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Research Article

Blended Therapy-Concept as Medical Treatment with Integrated Forms of Therapy for Post-COVID-19-Patients

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Abstract

Background: For the medical treatment of post-COVID-19-syndrome, no medical treatment or causal therapy based on evidence-based criteria is currently recommended. By linking digital therapy modules and classic on-site therapy, central data storage and structured information exchange between the actors, a cross-sector, doctor-led blended therapy was developed. This is aimed at the main syndromes of fatigue/immunometabolic depression and sensorimotor instability (easily manageable real-time cognition parameters). The aim is to reduce the key post-COVID-19 symptoms as well as motor and cognitive fatigue parameters. **Methodology**: The improvement of the leading syndromes of fatigue and sensorimotor instability through stress-controlled standardized training therapy and intensified cognitive behavioral therapy were the overarching goals of the intervention and observation study over a 3-year period (Q1-2021 - Q2-2024). From a population of 407 vaccinated nucleocapsid-positive patients, 78 patients took part in the study. The outcome assessment was carried out on the one hand based on the post-COVID-19-key symptoms and the motor fatigue parameters. On the other hand, secondary psycho-somatic syndromes that emerged during the course of treatment were examined using cognitive fatigue parameters. **Results:** With blended therapy, the Oost-COVID-19-key symptoms "fatigue", "neuropsychiatric symptoms" and "cardiopulmonary symptoms" were improved by over 70% as well as "pain" by around 14%. Overall (N=78), a therapeutic effect was ob-served for all motor fatigue parameters. The intensification of cognitive behavioral therapy, in which 19 patients took part, also had positive effects and an increasing development of the patients' own activity and their self-

control was achieved. **Conclusion**: Cross-sector blended therapy with central data storage can coordinate the structured exchange of information between the individual actors in the treatment process with an impact on the success of the therapy. A delay in the start of therapy is counteracted, service provision and coordination is accelerated at a central and peripheral level, and an effective, efficient, safe and scalable intervention is implemented. Real-time recording and analysis of outcome parameters become an important environmentally stable training item.

Keywords: Post-COVID-syndrome; Fatigue; Sensorimotor instability; Cognitive behavioral therapy; Cross-sector blended therapy

Introduction

Since the beginning of the SARS-CoV-2 pandemic, by the end of October 2024, over 770 million people worldwide have been infected with an immunogenic virus [31], which causes (long-term) health consequences of varying severity and duration (Figure 1). Following a SARS-CoV-2 infection, similar to other infectious diseases, persistent symptoms can occur in various organ systems (lungs, heart, brain, gastroenteric and other secondary organs) and/or various new symptoms can arise that persist over a longer period of time [12,18,19,29].

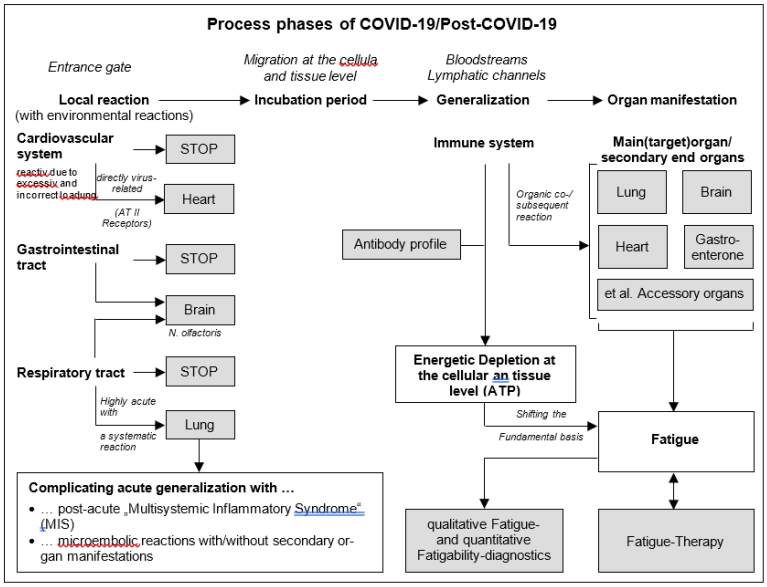

Figure 1: Process phases COVID-19/Post-COVID-19.

