



# The Prevalence of Sarcopenia and Its Association With Sleep Disorders, Stress, Anxiety, and Depression in Hemodialysis Patients

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## Abstract

**Background and aims:** Hemodialysis (HD) is associated with patients' onset and acceleration of sarcopenia progression. Sleep disorders and mental health issues potentially increase the risk of sarcopenia in patients. However, these associations have not been adequately evaluated in HD patients. Therefore, the current study aimed to estimate the prevalence of sarcopenia and its association with sleep disorders, stress, anxiety, and depression in HD patients.

**Methods:** This cross-sectional study consisted of patients undergoing HD in two hospitals in Hamadan between May and July 2023. Demographic and socioeconomic information, along with data on depression, anxiety, and stress (using the Depression, Anxiety, and Stress Scale-21 Items, DASS-21), sleep disorders (using the Athens Insomnia Scale), and SARC-F (strength, assistance with walking, rising from a chair, climbing stairs, and falls) questionnaire were collected through face-to-face interviews. Data were analyzed using independent *t* tests, ANOVA, and Pearson correlation coefficient using Stata software version 14.

**Results:** The study included 150 HD patients (age range: 18-88 years; 54.67% male). The results revealed a sarcopenia prevalence rate of 41.3%. Demographic and socioeconomic factors such as gender and education level were found to be associated with sarcopenia. Moreover, positive associations were identified between sarcopenia and various indicators such as stress ( $r=0.27$ ,  $P<0.001$ ), anxiety ( $r=0.49$ ,  $P<0.001$ ), depression ( $r=0.39$ ,  $P<0.001$ ), and sleep disorders ( $r=0.30$ ,  $P<0.001$ ).

**Conclusion:** The prevalence of sarcopenia among HD patients was observed to be high, particularly among females, less educated individuals, and those with elevated levels of depression, anxiety, stress, and sleep disorders.

**Keywords:** Sarcopenia, Mental health, Hemodialysis patients, Cross-sectional study

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Received: February 11, 2023

Accepted: December 18, 2023

ePublished: June 15, 2024



## Introduction

Chronic kidney disease (CKD) poses a significant global health challenge.<sup>1</sup> CKD is defined as kidney damage or decreased kidney function persisting for at least three months.<sup>2</sup> If kidney function falls below 15% of its normal capacity, it is considered end-stage renal disease (ESRD), necessitating hemodialysis (HD) or peritoneal dialysis for survival.<sup>3</sup> The global population experienced an annual growth rate of 1.1%, whereas the prevalence of patients with ESRD increased by approximately 6%.<sup>4</sup>

The prevalence of mental health issues in HD patients is significantly higher than that of those with other chronic conditions.<sup>5,6</sup> Depression is the most common mental health problem reported among these patients,<sup>7</sup> with a reported prevalence ranging from 22.8% to 39.3%.<sup>5</sup> Studies have indicated that 12% to 52% of HD patients

experience anxiety during their dialysis sessions.<sup>8,9</sup> The sources of anxiety in these patients are diverse and can stem from the stress associated with frequent hospital visits, transportation issues, and invasive HD procedures such as needle insertion into arteriovenous fistulas, placement of central venous catheters, alarm sounds in the dialysis machine, and staff shift changes at the dialysis station.<sup>8,10</sup> Additionally, prolonged time spent with other patients and the inability to take long trips significantly disrupt patients' social lives.<sup>8,11,12</sup>

During dialysis sessions, HD patients must adapt to specific limitations such as dietary restrictions, fluid intake control, chronic pain, and discomfort associated with arteriovenous fistulas.<sup>13</sup> Furthermore, these patients face multiple comorbidities, frequent hospitalizations, and repetitive injuries following dialysis. The daily

functioning challenges and fear of the future undoubtedly influence the onset of depression and anxiety symptoms.<sup>6</sup> The findings of the study by Kurita et al support the existence of a potential pathogenic pathway in which depression directly contributes to the onset of sarcopenia in patients with CKD undergoing HD.<sup>14</sup>

Sarcopenia is a chronic condition characterized by the loss of skeletal muscle mass and a gradual decrease in muscle strength and function with age.<sup>15,16</sup> Sarcopenia may be more severe among vulnerable populations such as those with end-stage kidney disease. In HD patients, the prevalence of sarcopenia has been reported between 12.7% and 33.7%,<sup>17,18</sup> and individuals with sarcopenia are at a higher risk of fractures, anxiety, depression, cardiovascular complications, and mortality. Therefore, early identification and interventions for HD patients with sarcopenia are crucial for effective disease management.<sup>19</sup>

Indeed, the association between mental health indicators such as stress, anxiety, depression, and disturbances in muscle-related clinical indices (e.g., sarcopenia) has not been extensively examined regarding the clinical status of patients. Therefore, the results of such a study would provide better insight into the management of mental health in these patients and help identify more vulnerable groups, thereby informing healthcare policymakers.

