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Exercise benefits and barriers perceived by hemodialysis patients: relationship with fatigue and physical activity level

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ABSTRACT

Aims: The aim of our study was to determine the attitudes of hemodialysis (HD) patients towards exercise and to determine the relationship between physical activity level (PAL) and fatigue.

Methods: This cross-sectional study was conducted with 113 HD patients (57.8±5.96) aged 18-65 years. Personal information form, fatigue impact scale (FIS), international physical activity questionnaire short form (IPAQ-SF), and dialysis patient-perceived exercise benefits and barriers scale (DPEBBS) were used as data collection tools.

Results: The mean DPEBBS total score was 64.35±6.15 and PAL was low. The most commonly perceived exercise benefits were preventing muscle atrophy and maintaining a stable body weight, while the most common exercise barriers (EB) were not understanding how to exercise and fatigue. There was a weak negative correlation between the PAL of the patients with the Perceived Exercise Barriers subscale (r=-0.275, p=0.003) and a weak positive correlation between the total scale score (r=0.318, p=0.001). There was a weakly significant positive correlation between the Cognitive, Physical, Psychosocial sub-dimension of Fatigue and Total FIS with the Perceived Exercise Barriers sub-dimension (r=0.337, p=0.000; r=0.358, p=0.000; r=0.334, p=0.000; r=0.387, p=0.000). A very weakly significant negative correlation was found between the Fatigue Cognitive, Physical, Psychosocial sub-dimension and Fatigue Total Impact Dimension with the total scale score (r=-0.247, p=0.008; r=-0.234, p=0.013), r=-0.222, p=0.018, r=-0.243, p=0.003) .

Conclusion: HD patients had higher perceptions of the benefits of exercise. It was concluded that the perception of EB decreased as PAL increased and the perception of EB increased as fatigue levels increased. It is recommended that specialized physiotherapists evaluate HD groups at risk in detail and create individual interventions that support HD patients' compliance with exercise.

Keywords: Dialysis, exercise, sedantary behavior, fatigue

INTRODUCTION

Chronic kidney disease (CKD) is a progressive public health problem affecting more than 10% of the general population and more than 800 million people worldwide.[1] Most patients with CKD eventually progress to end-stage renal disease (ESRD) and require renal replacement therapy (RRT) such as peritoneal dialysis (PD), haemodialysis (HD) or kidney transplantation to survive.[2]

The most commonly used RRT method in the treatment of ESRD is HD.[3] Although the rapid development of HD technology can lead to a significant increase in the life expectancy of patients with ESRD and alleviate the uremic symptoms of CKD, it does not change the underlying disease process.[4]

Fatigue is a common symptom in HD patients and its prevalence ranges from 60-97%. The reduced level of physical activity, low functional capacity and general muscle weakness in these patients lead to a general feeling of fatigue.[5] Fatigue reduces self-care activities, disrupts family and social roles, reduces the ability to perform routine activities, and can lead to unemployment and increased dependence on healthcare. This situation negatively affects the patient's quality of life and self-confidence.[6]

Exercise is one of the most effective strategies used to control or eliminate dialysis symptoms and complications experienced by patients. It is highly beneficial for the physical health of dialysis patients. It improves cardiovascular function, blood pressure, muscle strength, nutritional status, dialysis quality, reduces negative emotions such as

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anxiety and depression, makes them feel good, improves social interaction of patients and their families.[7] Safe aerobic and resistance exercise programs that can be applied intradialytically and interdialytically have been developed to prevent lack of physical function in the HD population.[8] Meta-analyses have reported that aerobic exercise during HD reduces fatigue, improves resting blood pressure, urea clearance, muscle cramps and dialysis-related symptoms such as fatigue[7,9], and resistance exercise increases muscle strength, power and muscle endurance.[8]

Even though the benefits of exercise are clearly documented in the literature, most patients with ESRD have sedentary lifestyles and only 6% of HD patients are shown to have physical activity 4 to 5 days a week.[10] With the progression of kidney disease, the level of physical activity continuously decreases and reaches its lowest level in hemodialysis patients. This lowest level is particularly pronounced in elderly patients.[11] In addition, physical inactivity of HD patients leads to muscle atrophy, decreased muscle strength, and dysfunction.[11]

Although many benefits of exercise for dialysis patients are known, it should be investigated why most dialysis patients have insufficient physical activity and do not exercise. The findings of the study will provide data for the holistic evaluation of patients and the planning to be made to improve exercise behaviors. The aim of our study was to determine the effect of fatigue and physical activity level on exercise perception of hemodialysis patients and to determine the attitude of dialysis patients towards exercise.

