

Validation of a Core Patient-Reported Outcome Measure for Fatigue in Patients Receiving Hemodialysis

The SONG-HD Fatigue Instrument

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Abstract

Background and objectives Fatigue is a very common and debilitating symptom and identified by patients as a critically important core outcome to be included in all trials involving patients receiving hemodialysis. A valid, standardized measure for fatigue is needed to yield meaningful and relevant evidence about this outcome. This study validated a core patient-reported outcome measure for fatigue in hemodialysis.

Design, setting, participants, & measurements A longitudinal cohort study was conducted to assess the validity and reliability of a new fatigue measure (Standardized Outcomes in Nephrology-Hemodialysis Fatigue [SONG-HD Fatigue]). Eligible and consenting patients completed the measure at three time points: baseline, a week later, and 12 days following the second time point. Cronbach α and intraclass correlation coefficient were calculated to assess internal consistency, and Spearman rho was used to assess convergent validity. Confirmatory factor analysis was also conducted. Hemodialysis units in the United Kingdom, Australia, and Romania participated in this study. Adult patients aged 18 years and over who were English speaking and receiving maintenance hemodialysis were eligible to participate. Standardized Outcomes in Nephrology-Hemodialysis, the Visual Analog Scale for fatigue, the 12-Item Short Form Survey, and Functional Assessment of Chronic Illness Therapy-Fatigue were used.

Results In total, 485 participants completed the study across the United Kingdom, Australia, and Romania. Psychometric assessment demonstrated that Standardized Outcomes in Nephrology-Hemodialysis is internally consistent (Cronbach $\alpha = 0.81-0.86$) and stable over a 1-week period (intraclass correlation coefficient = 0.68–0.74). The measure demonstrated convergence with Functional Assessment of Chronic Illness Therapy-Fatigue and had moderate correlations with other measures that assessed related but not the same concept (the 12-Item Short Form Survey and the Visual Analog Scale). Confirmatory factor analysis supported the one-factor model.

Conclusions SONG-HD Fatigue seems to be a reliable and valid measure to be used in trials involving patients receiving hemodialysis.

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Introduction

Fatigue is a highly prevalent and debilitating symptom that affects 60%–97% of patients receiving hemodialysis (1), and it is associated with a higher risk of cardiovascular disease, mortality, depression, and impaired quality of life (2,3). The experience of fatigue may be unique in hemodialysis because the causes are complex and multifactorial, exacerbated by the burden of hemodialysis, anemia, uremia, depression, anxiety, and other comorbidities (1,4,5). Fatigue can severely limit patients' physical and social functioning, life satisfaction, and ability to fulfill their roles and goals.

Through the Standardized Outcomes in Nephrology-Hemodialysis (SONG-HD) initiative, which involved

over 1300 patients and health professionals from >70 countries, fatigue was identified as a critically important core outcome to be assessed in all trials involving patients receiving hemodialysis (6–8). In order to facilitate the uptake of this core outcome in trials, the SONG-HD initiative sought to endorse a short yet meaningful measure of fatigue. Despite 18 different measures of fatigue that had previously been used in hemodialysis (9), none matched the characteristics of an ideal core outcome measure: short (fewer than five items) and assesses content deemed as important and meaningful by patients on hemodialysis, caregivers, and health professionals.

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To establish a core outcome measure for fatigue, the SONG-HD Fatigue measure was developed using the Core Outcome Measures Effectiveness Trials methodologic framework and other relevant frameworks for developing patient-reported outcome measures (PROMs) (10–12). This process involved patient input throughout all stages, both as research partners and participants. It included a systematic review of PROMs used to report fatigue in hemodialysis to identify all measures that had been used to evaluate fatigue (9); an international survey with patients receiving hemodialysis, caregivers, and health professionals to identify the critically important content and measurement dimensions of fatigue to include in a core outcome measure (13); a multistakeholder consensus workshop involving patients, caregivers, health professionals, researchers, and policy makers to discuss potential items (14); selection of items from existing measures for the initial measure; and pilot cognitive interviews with patients using a response model (13).

As the final phase in establishing SONG-HD Fatigue as a core outcome measure, this study aimed to assess the validity of its use in the hemodialysis population. We report the first psychometric evaluation of the core PROM for fatigue in hemodialysis and present the SONG-HD Fatigue measure.