## Materials and Methods

The current cross-sectional (descriptive-analytical) study was conducted on hospitalized HD patients in the dialysis departments of Besat and Shahid Beheshti hospitals in Hamadan in 2022. This study included cases of ESRD cases.

After obtaining ethical approval and the project's approval from the Deputy of Research and Technology, the SARC-F (strength, assistance with walking, rising from a chair, climbing stairs, and falls), Athens Insomnia Scale, and DASS-21 (Depression, Anxiety, and Stress Scale-2) questionnaires were administered to the patients by a trained specialist. The respective specialist assisted patients who were unable to read, write, or complete the questionnaires by conducting verbal questioning. Clinical information was also extracted from the patients' medical records. This study used a census method and included all HD patients in the dialysis departments of Shahid Beheshti and Besat hospitals in Hamadan (150 patients).

The 5-item SARC-F questionnaire was used to screen patients for sarcopenia. It includes muscle strength, assistance with walking, rising from a chair, climbing stairs, and a history of falls. Total scores range from 0 to 10, with each component scoring from 0 to 2 points. A score equal to 4 or higher indicates a risk of sarcopenia and poor outcomes.<sup>20</sup>

The stress, anxiety, and depression of the patients were measured by the DASS-21 questionnaire. It consists of 21 questions divided into three components: stress, anxiety, and depression, each containing seven questions, and the final score for each component is obtained by summing

the scores of the relevant questions. Each question is rated from 0 (not at all) to 3 (very much). Since the DASS-21 is a shortened version of the original 42-item scale, the final score for each subscale should be doubled (the score for each component ranges from 0 to 42). The validity and reliability of the Persian version of the DASS-21 questionnaire have been demonstrated in various studies.<sup>21,22</sup>

The Athens Insomnia Scale questionnaire was used to measure sleep disorders. This questionnaire includes eight items: five related to sleep quality and duration and three other items assessing the impact of sleep quality on daily functioning. Individuals are asked to indicate if they have experienced sleep disturbances at least three times a week over the past month. The score obtained by each individual is calculated, and those with a score of 6 or less are considered to have no sleep disorder, while those with a score above 6 are believed to have a sleep disorder. The validity and reliability of this questionnaire have been confirmed in previous studies conducted in the country.<sup>23</sup>

The mean (standard deviation) was used to describe the status of sarcopenia, sleep disorders, stress, depression, and anxiety in terms of the variables under investigation. Independent *t*-tests and ANOVA were employed to compare the means of these indicators based on the investigated qualitative variables for the baseline characteristics of the patient comparisons, respectively. In the case of categorizing the outcome variables for descriptive and statistically significant analysis, the number (percentage) and chi-square tests were used. The correlation between sarcopenia scores and psychological indicators scores was examined using the Pearson correlation coefficient. All analyses were performed using Stata software, version 14, with a significance level of 0.05 for *P* values.

## Results

This study investigated 150 HD patients. Table 1 presents the relationship between stress, anxiety, depression, sleep disorders, and sarcopenia scores within this patient's characteristics. Stress levels exhibited a significant gender difference ( $P < 0.001$ ), with females experiencing higher stress levels. Additionally, patients aged 30-60 years ( $P = 0.022$ ), those with limited literacy ( $P = 0.002$ ), and those with a disease duration exceeding five years ( $P < 0.01$ ) reported higher stress levels. Anxiety was significantly more prevalent in females ( $P < 0.001$ ), illiterate patients ( $P < 0.001$ ), those undergoing dialysis four times a week ( $P = 0.005$ ), and those with an extended disease duration ( $P = 0.002$ ). Depression scores were significantly elevated in females ( $P < 0.001$ ), illiterate patients ( $P < 0.001$ ), and those with a longer disease duration ( $P = 0.004$ ). Sleep disorders were significantly more common in females ( $P < 0.001$ ), illiterate patients ( $P < 0.001$ ), those undergoing dialysis three times a week ( $P = 0.004$ ), and non-hypertensive patients ( $P < 0.001$ ). Furthermore, sarcopenia scores showed significant differences in females ( $P = 0.008$ ) and