In the specialist literature and the AWMF-S1 guidelines, the term post-COVID syndrome (PCS) has become established for symptoms that occur or persist twelve weeks after a SARS-CoV-2 infection [3-5]. The frequency of occurrence of PCS is between 10 and 35% [13]. Using the Delphi consensus method, the WHO defined PCS as follows [22,29].

- Symptoms must still be present 12 weeks (3 months) after a SARS-CoV-2 infection and must last at least two months
- there is no other etiological explanation
- the course may be persistent, recurrent or fluctuating

There is currently no causal therapeutic approach based on evidence-based criteria for the treatment of post-COVID syndrome. The S2k guidelines of the German Society for Neurology (DGN) advocate that post-COVID-19 sufferers with sensory, sensorimotor, cognitive and/or emotional changes receive an adequate neurological evaluation and, if necessary, neuro rehabilitative care. The need for treatment arises either immediately after the acute treatment or during its course (e.g. after 3-6 months).

As an important aspect in the classic treatment of fatigue/ immunometabolism depression (e.g. in multiple sclerosis, in haemato-oncology and currently in immunotherapy), training and physiotherapy were considered strictly contraindicated just a few months ago. It was about protection in the convalescence phase (rest, relaxation techniques, avoiding stress and excessive demands). The greatest effects on fatigue are now seen under balance training and motor exercise therapies, followed by cognitive behavioral therapy designed to address fatigue [9].

Due to the diversity and medical range of Post-COVID-19-key symptoms, the patient's health status must be recorded and assessed by experts from different disciplines [6,14]. Such a multidisciplinary connection can be achieved, for example, with a cross-sector blended therapy structure (Figure 2). Blended therapy concepts implement a mixture of analog face-to-face therapy forms and digital intervention options. This combination can increase the effectiveness of face-to-face therapy [2]. For ex-ample, patient groups with little mobility or at great geographical distances are reached, and service providers can be integrated at a central and peripheral level as well as the coordination of patient treatment plans through shared data use.

The digital intervention in the blended therapy concept enables a real-time analysis of load, performance and strain as well as the transition from treatment control to a close-meshed information technology control [23,24, 32]. The technological basis for this is the specially developed "Reha-Planet" system [21]. The implemented applications realize the following functions (Figure 4):

- Implementation of individual stress-controlled training to build performance while specifically avoiding overload and crashes
- Integration of a therapist known to the patient from the therapy center and other therapy members
- Creating an emotional connection to the system in order to create closeness de-spite the spatial distance for proportionate practice at home

The cross-sector combination of analog and digital intervention modules along the treatment process and central data storage benefit, among others: the management, treatment satisfaction and the treatment results of the patients, but also the central and peripheral levels of service provision and service coordination (Figure 2). For ex-ample, service providers at a central and peripheral level can coordinate and coordinate treatment based on the data in the central database.

