported a previous experience with the usage of CIM treatments, such as herbal remedies, acupuncture, or homeopathy. Of those 88.5 % had experienced subjective benefit from it in the past (unrelated to PCS), which constituted 72.3 % of the entire study population.

Correlation analysis revealed no meaningful association between SF-36-PFS scores and either age or duration of PCS symptoms at baseline. Weak negative correlations were observed between SF-36-PFS and both PCS symptom severity (r = –0.297) and depressive symptomatology (PHQ-9; r = –0.213), suggesting modest links between fatigue

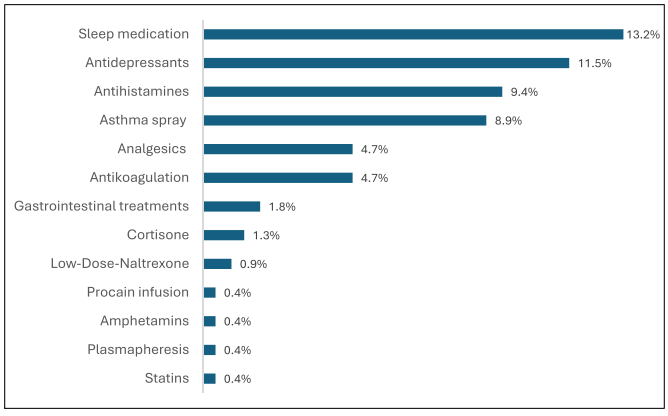

Fig. 1. A: Prescription drugs and off-label prescription drugs for PCS. One additional patient was using statins and lipid lowering injections alternating (data not shown). B: Supplement or complementary medicine use for PCS. Percentages are based on the part of patients with any kind of oral treatment for PCS (n = 216).

and overall symptom burden. Descriptive subgroup comparisons indicated no clinically relevant differences in SF-36-PFS scores across sex, menopausal status, vaccination status, or supplement use. However, a borderline clinically meaningful difference was observed based on depression severity, with lower physical functioning reported in participants with elevated PHQ-9 scores (≥10), consistent with prior findings on fatigue-depression interactions (Supplement 3).

4. Discussion

Our objective was to analyze self-medication behaviors, off-label prescriptions, and self-help strategies among patients suffering from post-COVID syndrome (PCS) during a period of significant clinical uncertainty. The results of the analysis of the baseline cohort align with previous observations in PCS patients: the disease burden is high, with many chronically ill patients unable to return to work, creating a substantial economic strain on the public healthcare system.[13]

Our findings underscore the prominence of self-medication in chronically ill patients, as evidenced by the extensive use of supplements, herbal remedies, and other complementary therapies. Additionally, the analysis of off-label drug prescriptions provides valuable insight into how physicians have approached this novel and complex syndrome. The characteristics of our study population are consistent with previously described PCS patients: predominantly middle-aged women who were otherwise healthy before the SARS-CoV-2 infection and did not require hospitalization for the acute infection.[14,15] A surrogate marker of the economic burden of PCS is reflected in the high rate of sick leave among middle-aged women with higher education. The economic burden of PCS has been documented in several studies.[16–18] Psychological well-being was rated as moderate to low, as assessed by the Patient Health Questionnaire-9 (PHQ-9) for depressive symptoms. This negative impact of PCS on psychosocial well-being has also been demonstrated in previous research involving a comparable patient cohort.[19] Moreover, women tend to report higher levels of fatigue and pain in long-term conditions compared to men, a pattern that has been observed in prior studies and should be considered in interpreting our findings, given that our cohort was predominantly female.[20]

When data collection began in 2022, PCS was a poorly understood condition with no established treatment protocols, and both general practitioners and specialists lacked guidance on how to manage these patients. The baseline analysis was therefore designed to capture real-world therapeutic patterns in this context, documenting both the first off-label therapies prescribed by physicians and the widespread use of complementary and integrative remedies initiated by patients themselves.