**Table 1.** Characteristics of Hemodialysis Patients According to Stress, Anxiety, Depression, Sleep Disorder, and Sarcopenia

Variable		N (%)	Stress	P Value	Anxiety	P Value	Depression	P Value	Sleep Disorder	P Value	Sarcopenia	P Value
Gender	Male	82 (54.67)	25.60±11.10	<0.001	19.31±7.48	<0.001	25.26±7.55	<0.001	15.39±5.16	<0.001	2.46±2.35	0.008
	Female	68 (45.33)	34.52±9.86		24.11±8.58		32.11±9.11		19.44±6.56		3.61±2.98	
Age Group	≤30	6 (4.0)	24.0±10.88		14.66±1.03		20.0±3.57		16.0±0.89		2.0±2.36	
	30-60	70 (46.67)	32.28±11.30	0.022	22.17±8.88	0.104	28.74±8.72	0.063	16.51±5.80	0.312	2.68±2.95	0.224
	≥60	74 (49.33)	27.62±11.14		21.40±7.91		28.70±9.20		18.0±6.66		3.35±2.45	
Location	Urban	128 (85.33)	29.21±11.09	0.262	21.09±7.71	0.157	28.28±8.92	0.762	17.29±6.18	0.737	2.84±2.38	0.119
	Rural	22 (14.67)	32.18±13.22		23.81±11.19		28.90±9.29		16.81±6.16		3.81±4.11	
Marriage	Single	26 (17.33)	29.23±10.65		20.30±7.62		25.84±6.71		16.23±4.14		2.30±2.09	
	Married	104 (69.33)	29.11±11.94	0.373	21.61±8.83	0.677	28.30±9.66	0.067	17.03±6.25	0.174	3.05±2.85	0.299
	Widowed	20 (13.33)	33.0±9.36		22.4±6.47		32.0±6.29		19.5±7.50		3.5±2.56	
Education	Illiterate	32 (21.33)	32.12±10.49		23.12±7.07		32.37±8.47		20.25±6.90		4.37±2.80	
	Elementary school	54 (36.0)	32.29±11.18		24.37±10.25		30.44±9.16		18.70±6.34		3.85±2.83	
	Middle school	16 (10.67)	30.75±22.57	0.002	19.25±2.90	<0.001	28.25±8.54	<0.001	14.62±4.03	<0.001	1.0±1.36	<0.001
	High school	28 (18.67)	22.57±10.76		16.42±5.11		21.14±5.99		12.92±3.38		1.64±1.74	
	Academic	20 (13.33)	27.6±9.78		20.0±7.28		26.6±6.93		16.5±4.83		1.9±1.97	
Occupation	Unoccupied	124 (82.67)	29.12±11.37	0.221	21.03±7.68	0.139	27.87±9.05	0.133	17.46±6.38	0.296	3.03±2.60	0.654
	Occupied	26 (17.33)	32.15±11.57		23.69±10.81		30.76±8.17		16.07±4.92		2.76±3.20	
Dialysis session Week	2 times	24 (16.0)	26.16±10.82		19.0±7.24		26.66±8.83		14.0±3.88		2.41±2.68	
	3 times	114 (76.0)	29.75±11.15	0.061	21.29±7.60	0.005	28.77±8.85	0.574	18.14±6.26	0.004	2.92±2.59	0.056
	4 times	12 (8.0)	35.66±13.39		28.33±13.06		28.0±10.37		15.0±6.55		4.66±3.33	
Disease duration	5≥	62 (41.33)	26.25±12.41		19.74±7.77		26.19±8.55		16.09±5.41		2.77±2.54	
	5-15	50 (33.33)	30.8±9.88	0.010	20.48±5.72	0.002	28.8±7.47	0.004	17.76±6.27	0.065	2.48±2.50	0.053
	15-30	34 (22.67)	34.0±10.74		25.29±10.85		32.47±10.57		19.0±7.09		4.05±3.14	
	30≤	4 (2.67)	31.0±3.46		29.0±8.08		22.0±0.0		13.0±1.15		3.5±1.73	
Diabetes	Yes	38 (25.33)	28.73±12.77	0.569	22.84±8.58	0.249	28.0±9.06	0.767	16.57±6.82	0.455	2.63±2.63	0.351
	No	112 (74.67)	29.96±10.98		21.03±8.23		28.5±8.94		17.44±5.93		3.10±2.73	
Hypertension	Yes	48 (32.0)	30.0±10.96	0.799	20.58±7.98	0.360	29.75±9.26	0.197	19.95±5.80	<0.001	3.58±2.79	0.064
	No	102 (68.0)	29.49±11.69		21.92±8.48		27.72±8.76		15.94±5.92		2.70±2.63	
Vein access	Fistula	92 (61.33)	29.91±12.01		21.65±8.89		28.95±8.99		16.56±6.06		3.0±2.66	
	Graft	6 (4.0)	36.0±6.44	0.293	22.0±6.44	0.932	30.0±4.73	0.462	19.0±5.58	0.243	2.66±1.86	0.957
	Permanent catheter	52 (34.67)	28.46±10.66		21.15±7.55		27.15±9.22		18.19±6.32		3.0±2.91	