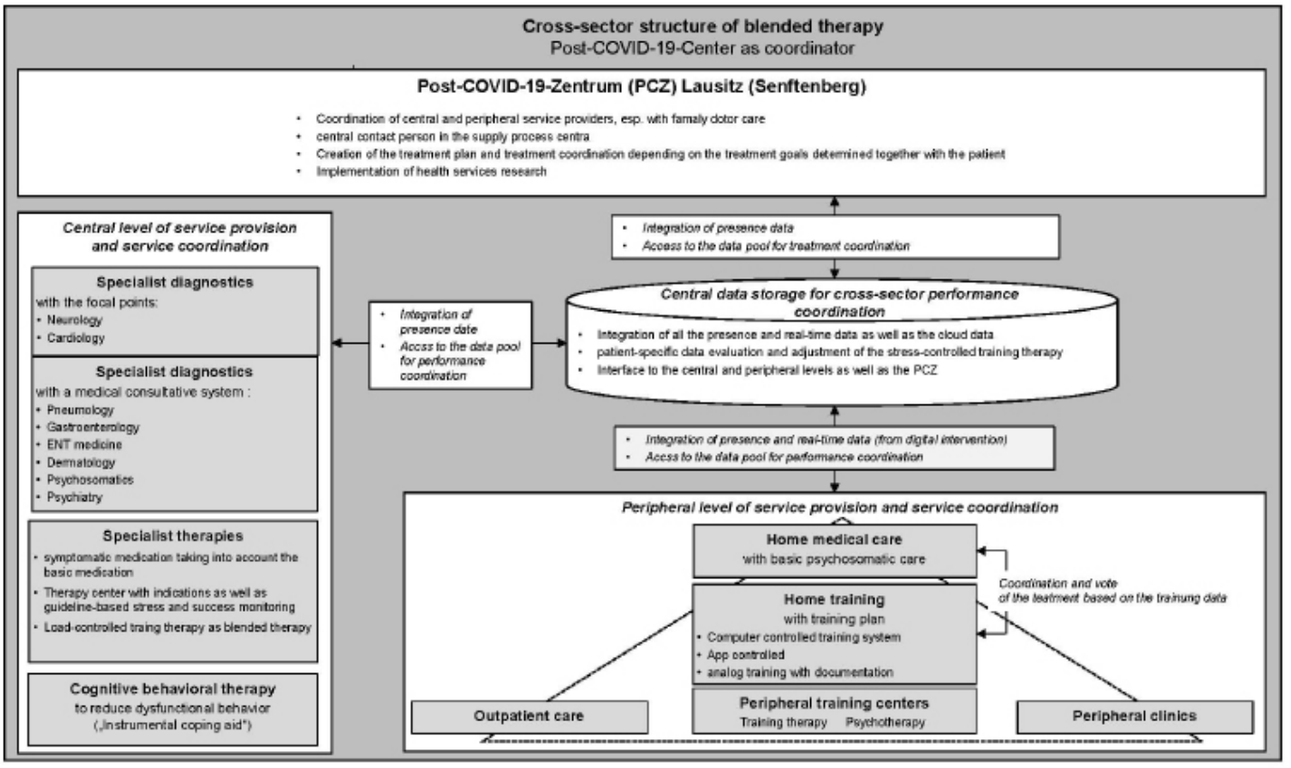

Figure 2: Cross-sector structure of blended therapy.

Methodology

The combination of analog and digital forms of therapy (blended therapy) achieves a high level of flexibility in therapy design as well as better patient adherence [8,9,11]. The guidelines §3 (4) point 4 of the Federal Joint Committee recommend the use of digital therapy offers that take different symptoms of the basic assessment and individual stress levels into account [6,14].

A doctor-led intervention and observation study was implemented in the post-COVID-19-Center (PCZ) Lausitz (Senftenberg) from Q1-2021 to Q2-2024. The main syndromes "fatigue" and "sensorimotor instability" were treated with monocentric stress-controlled training therapy (analog and digital intervention). At the same time, secondary psychosomatic treatment needs that often arise in the post-COVID-19-course with fatigue were treated.

407 vaccinated nucleocapsid-positive patients were available for screening in the PCZ (Table 1).

The nucleocapsid protein was determined through a blood sample and laboratory examination in the period from Q1-2021 to Q1-2023. At the same time, a functional status survey was carried out using a method developed by KLOK ET AL. [16] validated scale with five levels of severity, ranging from grade 0 = no functional limitation to grade 4 = severe functional limitation [18]. The 78 patients with reduced sensorimotor performance and fatigue (Table 1) were admitted after a standardized diagnosis in accordance with guidelines and considering the following exclusion criteria.

- Irreconcilable communication problems
- vestibular dysfunction (video head impulse test)
- Pacemaker
- non-compensatory visual limitations
- orthopaedic deficits of the lower extremities
- Inability to stand independently without the use of assistive devices

All patients were of legal age and gave written informed consent before inclusion in the study. The implemented study design and the computer-controlled training sys-tem used were approved by the ethics committee of the TU Dresden (reference numbers EK 378092016, EK 356092017).

Study design

The treatment plan of the intervention and observation study at the PCZ consisted of two phases (Figure 3):

Treatment phase 1 (Intervention Study)

Stress-controlled training therapy to improve the quantified sensorimotor parameters and the Post-COVID-19-key symptoms (Q1-2021 - Q2-2023) with 78 patients.

Treatment phase 2 (Intervention and Observation Study)

Intensified cognitive behavioral therapy to improve fatigue and secondary psychosomatic symptoms (Q2-2023 - Q4-2023) with 19 patients from treatment phase 1. Questionnaire-based assessment of participation (IMET), health-related quality of life (VR-12), generalized anxiety disorders (GAD-7) and depressive disorders (PHQ-9) in Q2-2024 with 26 patients.