METHODS

Ethics

The study was carried out with the permission of the Sakarya University of Applied Sciences Ethics Committee (Date: 07.07.2023, Decision No: 33/4). We obtained an informed consent form from all patients for procedure. All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

Patients

This cross-sectional study was carried out on HD patients treated at Dialysis Center in Sakarya province between September and October 2023. Participants between the ages of 18-65 years, who had the cognitive ability to understand the tests and assessments, could communicate verbally, and had been on HD treatment for at least 3 months were included in the study. As exclusion criteria: It was stated that lower extremity functions were affected due to any orthopedic problem or neurological disease (as it would affect the physical activity level), incomplete or invalid filling of the scale/questionnaire. Information was given before the study and signed informed consent was obtained from the participant who agreed to participate in the study.

Data Collection

"Personal Information Form, Fatigue Impact Scale, International Physical Activity Questionnaire Short Form and Exercise Benefits/Barriers Scale" were used as data collection tools. Data were collected in approximately 30 minutes by face-to-face questionnaire method. The Personal Information Form consisted of questions determining the participants' characteristics such as age, gender, body mass index, disease history, job and marital status.

Fatigue Impact Scale was used to define how fatigue creates problems in daily life in HD patients.[12] It is a scale consisting of a total of 40 questions, including 20 questions on psychosocial effects, 10 questions on social effects and 10 questions on cognitive effects. Each question is scored between 0-4 and the maximum score is 160. High scores indicate functional limitations due to fatigue.[12]

The International Physical Activity Questionnaire Short Form (IPAQ Short Form), which has Turkish validity and reliability, was used to determine the physical activity level of HD patients.[13] In the IPAQ, the criterion was that physical activities should be performed for at least 10 minutes (min) at a time. The questionnaire asked the duration of sitting, walking, moderate and vigorous physical activity in minutes in the last 7 days. These durations were converted to metabolic equivalents (MET). According to the total physical activity score, the physical activity levels of the individuals were categorized as "low, moderate and high". According to IPAQ, above 3000 MET-min/week(wk) is classified as high level, 600-3000 MET-min/wk as moderate level and below 600 MET-min/wk as low level physical activity.[13]

Dialysis Patient-perceived Exercise Benefits and Barriers Scale (DPEBBS) was used. Turkish validity and reliability were performed by Taş and Akyol.[14] The scale consists of 24 items, 2 open-ended questions and six sub-dimensions. Twelve of the 24 items (1, 2, 3, 4, 6, 7, 10, 13, 16, 20, 22 and 23) consisted of statements about the benefits of exercise, while the other 12 (5, 8, 9, 11, 12, 14, 15, 17-19, 21 and 24) consisted of statements that prevent exercise. Negative items were reversed and coded. The scale is a 4-point Likert scale (1=Strongly disagree, 2=Disagree, 3=Agree, and 4=Strongly agree) with a minimum score of 24 and a maximum score of 96. Higher scores indicate more perceived exercise benefits and fewer exercise barriers.[14]

Statistical Analysis

The effect size obtained in the reference study was found to be at a medium level (r=0.548).15 Considering that a lower effect size could be obtained (r=0.3), as a result of the power analysis; It was calculated that 90%

power could be achieved at a 95% confidence level if at least 109 people were included in the study. SPSS 25.0 (IBM SPSS Statistics 25 software (Armonk, NY: IBM Corp.)) package program was used for data analysis. Continuous variables were expressed as mean±standard deviation and categorical variables as number and percentage. Correlation analyses were used to examine the relationships between numerical variables. In all examinations, $p<0.05$ was considered statistically significant.15

RESULTS

Sociodemographic characteristics of the HD patients who participated in the study are shown in Table 1. The mean age of the participants was 57.8±5.96 years and 53.1% were male. It was determined that 72.6% of the participants were married, 49.6% were primary school graduates, 42.5% were retired and 37.2% were not working.