Materials and Methods

Participant Selection and Recruitment

Participants were eligible if they were adult patients aged 18 years or over receiving maintenance hemodialysis for >6 months who could read and speak English and were able to provide informed consent. Patients were excluded if they were cognitively impaired, such that they would not be able to complete a PROM on their own. Through the authors' professional network, we used convenience sampling to recruit patients across seven sites in the United Kingdom, three sites in Australia, and one site in Romania. All measures were administered in English across all three countries. A sample size of 450 participants was calculated to allow the estimation of the intraclass correlation coefficient with a precision of 0.05, assuming an expected intraclass correlation coefficient of 0.7 for the agreement between SONG-HD Fatigue measured at time point 1 and time point 2 (1 week apart). This sample size also allows us to estimate the Pearson correlation coefficient between the SONG-HD Fatigue measure and Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-F), with a precision superior to 0.07 (*i.e.*, <0.07), for correlations stronger than 0.7. Ethics approval was obtained from East Midlands Nottingham 1, Princess Alexandra Hospital, Western Sydney Local Health District, and University of Sydney Human Research Ethics Committees.

Measures

Standardized Outcomes in Nephrology-Hemodialysis Fatigue. The SONG-HD Fatigue measure consists of three items that assess (1) the effect of fatigue on life participation, (2) tiredness, and (3) level of energy. These dimensions are assessed on a four-point Likert scale indicating increasing severity, ranging from zero (not at all) to three (severely). Patients respond on the basis of their experience

of fatigue in the past week. An overall score for fatigue is obtained by summing the responses across the three questions, resulting in a scale ranging from zero (no fatigue) to nine (maximum fatigue). We also assessed the possibility of weighting each question differently in the calculation of the overall score. The final instrument is provided in Figure 1.

Functional Assessment of Chronic Illness Therapy–Fatigue. This measure was selected to assess the convergent validity of the SONG-HD Fatigue total scores (14). Although FACIT-F has not been validated in the hemodialysis population, it assesses the construct of fatigue with multiple items and has been tested for psychometric robustness in the general population (15) as well as in other chronic conditions such as cancer and rheumatoid arthritis (15,16). We determined that FACIT-F had good face validity for hemodialysis because the items and wording most closely operationalized dimensions of fatigue as described by patients receiving hemodialysis (17). Owing to the similarity in construct, we hypothesized that the FACIT-F scores would be highly correlated to the SONG-HD Fatigue scores.

The Visual Analog Scale for Fatigue. The Visual Analog Scale (VAS) was used to assess the patients' level of fatigue at the time of assessment. We anticipated a moderate to high correlation between SONG-HD Fatigue and VAS because both measures assess the same construct (fatigue) but with different recall periods and dimensions.

The 12-Item Short Form Survey Version 2. This measure (the 12-Item Short Form Survey [SF-12]) was chosen because it is a relatively brief, simple measure, which is regarded to be of minimal burden to respondents (18). Although this measure assesses constructs related to fatigue, such as vitality and physical functioning, the physical and mental composite scores produced are not indicative of the same construct, and thus, we hypothesized that the scores will be moderately correlated.

Data Collection

Each participant was given the completed the SONG-HD Fatigue measure and a VAS at three time points (at time point 1: baseline; at time point 2: a week later; and at time point 3: 12 days after time point 2). At baseline, they were also asked to complete either SF-12 or FACIT-F. All measures were self-completed before the start of hemodialysis on each occasion to minimize the confounding effects of the hemodialysis process itself on experiences of fatigue. Although limited assistance was provided to facilitate the reading of the questions, no assistance was provided to aid the interpretation of the questions nor the retrieval of responses.

Data Analyses

A psychometric evaluation was conducted in SPSS Version 25.0 (IBM Corp., Armonk, NY) and MPlus Version 8.3 to assess data quality (completeness of item- and scale-level data), reliability (internal consistency and test-retest between time point 1 and time point 2), and validity (convergent validity and exploratory known groups for dialysis vintage).

Mean scores of SONG-HD Fatigue were compared between countries to identify any systematic differences.



SONG-HD Fatigue

Please indicate your response by ticking one box for each question.

In the past week:

Questions	Not at all	A little	Quite a bit	Severely
1. Did you feel tired?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
2. Did you lack energy?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
3. Did fatigue limit your usual activities?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

Standardized Outcomes in Nephrology © 2019

Figure 1. | Standardized Outcomes in Nephrology-Hemodialysis (SONG-HD) Fatigue measure.

Because of statistically significant mean differences, a *post hoc* decision was made to test and report psychometric properties separately by country with the following criteria.

Content Validity. Previous work (9,17,19) was conducted to ensure content validity.

Internal Consistency. Cronbach $\alpha \geq 0.70$ indicates adequate scale consistency.

Test-Retest Reliability. Intraclass coefficient between time point 1 and time point 2 >0.70 indicates reliable stability.

Construct Validity. For construct-convergent validity, Spearman $\rho >0.7$ indicates high correlation, 0.3–0.7 indicates moderate correlation, and <0.3 indicates low correlation.