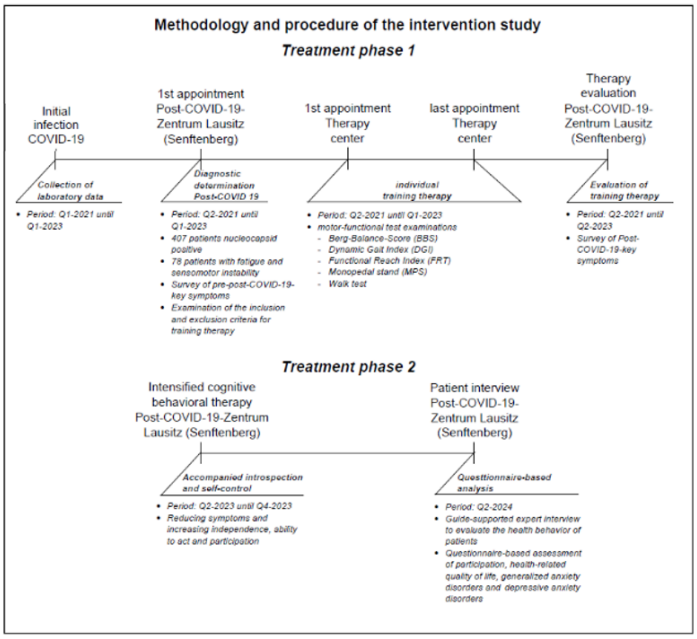

Figure 3: Methodology and procedure of the intervention- and observation-study.

Evaluation of Post-COVID-19-key Symptoms, Motor and Cognitive Fatigue

The stress-controlled training therapy was evaluated based on the key Post-COVID-19-symptoms (fatigue, sensorimotor instability, cardiopulmonary/autonomic dysfunction, neuropsychiatric symptoms, secondary psycho-somatic symptoms and pain) as well as motor fatigue parameters (Berg Balance Scale, Dynamic Gate Index, Functional Reach Test, Monopedal Stand and 10-meter-walk test).

Motor fatigability rep-resents an objectively measurable indicator of motor performance and allows for a higher medical assessment of the effectiveness of therapy [3,10,17,27,28]. The statistical analysis of the quantitatively collected data was carried out with instruments of descriptive statistics and inferential statistics, using the statistical program SPSS. The effect size (Cohen's d) was used

to evaluate the pre-post results of motor fatigability. It represents the ratio of the mean treatment difference based on the pooled standard deviation. The following effect sizes are distinguished [15].

- low effect: 0.2 < d £ 0.5
- medium effect: 0.5 < d £ 0.8
- large effect: d > 0.8

As part of treatment phase 2 (Figure 2), intensified cognitive behavioral therapy was carried out for the group of therapy participants from treatment phase 1 with "secondary psychosomatic symptoms". A connection between the organic and psycho-logical-emotional sides is the patient's self-control (control of thoughts, feelings and behavior) [1]. With the intensification of cognitive behavioral therapy (structured, pre-sent-oriented short-term psychotherapy) in the period Q2-2023 to Q4-2023, the changes in secondary psychosomatic syndromes were examined (cognitive fatigue parameters). In Q2-2024, an assessment of participation (IMET), health-related quality of life (VR-12), generalized anxiety disorders (GAD-7) and depressive disorders (PHQ-9) was also carried out.

Control of Blended Therapy

Blended therapy in treatment phase 1 is based on the building blocks "presence", "computer-aided training system" and "mobile application". On the one hand, it took place in a training center belonging to the PCZ and, on the other hand, in the patient's home in order to achieve sufficient training density (at least 2 training units per week). A computer-based training system was used in the training center (in-person) and in the home. The system structure and the methodology used in blended therapy are based on three steps (Figure 4).

- Initial determination of the severity of functional limitations in the training center
- Digital intervention of stress-controlled training therapy in the training center and at home
- Load control and monitoring of training therapy

Patients for whom a computer-controlled training system could not be used at home due to spatial and/or technical restrictions either a) carried out the exercises independently with measurement of the pulse rate (ECG recordings if necessary) via a) smartwatch and documentation of the results, or b) used the computer-aided training system based on a mobile application with the following functionalities.