Table 1. Sociodemographic characteristics

	Mean±S.D	Med (IQR)	Min-Max	
Age, year	57.8±5.96	60 (55-61.5)	38-70	
			n	%
Gender				
Male			60	53.1
Woman			53	46.9
Marital Status				
Married			82	72.6
Single			11	9.7
Widow			20	17.7
Education Status				
Literate only			10	8.8
Primary school graduate			56	49.6
Secondary school graduate			27	23.9
High school graduate			16	14.2
Higher education graduate			2	1.8
University graduate			2	1.8
Job Status				
Works full time			4	3.5
Works part-time			1	.9
Not working-unemployed			42	37.2
Retired			48	42.5
Disability pensioner			18	15.9

HD: Hemodialysis, SD: Standard deviation, Med: Median, IQR: Interquartile range, min-max: minimum-maximum

The clinical characteristics of HD patients are shown in Table 2. The etiology of CKD was hypertension in 46.9% and diabetes mellitus in 25.7%, 90.3% had an additional chronic disease, 32.7% had hypertension as a comorbidity, and 85% had a dominant right extremity. The mean duration of CKD was 7.75±6.09 years, the mean duration of HD was 7.17±5.92 years, the mean BMI was 25.25±3.82 kg/m2, 43.4% were overweight and It was found that 48.7% had a low level of physical activity.

Table 2. Clinical features of the HD patients

	Mean±SD	Med (IQR)	Min-Max
BMI, kg/m²	25.25±3.82	25.39 (22.89-27.51)	16.85-39.19
Duration of CKD, years	7.75±6.09	6 (3-10)	1-32
HD duration, years	7.17±5.92	6 (3-9.5)	1-30
		n	%
BMI classification			
<18.5 kg/m² Weak		6	5.3
18.5-24.9 kg/m² Normal		48	42.5
25.0-29.9 kg/m² Overweight		49	43.4
30.0-34.9 kg/m² Grade I obesity		9	8.0
35.0-39.9 kg/m² Grade II obesity		1	.9
Dominant hand			
Right		96	85.0
Left		17	15.0
Etiology of CKD			
Hypertension		53	46.9
Glomerulonephritis		7	6.2
Diabetes		29	25.7
Urinary tract infections		5	4.4
Urinary stones		2	1.8
Polycystic kidney disease		8	7.1
Idiopathic		6	5.3
Urethral stricture		1	.9
Vesicoureteral reflux		1	.9
Long-term medication use		1	.9
Comorbidete status			
Diabetes		7	6.2
HT		37	32.7
Peripheral vascular disease		4	3.5
Chronic heart disease		6	5.3
Chronic lung disease		4	3.5
Cancer		3	2.7
Diabetes+HT		22	19.5
HT+chronic Lung Disease		2	1.8
Atherosclerosis		3	2.7
HT+atherosclerosis		2	1.8
HT+chronic heart disease		8	7.1
DM+ atherosclerosis		2	1.8
HT+COPD		2	1.8
No		11	9.7
Physical activity level			
Low level activity		55	48.7
Moderate activity		53	46.9
High level of activity		5	4.4

HD: Hemodialysis, BMI: Body Mass Index, CKD: Chronic kidney disease, HD: Hemodialisis, HT: Hypertension, COPD: Chronic Obstructive Pulmonary Disease, kg: kilogram, m: metre, SD: Standard deviation, Med: Median, IQR: Interquartile range, min -max: minimum-maximum

The mean scores of the scales used in the study are shown in Table 3. The mean IPAQ score was 925.54±921.93 and the mean total score of the exercise benefits/barriers scale was 64.35±6.15. While the mean of fatigue total effect dimension was 5±3.91, the mean of fatigue cognitive sub-dimension (12.9±13.71) was higher than the mean of physical (3.04±2.19) and psychosocial (6.54±8.7) fatigue sub-dimensions.