A confirmatory factor analysis was undertaken to examine the hypothesized one-factor structure of SONG-HD Fatigue for each country. A multigroup confirmatory factor analysis was conducted to examine whether the same structure of SONG-HD Fatigue held for each country by analyzing the complete dataset, with each country included in the model as a group but loadings and thresholds constrained to be equal across groups. The variance of the latent variable was fixed to one to identify the model. Adequacy of the model fit was determined on the basis of the following criteria: ratio of chi square to degrees of freedom less than three, the root mean square error of approximation <0.08 , comparative fit index >0.9 , and standardized root mean square residual <0.08 .

Known Groups. Hemodialysis vintage was selected as a grouping variable for an exploratory known-groups analysis as there is mixed evidence concerning the relationship between hemodialysis vintage and fatigue. Relatively more recent studies have found a significant association between these two outcomes (20,21), whereas earlier studies did not (22,23).

Scoring. We assessed the possibility of using weights when summing the answers of the three questions because our previous work indicated greater importance of one dimension (effect of fatigue) above the other two (tiredness and level of energy) (17,19). We used a linear regression

with the FACIT-F score as the dependent variable and the three questions of SONG-HD Fatigue as covariates. The regression coefficients rounded to the nearest integer were used as weights in the sum of the answers and compared with the score on the basis of the raw (nonweighted) sum of the answers.

Results

Participant Characteristics

In total, 485 patients from Australia ($n=106$), the United Kingdom ($n=303$), and Romania ($n=76$) participated; 289 (60%) were men. Most of the participants were aged from 51 to 70 years (322; 66%), and most were White (184; 79%). Also, the majority had been on hemodialysis for up to 5 years (405; 84%). The participant characteristics are presented in Table 1. The number of eligible, recruited patients and those lost to follow-up can be seen in Figure 2.

Data Quality

Data quality was high, with a complete response rate of 93%, and mean scores were near scale midpoints for all three items. Scores spanned the scale range with no notable skew, and floor and ceiling effects were negligible (Supplemental Table 1). The main reason for missing data is losing patients to follow-up due to change in their hemodialysis sessions.

Mean Scores across Countries

The SONG-HD Fatigue mean scores for the United Kingdom were different from the mean scores in Australia (mean difference =0.93; $P=0.004$) and Romania (mean difference =1.38; $P<0.001$). There were no differences between Australia and Romania. Mean scores for all measures by countries are presented in Table 2.

Psychometric Evaluation

Internal Consistency. Cronbach α for the total SONG-HD Fatigue score demonstrated good consistency of the items for the United Kingdom (0.86), Australia (0.81), and

Table 1. Patient characteristics at baseline

Demographics	United Kingdom, <i>n</i> =303	Australia, <i>n</i> =106	Romania, <i>n</i> =76	Total, <i>n</i> =485
Sex, <i>n</i> (%)				
Men	181 (60)	67 (63)	41 (54)	289 (60)
Women	113 (37)	36 (34)	35 (46)	184 (38)
Missing	9 (3)	3 (3)	0 (0)	12 (2)
Age, yr, <i>n</i> (%)				
18–40	26 (8.6)	10 (9.4)	25 (33)	66 (14)
41–50	33 (11)	8 (7)	21 (20)	62 (13)
51–60	69 (23)	26 (25)	17 (22)	112 (23)
61–70	68 (22)	30 (28)	11 (14)	109 (22)
71+	106 (36)	32 (30)	2 (2)	140 (29)
Missing	1 (0)	0 (0)	0 (0)	1 (0)
Ethnicity, <i>n</i> (%)				
White	253 (83)	55 (52)	76 (100)	384 (80)
Asian	30 (10)	15 (14)	0 (0)	45 (10)
Black British/Afro-Caribbean	14 (5)	0 (0)	0 (0)	14 (3)
Aboriginal/Torres Strait/First Nation	1 (0)	10 (10)	0 (0)	11 (10)
Other	3 (1)	25 (24)	0 (0)	28 (6)
Missing	2 (0)	1 (1)	0 (0)	3 (1)
Marital status, <i>n</i> (%)				
Single	87 (29)	25 (24)	20 (26)	132 (3)
Married	133 (44)	49 (46)	39 (51)	221 (46)
Partner (living with/not living with)	19 (18)	5 (5)	7 (10)	31 (6)
Widowed	39 (13)	13 (12)	2 (3)	54 (11)
Divorced/separated	25 (8)	12 (11)	8 (11)	45 (10)
Missing	0 (0)	2 (2)	0 (0)	2 (0)
Employment, <i>n</i> (%)				
Full time/part time/casual	36 (12)	18 (17)	22 (29)	76 (16)
Student	2 (1)	0 (0)	1 (1)	3 (1)
Unemployed	259 (85)	87 (82)	53 (70)	399 (82)
Missing	6 (2)	1 (1)	0 (0)	7 (1)
Education level, <i>n</i> (%)				
Did not complete primary school	23 (8)	8 (8)	1 (1)	32 (7)
Completed high school before or up to tenth grade	181 (60)	33 (31)	12 (11)	226 (47)
Completed high school 12th grade/ professional certificate	75 (25)	36 (34)	29 (27)	140 (29)
Undergraduate/postgraduate	23 (8)	26 (25)	34 (32)	83 (17)
Missing	1 (0)	3 (3)	0 (0)	4 (1)
Years on dialysis, <i>n</i> (%)				
<1	226 (75)	34 (32)	10 (13)	270 (56)
1–5	44 (15)	43 (41)	48 (63)	135 (28)
6–10	18 (6)	18 (17)	9 (12)	45 (10)
11+	14 (5)	11 (10)	9 (12)	34 (7)
Missing	1 (0)	0 (0)	0 (0)	1 (0)