- Training plan with video instructions for carrying out the standardized exercises
- regular training reminder
- Digital trainer that optimizes exercise complexity and length through user feed-back
- Overview of the practice times with review
- Recording and recording quality of life using the SF 36 questionnaire
- Point system to increase motivation and adherence
- Meditation tool with guided relaxation exercises

In the experience of post-COVID-19 sufferers, increasing thought dysfunction can develop over time (including during the course of therapy in treatment phase 1) from stress insufficiency experienced in everyday work and at home [12,25]. The aim of treatment phase 2 was to improve the self-management of reduced resources as well as the often largely limited participation in social and professional life.

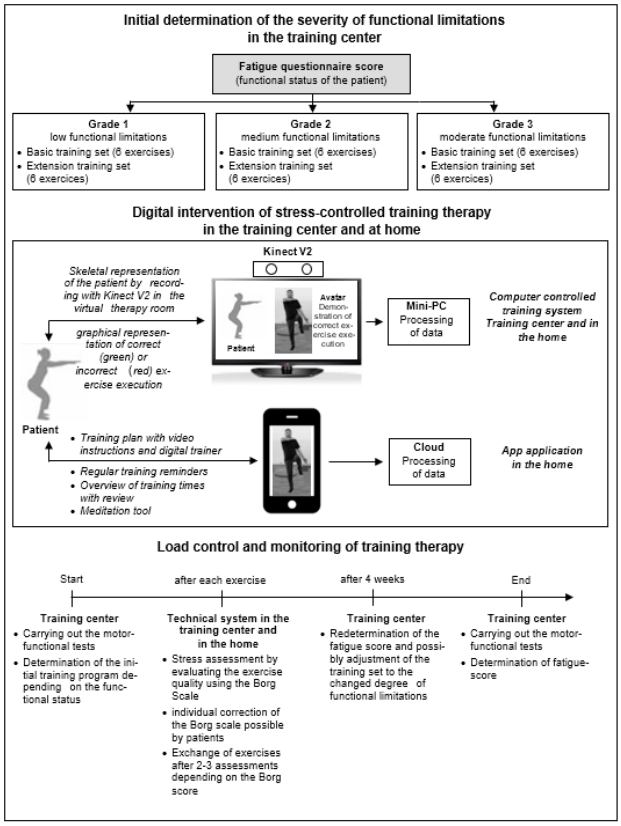

Figure 4: System structure and methodology of blended therapy.

Results

An example of a cross-sector blended therapy was implemented, which puts the post-COVID syndromes fatigue and sensorimotor instability at the center of the considerations. The therapy evaluation is based on the qualitative and quantitative evaluation parameters presented as well as the analysis of the management process of the stress-controlled intervention. There were no strong gender differences. Deviations exist in individual sub-phases and have an impact on the timing of the therapy process and on the outcome.

Post-COVID-19-key Symptoms

The overall analysis with N=78 (Table 1) produced the following results:

- Improvement in "fatigue" by around 71%, "sensorimotor instability" by around 56%, "neuropsychiatric symptoms" by around 72%, "cardiopulmonary/autonomic dysfunction" by around 76% and "pain" by around around 14% through pre-post survey of post-COVID-19 key symptoms (Fig. 2)
- Worsening of "secondary psychosomatic symptoms" by around 72%

In the men (N = 37), all values improved compared to the women except for "pain" (no improvement). One reason may be the faster process flow in the period "Initial infection-1. Appointment PCZ" and "1. Appointment PCZ-1. Appointment therapy center" can be seen. Women showed a very strong deterioration in the "secondary psychosomatic symptoms". The slower process flow in the above-mentioned cases can be the cause. Periods compared to men, overestimation of (residual) performance or evasive behavior, especially in hyperdynamic young women in the form of dysfunctional psychological reactions.

Motor Fatigability Parameters

The Wilcoxon test was carried out to evaluate the effectiveness of therapy because there was no normal distribution in the pre- and post-data sets. The strength of the effect of the training therapy on the respective fatigue parameter is determined using the Cohen's d value (Table 1).

Overall (N = 78), a therapeutic effect was demonstrated for all motor fatigue parameters. The Functional Reach Test (FRT) achieved a medium effect size. There was a small effect size for all other motor fatigability parameters.

In men, no treatment effect could be demonstrated for the 10 m walk test. The Berg Balance Score (BBS) and the FRT showed medium effect sizes. Small effect sizes were found for the dynamic gait index (DGI) and monopedal stance (MPS).