Table 3. Average scores of the scales (n=113)

	Mean±S.D	Med (IQR)	min-max
IPAQ value	925.54±921.93	610 (274.5-1386)	66-4751
Exercise benefits/ barriers scale total score	64.35±6.15	65 (60-69)	45-81
Exercise benefits	27.58±4.25	28 (25-30)	15-40
Exercise barriers	36.77±5.5	37 (33-40)	20-51
Fatigue total impact dimension score	5±3.91	3.8 (2,56-6.15)	1.63-22.85
Fatigue cognitive	12.9±13.71	5.71 (3.33-20)	1.73-40
Fatigue physical	3.04±2.19	2.5 (1.9-3.63)	1.02-20
Fatigue psychosocial	6.54±8.7	4.7 (2.71-6.66)	1.7-80

IPAQ: International Physical Activity Questionnaire, SD: Standard deviation, Med: Median, IQR: Interquartile range, min -max: minimum-maximum

Table 4 shows the distributions of the item means of the DPEBBS scale. Among the twelve statements regarding the benefits of exercise, "exercise prevents muscle atrophy" received the highest score (2.96±0.78), followed by "exercise can keep my body weight at a constant level" (2.94±0.7). The statements "Exercise will help reduce my total health expenditures" and "Exercise will protect me from developing other diseases" received the lowest scores (2.23±0.81; 2.36±0.89, respectively). Among the twelve statements that prevent exercise, "I lack understanding of how exercise is done" (3.28±0.85) received the highest score, followed by "frequent fatigue prevents me from participating in exercise" (3.08±0.92). The statements "I need my family to be with me when I am outside, so exercising outdoors puts a burden on my family" and "exercise negatively affects the health of dialysis patients" received the lowest exercise barriers score (1.96±0.83; 2.19±0.77, respectively).

The relationship between patients' DPEBBS and IPAQ and FIS is shown in Table 5. There was a weak negative correlation between the Physical Activity Level of the patients with the Perceived Exercise Barriers subscale (r=-0.275, p=0.003) and a weak positive correlation between the total scale score (r=0.318, p=0.001), (p<0.05). There was a weakly significant positive correlation between the Cognitive, Physical, Psychosocial sub-dimension of Fatigue and Total Impact of Fatigue with the Perceived Exercise Barriers sub-dimension (r=0.337, p=0.000; r=0.358, p=0.000; r=0.334, p=0.000; r=0.387, p=0.000) (p<0.05). A very weakly significant negative correlation was found between the Fatigue Cognitive, Physical, Psychosocial sub-dimension and Fatigue Total Impact Dimension with the total scale score (r=-0.247, p=0.008; r=-0.234, p=0.013), r=-0.222, p=0.018, r=-0.243, p=0.003) (p<0.05).

Table 4. Distribution of DPEBBS item averages

	Mean±S.D	Med (IQR)	min-max
Benefits			
Q1. Exercise helps reduce my total medical costs.	2.23±0.81	2 (2-3)	1-4
Q2. Exercise helps reduce my body pain.	2.68±0.84	3 (2-3)	1-4
Q3. Exercise can postpone a decline in body function.	2.64±0.79	3 (2-3)	1-4
Q4. Exercise prevents muscular wasting.	2.96±0.78	3 (3-3)	1-4
Q6. Exercise improves my mood.	2.71±0.72	3 (2-3)	1-4
Q7. Exercise improves bone disease.	2.78±0.73	3 (2-3)	1-4
Q10. Exercise improves my appetite.	2.77±0.87	3 (2-3)	1-4
Q13. Exercise helps me to lead an optimistic and active life.	2.79±0.56	3 (2,5-3)	1-4
Q16. Exercise improves my quality of life.	2.82±0.49	3 (3-3)	1-4
Q20. Exercise can keep my body weight at a steady level.	2.94±0.7	3 (3-3)	1-4
Q22. Exercise helps enhance my self-care abilities.	2.65±0.56	3 (2-3)	1-4
Q23. Exercise will keep me free from having other diseases (e.g., cold).	2.36±0.89	2 (2-3)	1-4
Barriers			
Q5. Frequent tiredness impedes my exercise participation.	3.08±0.92	3 (3-4)	1-4
Q8. Exercise is adverse to health of dialysis patients.	2.19±0.77	2 (2-3)	1-4
Q9. I worry about a fall during exercise.	2.58±1.09	3 (2-3)	1-4
Q11. Frequent lower-extremity muscle fatigue impedes my exercise	2.96±0.89	3 (2-4)	1-4
Q12. I lack an understanding of the benefits of exercise.	2.98±0.93	3 (2-4)	1-4
Q14. Exercise is not suitable for me since I have other medical conditions.	2.45±0.81	2 (2-3)	1-4
Q15. Body pain impedes my exercise participation.	2.85±0.84	3 (2-3)	1-4
Q17. I lack an understanding of the knowledge on how to carry out exercise.	3.28±0.85	3 (3-4)	1-4
Q18. I worry that exercise may make me feel thirsty.	2.86±1.07	3 (2-4)	1-4
Q19. Exercise is not suitable for me since I have kidney disease	2.41±0.82	2 (2-3)	1-4
Q21. I worry that exercise may affect my arteriovenous fistula.	2.98±1.03	3 (2-4)	1-4
Q24. Outdoor exercise adds burden to my family (since I need their company while I am out).	1.96±0.83	2 (1-2)	1-4