illiterate patients ( $P<0.001$ ). In total, the prevalence of severe stress, anxiety, and depression among the patients was 41.33%, 46.67%, and 50.67%, respectively. Out of the patients examined, 62 individuals (41.33%) were diagnosed with sarcopenia.

Table 2 presents a comparative analysis of stress, anxiety, depression, and sleep disorder levels between sarcopenic and non-sarcopenic patients. The sarcopenic patients experienced significantly higher levels of very severe stress ( $P=0.032$ ) and depression ( $P<0.001$ ), while the very high intense level of anxiety was significantly higher in non-sarcopenic patients ( $P<0.001$ ). Moreover, sleep disorder was considerably higher in non-sarcopenic patients (45.45% vs. 16.13%,  $P<0.001$ ).

As evident in Table 3, there is a direct and significant correlation between stress ( $r=0.27$ ,  $P<0.001$ ), anxiety ( $r=0.49$ ,  $P<0.001$ ), depression ( $r=0.39$ ,  $P<0.001$ ), sleep

disorder ( $r=0.3$ ,  $P<0.001$ ), and sarcopenic scores of the HD patients.

## Discussion

The findings of this study indicated a relatively high prevalence of sarcopenia among HD patients in Hamadan. Furthermore, the study highlighted the connection between psychological and sleep disorders in HD patients suffering from sarcopenia.

The prevalence of sarcopenia in the current study was 41.3%. In a study on the Japanese population, the prevalence was 40%.<sup>19</sup> Fu et al reported severe sarcopenia among HD patients as 22.4%.<sup>24</sup> The difference in the prevalence of sarcopenia between the current study and previous studies can be attributed to differences in the studied populations (hospital-based vs. community-based),<sup>24</sup> variations in the stage of kidney failure, and the lack of international

**Table 2.** Characteristics of Hemodialysis Patients According to Sarcopenic Status (N = 150)

Variable		Total No. (%)	Sarcopenic (n=62) No. (%)	Nonsarcopenic (n=88) No. (%)	P Value
Stress	Normal	10 (6.67)	2 (3.23)	8 (9.09)	0.032
	Mild	24 (16.0)	4 (6.45)	20 (22.73)	
	Moderate	34 (22.67)	16 (25.81)	18 (20.45)	
	Severe	20 (13.33)	10 (16.13)	10 (11.36)	
	Very severe	62 (41.33)	30 (48.39)	32 (36.36)	
Anxiety	Moderate	28 (18.67)	24 (27.27)	4 (6.45)	<0.001
	Severe	52 (34.67)	38 (43.18)	14 (22.58)	
	Very severe	70 (46.67)	26 (29.55)	44 (70.97)	
Depression	Moderate	32 (21.33)	8 (12.90)	24 (27.27)	<0.001
	Severe	42 (28.0)	10 (16.13)	32 (36.36)	
	Very severe	76 (50.67)	44 (70.97)	32 (36.36)	
Sleep disorder	With sleep disorder	100 (66.67)	10 (16.13)	40 (45.45)	<0.001
	Without sleep disorder	50 (33.33)	52 (83.87)	48 (54.55)	

**Table 3.** Correlation Between Stress, Anxiety, Depression, Sleep Disorder, and Sarcopenic Scores of Hemodialysis Patients