In the women's cohort (N = 41), there were no treatment effects for the dynamic gait index (DGI) and monopedal stance (MPS). The FRT achieved a medium effect size. Small effect sizes were found for the BBS and 10 m walking test.

Nucleocapsid positive patuents (vaccinated)								
	< 24 Years	25-34 Years	35-44 Years	45-54 Years	55-64 Years	> 65 Years	M (Years)	SD (Years)
Total (N = 407)	9	16	46	79	123	134	58,26	14,79
Men (N = 169)	5	4	16	25	51	68	60,41	14,80
Women (N = 238)	4	12	30	54	72	66	56,74	14,6

Cohort intervention study (fatigue and sensorimotor instability)								
	< 24 Years	25-34 Years	35-44 Years	45-54 Years	55-64 Years	> 65 Years	M (Years)	SD (Years)
Total (N = 78)	0	0	8	12	26	32	59,1	12,76
Men (N = 37)	0	0	4	2	12	19	62,2	11,91
Women (N = 41)	0	0	4	10	14	13	56,6	13,01

Motor fatigability-parameters (treatment phase 1 of intervention study)						
		Berg-Balance-Score (BBS)	Dynamic GaitIndex (DGI)	Functional ReachTest (FRT)	Monopedalstand (MPS)	10 m-Walk testm
Total (N = 78)	**Pre**	M = 48,5	M = 21,8	M = 32 cm	M = 88,8 sec.	M = 6,6 sec.
	Post	M = 51	M = 22,9	M = 36,7 cm	M = 100,8 sec.	M = 6,3 sec.
	Significance (Wilcoxon-Test2-sided)	**< 0,001**	**< 0,001**	**< 0,001**	**0,036**	**0,017**
	Improvement	**5,1 %**	**4,6 %**	**14,7 %**	**13,6 %**	**4,5 %**
	Effekt size (Cohens d)	**- 0,48** (low)	**- 0,42** (low)	**- 0,61** (medium)	**- 0,22** (low)	**0,201** (low)
Men (N = 37)	**Pre**	M = 49	M = 21,9	M = 33,7 cm	M = 75 sec.	M = 6,21 sec.
	Post	M = 51,7	M = 23	M = 37,7 cm	M = 96,8 sec.	M = 6,24 sec.
	Significance (Wilcoxon-Test2-sided)	**< 0,001**	**0,020**	**0,001**	**0,044**	**0,551**
	Improvement	**5,5 %**	**5 %**	**11,8 %**	**29 %**	**0,5 %**
	Effekt size (Cohens d)	**- 0,7** (medium)	**- 0,38** (low)	**- 0,56** (medium)	**- 0,30** (low)	**0,02** (very low)

	Motor fatigability-parameters (treatment phase 1 of intervention study)					
Women (N = 41)	**Pre**	M = 48,1	M = 21,8	M = 30,4 cm	M = 99,3 sec.	M = 7,0 sec.
	Post	M = 50,5	M = 22,8	M = 35,8 cm	M = 104,4 sec.	M = 6,3 sec.
	Significance (Wilcoxon-Test2-sided)	**0,017**	**0,007**	**< 0,001**	**0,382**	**0,005**
	Improvement	**5 %**	**4,6 %**	**15,1 %**	**5,1 %**	**10 %**
	Effekt size (Cohens d)	**- 0,38** (low)	**- 0,45** (low)	**- 0,64** (medium)	**- 0,12** (very low)	**0,4** (low)

Secondary psychosomatic syndromes (treatment phase 2 of the intervention study)			
	Total	**Men**	**Women**
Therapy evaluation at the PCZ (end of phase 1) = start of intensification ofcognitive behavioral therapy (start of phase 2)	N = 19 (100 %)	N = 4	N = 15
after 3 quarters of intensive cognitive behavioral therapy (end of phase 2)	N = 9 (47,4 %)	N = 2	N = 7
Improvement	**N = 10** (52,6 %)	**N = 2** (50 %)	**N = 8 (53,3 %)**

Development of further health parameters (observational study)					
	IMET	**VR-12** physicalhealth	**VR-12** mental health	**GAD 7**	**PHQ-9**
without intensive cognitivebehavioral therapy	M = 31,2	M = 38,45	M = 38,89	M = 10,5 (moderate symptoms)	M = 11,5 (mild symptoms)
with intensive cognitivebehavioral therapy	M = 35,6	M = 36,25	M = 34,64	M = 15 (severe symptoms)	M = 17 (moderate symptoms)

Table 1: Presentation of the total results.