DPEBBS: Dialysis patient-perceived exercise benefits and barriers scale

Table 5. Relationship between patients' DPEBBS and IPAQ and FIS

		Exercise benefits	Exercise barriers	Total scale score
Physical activity level	r	-0.010	-0.275*	0.318*
	p	0.916	0.003	0.001
Fatigue cognitive	r	0.135	0.337*	-0.247*
	p	0.155	0.000	0.008
Fatigue physical	r	0.192	0.358*	-0.234*
	p	0.052	0.000	0.013
Fatigue psychosocial	r	0.163	0.334*	-0.222*
	p	0.085	0.000	0.018
Fatigue total impact Dimension	r	0.177	0.387*	-0.243*
	p	0.060	0.000	0.003

Fatigue Impact Scale (FIS), International Physical Activity Questionnaire Short Form (IPAQ-SF), Exercise Benefits/Barriers Scale ((DPEBBS), p<0,05

DISCUSSION

In this study, which was conducted to determine the attitudes of hemodialysis patients towards exercise and to determine the relationship between physical activity level and fatigue, it was found that the patients' perceptions of the benefits of exercise were at a moderate level according to the DPEBBS value and the patients were stated to have low levels of physical activity. A significant relationship was found between the total scale score of benefits and barriers of exercise and the dimensions of physical activity and fatigue.

Considering that the mean total score of the Exercise Benefits and Barriers Scale in this study shows that higher scores indicate more perception of exercise benefits and less perception of exercise barriers (the lowest score that can be obtained from DPEBBS is 24 and the highest score is 96), it can be said that their perception of the benefits of exercise is at a moderate level. When the relevant studies conducted in hemodialysis patients in the literature were examined, it was shown that the mean DPEBBS score was 61.76±13.97 in the study of Kılıc and Uzdil[15], while the mean DPEBBS score was 62.47±10.60 in the study of Dogru and Kasal[10] and these scores were similar to the results of our study. The results of these studies revealed that most of the patients receiving HD treatment had a positive perception of the benefits of exercise and stated that exercise could be beneficial for their health. However, in our study, the most frequently perceived exercise benefits were preventing muscle atrophy and keeping body weight at a constant level, while the most common exercise barriers were lack of understanding of how to do exercise and fatigue prevents me from participating in exercise. In Darawad and Khalil's[16] study, the most frequently perceived benefits of exercise in hemodialysis patients were prevention of muscle atrophy and improvement of mood, while fatigue and lower extremity fatigue were the most common barriers to exercise. Jayaseelan et al.[17] reported that most patients reported that exercise was positive in terms of preventing bone disease, maintaining body weight at a stable level, improving mood, quality of life and barriers to exercise such as fear of falling, family burden, vascular access. Lightfoot et al.[18] 53-76% of patients reported "lack of knowledge about how to exercise in dialysis patients" and "lack of understanding of the benefits of exercise". Although patients' knowledge of the benefits of exercise is high, their knowledge of exercise in HD is relatively poor and the results of this study provide evidence for this view. When examining HD patients' perceptions of exercise, the dialysis team should focus on the direct benefits and barriers of exercise, identify exercises appropriate for the individual, and encourage patients to exercise regularly.