	Stress	Anxiety	Depression	Sleep Disorder	Sarcopenia
Stress	1.00				
Anxiety	r=0.65 P<0.001	1.00			
Depression	r=0.78 P<0.001	r=0.66 P<0.001	1.00		
Sleep disorder	r=0.31 P<0.001	r=0.31 P<0.001	r=0.49 P<0.001	1.00	
Sarcopenia	r=0.27 P<0.001	r=0.49 P<0.001	r=0.39 P<0.001	r=0.30 P<0.001	1.00

consensus on a uniform criterion for assessing sarcopenia in CKD patients.<sup>12</sup> Therefore, establishing a standard definition for sarcopenia is necessary for accurate assessment. The current study used the SARC-F tool to evaluate the prevalence of sarcopenia. Tsekoura et al in Greece also estimated a prevalence of 41.7% using this tool.<sup>25</sup> Sarcopenia is a clinical syndrome characterized by progressive muscle loss and reduced muscle function and is associated with chronic diseases such as CKD.<sup>12</sup> CKD patients are more likely to develop sarcopenia due to factors such as toxin accumulation, oxidative stress, and increased insulin resistance compared to the general population.<sup>26</sup> Evidence of molecular muscle breakdown mechanisms due to uremic toxin accumulation in HD patients is well-documented.<sup>25</sup> According to the results of a meta-analysis in 2022, the prevalence of sarcopenia in the general population was reported as 27%-10%.<sup>27</sup> Another meta-analysis estimated sarcopenia prevalence among kidney transplant recipients as 26%.<sup>28</sup> Findings of an Iranian study in 2018 reported a prevalence of 11.5% in peritoneal dialysis patients.<sup>29</sup>

The results of this study indicated that patients with a longer CKD duration were at a higher risk of developing sarcopenia, but this difference was not statistically significant. The study by Mattera et al also demonstrated that sarcopenia progression in dialysis patients is faster compared to CKD patients in the pre-dialysis stage and worsens with longer HD duration.<sup>12</sup>

Our findings showed no significant correlation between the average sarcopenia score and the number of dialysis sessions per week. However, some evidence suggests that systemic inflammation resulting from contact with dialysis membranes, reduced physical activity, amino acid loss, and prolonged immobility during HD are associated with sarcopenia.<sup>12</sup> There is a bidirectional relationship between CKD and sarcopenia. Wilkinson et al reported that CKD patients with sarcopenia were twice as likely to progress to advanced stages of kidney failure.<sup>30</sup> Likewise, Souza et al reported a significant association between a higher sarcopenia prevalence and a greater decline in kidney function in non-dialysis CKD patients.<sup>31</sup>

In our study, the prevalence of sarcopenia was higher in women than in men. This contrasts with Ashabi and colleagues' findings, where sarcopenia was more prevalent in men undergoing peritoneal dialysis.<sup>29</sup> In this study, the higher prevalence in men can be attributed to reduced testosterone levels and, consequently, decreased muscle protein synthesis.

Muscle mass reduction is associated with decreased glucose metabolism capacity, and patients with sarcopenia may have higher blood sugar levels. Therefore, individuals with type 2 diabetes are at a higher risk of sarcopenia.<sup>32</sup> Mori et al found that diabetes is an independent predictor of mortality in HD patients with sarcopenia.<sup>20</sup> Formiga et al also demonstrated a higher prevalence of severe sarcopenia in diabetic patients.<sup>33</sup> However, our study



found no statistically significant difference in sarcopenia levels between insulin-dependent and non-insulin-dependent patients. Unexpectedly, our findings did not report any association between diabetes and sarcopenia. We hypothesized that this lack of correlation could be due to glucose intolerance in the non-sarcopenic group.<sup>25</sup>

Moreover, a significant relationship was reported between sleep disorders and sarcopenia prevalence among patients in our study. This finding is consistent with Ida and colleagues' results.<sup>34</sup> However, Fábrega-Cuadros and colleagues' findings did not report any association between sleep quality, duration, and sarcopenia.<sup>35</sup> Likewise, Szlejf et al did not find any association between sarcopenia and sleep duration or frequent insomnia complaints.<sup>36</sup> The results of a meta-analysis in 2023 associated changes in sleep duration with an increased risk of sarcopenia in the elderly.<sup>37</sup> Although the primary mechanism by which sarcopenia affects sleep is not well understood, insulin resistance may impact sleep through the suprachiasmatic nucleus and thalamus, leading to disruptions in sleep rhythms and sympathetic stimulation.<sup>34</sup> Poor sleep quality in CKD patients can lead to decreased insulin-like growth factor and growth hormone levels, increased cortisol and inflammatory cytokines, and reduced muscle mass.<sup>38</sup> The assumption is that chronic hypoxia and interrupted sleep may adversely affect the nervous system and endocrine glands, explaining the relationship between sleep disorders and sarcopenia.<sup>36</sup>