Cognitive Fatigability Parameters

Table 1 shows the development of the study participants with fatigue and secondary psychosomatic symptoms after the end of phase 1 and the subsequent intensified cognitive behavioral therapy over 3 quarters (phase 2: Q2-2023 to Q4-2023). The positive effect of self-observation with accompanied self-control can be seen both in the overall view (improvement around 53%) and in the gender-specific analysis (improvement for men: 50%; improvement for women: around 53%).

Questionnaire-Based Analysis of Participation, Quality of Life and Mental Health

The survey with the validated individual questionnaires took place in Q2-2024 and at the earliest 3 months after the stress-controlled training therapy and, if necessary, additional intensified cognitive behavioral therapy. Restrictions on participation were recorded with the IMET, health-related quality of life was measured with the VR-12 and aspects of mental health were recorded with the GAD-7 and PHQ-9. Of the 78 participants in the intervention

study, 26 participants took part. As can be seen in Table 1, the participants with intensive cognitive behavioral therapy (treatment phase 2) continue to have severe anxiety symptoms and moderate depressive symptoms. Psychotherapeutic treatment should therefore continue to take place in order to improve participation and physical and mental health.

Discussion

The SARS-CoV-2 pandemic has shown that medical management functions stably, even with a large number of patients, if it can rely on established structures that are stably networked in routine operations. For example, specific treatment resources were available for stroke care in Germany, which linked the medical practice with the local university structures and could be used immediately for pandemic care. Initially this applied with the necessary precision, but only at intersections, such as TU Dres-den and BTU Cottbus-Senftenberg. This was the reason for the initially implemented monocentric design of the intervention study. This must be seen as a limitation for the overall conclusion of the study.

As part of the neurologically controlled conversion in the form of blended therapy for post-COVID-19-patients with fatigue and sensorimotor instability, it was demonstrated that individual stress-controlled training accompanying the main medical process at the post-Covid-19-center - and in approaches also cognitive behavioral therapy (treatment phase 1) as well as intensified cognitive behavioral therapy with a focus on self-control at home (treatment phase 2) the post-COVID-19-key symptoms “fatigue”, “sensorimotor instability”, “neuropsychiatric symptoms”, “cardiopulmo-nary/autonomic dysfunction”, “secondary psychosomatic symptoms” and “pain” could be reduced.

The digital interventions integrated into blended therapy in the form of a computer-supported training system and a mobile application support physical health. They improve the ability to maintain everyday activities and are independent of the location and time of the provision of analogue therapies by medical providers. At the same time, they prove to be particularly effective in dealing with fatigue symptoms. In order to increase adherence and effect strength among patients, digital therapy offers must be individually tailored to patients and their symptoms [6,7,20,22,26,30]. With hybrid training therapy, it is possible to implement a high training density.

The analysis of the gender-specific motor fatigability parameters showed that a timely implementation of the individual process stages of the therapy can lead to a better outcome. By integrating different service providers, 19 study participants (Table 1) with fatigue and secondary psychosomatic symptoms were integrated into a subsequent intensified cognitive behavioral therapy (treatment phase 2) after the end of treatment phase 1. The outcome was significantly improved.

With the cross-sector structure of blended therapy, the goal of a low-threshold primary care screening can be achieved in order to determine at an early stage the persistence of mainly neurological and neuroradiological manifestations of a COVID-19-disease requiring treatment, or the need for treatment in post-COVID-19-patients’ neurological functional disorders after a primarily non-severe course [4].

The family doctor will differentiate between existing and/or persistent (possibly activated by it) syndromes before the acute COVID illness, as well as the persistence of acute COVID syndromes (possibly as developing secondary syndromes) and, if necessary impending complications. The family doctor controls the symptomatic drug treatment. He decides which external expertise is necessary for screening and whether this should be obtained on an inpatient basis or whether the expertise of the post-COVID center (PCZ) or service providers at a central level is required.

As shown in Figure 1, the structured exchange of information between the individual actors can be coordinated via central data storage in order to achieve the best possible treatment success. This counteracts any delay in the start of therapy and accelerates the provision and coordination of services at the central and peripheral levels.

Compliance with Ethical Guidelines

All authors declare that they have no conflict of interest.

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