Sarcopenia, muscle wasting, nutritional deficiencies, decreased exercise tolerance, significant arterial hypotension during HD sessions and fatigue after HD sessions cause individuals with ESRD to be sedentary.[19,20] In this study, 48.7% of HD patients had low physical activity levels. Musolino et al.[21] found that ESRD patients were severely sedentary and METs of these patients was 590. Observational and epidemiologic studies have reported that 45% of patients with ESRD do not exercise at all and individuals with CKD participate in physical activity 9 days per month.[22] In addition, physical inactivity has been reported as a strong predictor of mortality in hemodialysis patients.[23] A cohort study in Taiwan found that patients with CKD who switched from a highly active to a less active state were at risk for all-cause mortality, ESRD and unintentional cardiovascular events.[24] In a study by Matsuzawa et al.[23] in which physical activity was objectively assessed, it was found that every 10 minutes of daily increase in physical activity decreased the risk of death by 22% in hemodialysis patients. However, in our study, it was found that as the physical activity level of the patients increased, the perceived Exercise Barriers subscale score decreased and the total scale score increased. In another study conducted in the literature to compare the perception of exercise in HD patients with different physical activity levels, fatigue, muscle fatigue and lack of exercise knowledge were found to be common barriers and these barriers were shown to have a significant effect on the physical activity level of the patient.[25] Regolisti et al.[26] problems such as experiencing fatigue and pain on HD days, lack of motivation, and feeling helpless are reported as the main barriers perceived by patients in physical activity. In addition to lack of confidence due to lack of guidelines, the dialysis medical team does not encourage HD patients to exercise due to lack of time.[26]

Currently, the concept of physical literacy in CKD, which includes confidence, ability and motivation to engage in physical activity, has entered the literature.[27] Physical literacy involves learning in the psychomotor, cognitive and emotional domains; therefore, interventions should be supported by effective cognitive strategies to enable inactive middle-aged and older adults with CKD to learn the value of physical activity. From this perspective, patients' physical activity status should be assessed and managed as part of routine renal care.[25]

In our study, it was found that as the fatigue sub-dimensions and total scores of the patients increased, the perceived Barriers to Exercise score increased and the total scale score of Exercise Benefits/Barriers decreased. In previous studies, symptom-related fatigue and hemodialysis were found to be the most common barriers to exercise. In a literature review by Hannan and Bronas[28], fatigue and low energy levels were the most commonly reported barriers to regular exercise in patients with CKD or receiving dialysis treatment. Kılıc and Uzdil15 reported that the majority of participants were unable to exercise due to fatigue, and other studies in the literature emphasize that fatigue is the biggest barrier to exercise.[29,30] Considering this information, if fatigue is managed effectively in HD patients, the fatigue factor that prevents exercise can be eliminated and the opportunity to exercise can be created for them.

In this study, the most frequently perceived exercise benefits were preventing muscle atrophy and maintaining body weight at a constant level, whereas the most common exercise barriers were lack of understanding of how exercise is performed and fatigue prevents me from participating in exercise. Over time, aerobic capacity and muscle strength decline in CKD. Meta-analyses have reported that aerobic exercise during HD reduces fatigue, improves resting blood pressure, urea clearance, muscle cramps and dialysis-related symptoms, and resistance exercise increases muscle strength and muscular endurance.[7,9] However, in our study, as the physical activity level of the patients increased, the perceived Exercise Barriers subscale score decreased and the total scale score increased. In addition, it was found that as the fatigue sub-dimensions and total scores of the patients increased, the perceived Exercise Barriers score increased and the Exercise Benefits/Barriers total scale score decreased. According to the findings of the study, physical activity and fatigue levels of HD patients are associated with exercise perception. For this reason, physical activity and fatigue levels of HD patients should be evaluated and individualized treatment interventions should be developed.

Finally, in this study, patients' perceived exercise benefits were found to be higher than exercise barriers. In another study, exercise was perceived positively for HD recipients in the majority of participants.[8] Although this finding is considered to be positive, it is thought that additional research is needed to determine the barriers that patients perceive in exercise and that interventions specific to each patient should be developed to overcome these barriers.

Limitations

The limitations of the study are that the study was conducted in a single center and self-report scales were used.

CONCLUSION

Our study found that HD patients had higher perceptions of the benefits of exercise and low physical activity levels. As physical activity levels increased, the perception of exercise barriers decreased and concluded that the perception of exercise barriers increased as fatigue levels increased. It is recommended that specialized physiotherapists evaluate HD groups at risk in detail and create individual interventions that support HD patients' compliance with exercise.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was carried out with the permission of Sakarya University of Applied Sciences Ethics Committee (Date: 07.07.2023, Decision No: 33/4).

Informed Consent

All patients signed and free and informed consent form.

Referee Evaluation Process

Externally peer reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

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Author Contributions

All the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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