Our post hoc subgroup analysis of the baseline cohort examining correlations between various variables and the severity of post-COVID syndrome (PCS) yielded results consistent with previous findings from a larger cohort study (n = 958), which reported no protective effect of vaccination on PCS severity.[3] In contrast, an analysis of data pooled from 25 observational studies (n = 14,128,260) suggested that receiving two doses of a COVID-19 vaccine prior to infection was associated with a reduced risk of developing long COVID with severe fatigue.[21]

Participants in this CIM trial showed a propensity for CIM usage, with 79.6 % reporting the use of supplements and/or remedies from herbal medicine and homeopathy for their PCS. Regarding off-label antihistamines, evidence was limited to insufficient to support their use; similarly, there was no robust evidence supporting supplement treatments for PCS at the time of data collection. Expert Consensus Decision Pathways and guidelines for PCS, informed by ME/CFS experiences, recommended symptomatic treatment for sleep disorders and pain during that period.[6]

Additionally, evidence for vitamin C, vitamin D, or zinc supplementation in the treatment of COVID-19 or its post-acute sequelae remains insufficient.[22] Nonetheless, their usage is widespread, and patients do not appear to be discouraged by their physicians.

Regarding self-medication among post-COVID patients, an interesting study from 2022 mined social media to provide an overview of medication strategies and commonly used agents. An analysis of 70,000 posts highlighted frequently mentioned substances such as “histamine antagonists,” “famotidine,” “magnesium,” “vitamins,” and “steroids.”[22]

Widespread use of traditional medicine remedies, including herbal and homemade treatments, has also been documented for the treatment and prevention of acute COVID-19.[23,24] Notably, CIM usage during the pandemic was high among the German population.[25]

4.1. Strengths and limitations

A methodological limitation is that part of this analysis is post-hoc, based on cross-sectional data. The analysis reflects only the recruitment period from June 2022 to June 2023, during and after the SARS-CoV-2 pandemic, and captures the state of knowledge at that time. For example, prescriptions for low-dose naltrexone (LDN) were still rare in 2022, before a small cohort study by O’Kelly et al. was published.[25] Currently, LDN prescriptions may be more prevalent, as it is recommended in the German medicines agency’s guidelines.[26] Among supplements, e.g. vitamin D has been more extensively researched, and results might contribute to a more rigorous prescription of higher doses of vitamin D today.[27]

Another limitation is the lack of ethnic and economic diversity in the study population. While the demographic characteristics are typical of PCS patients in Northern Europe (comparable to data from Sweden and the UK), the sample is not representative of global PCS populations in terms of ethnic diversity.[13,14] Selection bias is also a concern; this trial predominantly included patients interested in CIM treatments such as acupressure and Qigong. Taking part in a CIM trial our study population may indicate towards an affinity to CIM usage, with 79.6 % of study participants using supplements and/or remedies from herbal medicine and homeopathy for their PCS.

Participants were generally highly educated, exhibited better health-related behaviors, and had more healthcare resources and lower morbidity than those with lower socioeconomic status.[28,29] Population based cohort analysis of samples with lower fraction of highly educated participants though could show, that use of CIM remains frequent.[30] Additionally, 72.3 % of participants reported perceived benefits from prior CIM experiences, which could introduce selection bias.

4.2. Implications for future research

Future research should incorporate the perspectives of PCS patients. Patient-reported choices of over-the-counter drugs, dietary supplements, and phytotherapy regimens should be assessed at baseline to provide a realistic perspective on self-medication strategies and perceived benefits.

4.3. Conclusion

PCS patients are burdened with long-term disease, high rates of sick leave, and frequent use of off-label medications, dietary supplements, and complementary medicine remedies. In the absence of evidence-based treatment options, off-label prescriptions and complementary medicine often serve as a pragmatic and accessible strategy. However, this reliance also underscores the urgent need for systematic documentation in clinical care and rigorous evaluation, as widespread use without robust evidence may expose patients to ineffective - or potentially harmful - interventions.

Author contributions

Conceptualization: JD, BB. Methodology: BB, SW, SR, RN, JH, UE, AM. Software: WG, TB. Validation: MO. Formal analysis: WG,SR. Investigation: TB, JD, MO, BS, HB. Resources: SW. Data curation: TB, WG.

Writing – Original Draft: TB,JD. Writing – Review & Editing: all authors, Visualization: WG. Supervision: AMic, SW, FP, CS, JBS, Project administration: JD, MO, BB. Funding acquisition: JD, BB.

Declaration of competing interest

The authors declare that they have no conflicts of interest.

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Ethical statement

This research was reviewed and approved by the institutional review board of Charité University Hospital (registration number (A2/073/22)). Informed consent was obtained from all participants.

Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.imr.2025.101197.

Supplement 1. Trial design and assessment time points.

Supplement 2: Flow-chart.

Supplement 3. Scatter plots for the post-hoc correlations between the SF-36 PFS and age, duration of PCS, severity of PCS symptomology, and PHQ-9 score.

Supplement 4. CONSORT checklist.

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