Existing evidence suggests that patients with kidney failure are at a higher risk for psychological problems such as depression and anxiety. Furthermore, the presence of depression in patients with sarcopenia is not unexpected.<sup>25</sup> Anxiety and depression are highly prevalent in dialysis patients and are associated with reduced quality of life in these patients.<sup>39</sup> In our study, 70.97% of sarcopenic patients had severe depression, compared to 36.36% in the nonsarcopenic group. However, a study conducted in Korea did not find a significant association between sarcopenia and depression.<sup>40</sup> Our findings align with Fábrega-Cuadros et al who identified a correlation between higher depression scores and sarcopenia.<sup>35</sup> Ida et al also reported higher depression prevalence among patients with sarcopenia.<sup>34</sup> Reduced physical activity and dietary intake in depressed individuals were also recognized as contributing factors to sarcopenia development.<sup>41</sup> Therefore, sarcopenia and depression have a bidirectional relationship through shared risk factors and pathophysiology. The results of another study showed that depression plays a role in reducing muscle strength and causing sarcopenia through low-grade chronic inflammation and increased oxidative stress.<sup>42</sup> The findings of the study by Kurita et al support the existence of a potential pathogenic pathway in patients with CKD undergoing HD, wherein depression directly contributes to sarcopenia onset.<sup>14</sup> However, the exact mechanism underlying the relationship between sarcopenia and depression is still a subject of debate.<sup>43</sup>

Our study reported a significant relationship between sarcopenia and anxiety. However, another study found no association between muscle strength and anxiety.<sup>42</sup> The findings of the study by Zhang et al demonstrated that depression significantly affects muscle strength in sarcopenia but did not show any correlation between anxiety and muscle strength or mass.<sup>42</sup> Tsekoura et al reported a correlation between anxiety and sarcopenia.<sup>25</sup> Stasiak et al found higher levels of anxiety in HD patients compared to peritoneal dialysis patients, despite expectations that peritoneal dialysis patients would have higher anxiety due to longer connection times to the dialysis machine and their independence and dietary restrictions.<sup>11</sup>

However, this study had limitations. It only assessed the risk of sarcopenia, so future studies are recommended to use appropriate tools to determine its severity. Additionally, it did not investigate the relationship between biological markers, oxidative stress, and the impact of HD adequacy on the prevalence of sarcopenia and psychosocial consequences. Another limitation of this study was related to the use of the SARC-F questionnaire, which despite its high specificity, has lower sensitivity. Nevertheless, its sensitivity for screening severe cases is higher.<sup>14</sup> Further evidence is needed to evaluate diagnostic indicators in detecting sarcopenia. In addition, research samples were collected from two dialysis centers in western Iran, representing attendees from various ethnic backgrounds due to their geographical location. However, due to lifestyle and geographical differences, the results of this study cannot be generalized to other regions of Iran. Furthermore, the observational design used in this study precludes causal inferences. Moreover, biochemical markers, oxidative stress, and inflammation were not assessed.

## Conclusion

The findings of this study indicate a high prevalence of psychosocial and sleep disorders among HD patients with sarcopenia. Given the importance of early muscle analysis diagnosis for effective intervention, it is recommended that this program be included in the evaluation of HD patients. Furthermore, the findings of this study underscore the need for careful attention to these vulnerable patients, the development of educational programs, and the enhancement of mental health to prevent the growth of sarcopenia in HD patients.

## Acknowledgments

This study was derived from a project approved by the Research and Technology Deputy of the Hamadan University of Medical Sciences (approval no. 140105183696). The researchers gratefully thank the patients who participated in this study.

## Authors' Contribution

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### Competing Interests

The authors declare that there is no conflict of interests.

### Ethical Approval

The study was approved by the Research Ethics Committee of the Hamadan University of Medical Sciences (Ethical code: IR.UMSHA.REC.1401.391).

### Funding

This research was financially supported by the Hamadan University of Medical Sciences, Hamadan, Iran (No. 140105183696).

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