Romania (0.83) (Table 3). None of the items had a significant effect on the Cronbach α when removed.

Test-Retest Reliability. The intraclass correlation coefficients were 0.68, 0.74, and 0.72 for the United Kingdom, Australia, and Romania, respectively, indicating stability between time point 1 and time point 2 (Table 3).

Convergent Validity. Convergent validity was assessed with FACIT-F in 244 patients and with SF-12 in 241 patients. There was a high correlation between the FACIT-F and SONG-HD Fatigue total scores for all three countries, ranging from -0.72 to -0.83 . The SONG-HD Fatigue total scores had a moderate correlation with the mental and physical composite scores for all three countries, with correlations ranging from -0.30 to -0.53 . The VAS scores for fatigue had a slightly higher and moderate correlation with the SONG-HD Fatigue total scores for all three countries (0.61–0.67). Table 3 presents the correlation values by country. We have explored the possibility of weighting each item of SONG-HD Fatigue differently

when summing the answers. The linear regression predicting the FACIT-F scores gave more weight to item 3, followed by item 1 and item 2 (data not shown). However, the overall correlation of the weighted score was only slightly higher than the unweighted one (0.80 versus 0.79). Thus, we chose the more parsimonious approach of the unweighted sum.

Exploratory Known-Groups Validity. There were five categories for hemodialysis vintage (<1, 1–5, 6–10, 11–15, and 16 or more years). Because of limited number of patients who had been on hemodialysis for >6 years, the categories were recoded, and two analyses were performed to assess exploratory known-groups validity: one with two categories (<1 and 1 or more years) and another with three categories (<1, 1–5, and 6 or more years). Patients who had been on hemodialysis for less than a year had higher SONG-HD Fatigue scores than those who had been on hemodialysis for more than a year (mean difference = 0.66; $P=0.004$; 95% confidence interval, 0.21 to 1.10). Similarly,

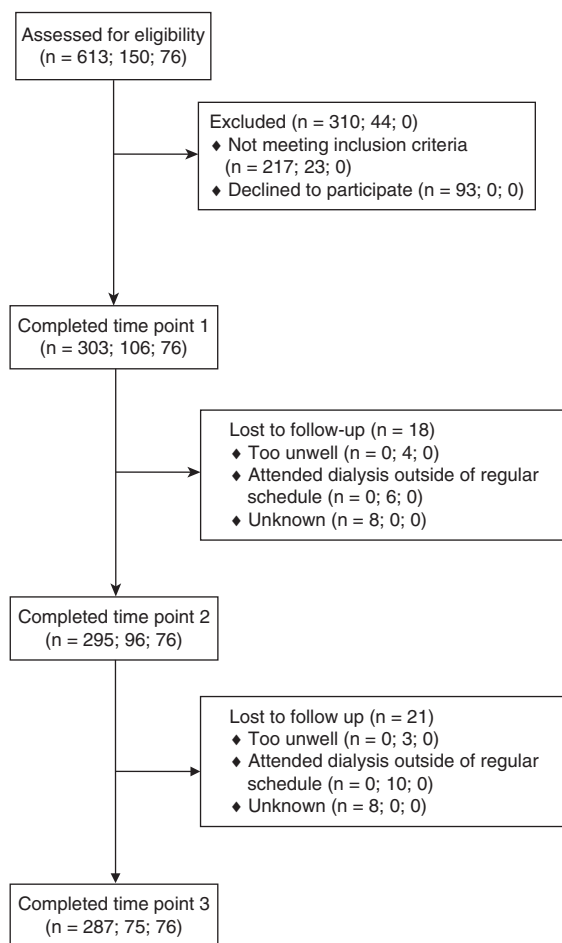


Figure 2. | Number of participants who were eligible, recruited, and lost to follow-up (*n* presented as United Kingdom; Australia; Romania).

scores were significantly higher for patients who had been on hemodialysis for less than a year compared with those with dialysis vintage of 1–5 years (mean difference = 0.67; $P=0.03$; 95% confidence interval, 0.06 to 1.29) but not when compared with those with dialysis vintage >6 years. There were no significant differences between groups by country.

Confirmatory Factor Analyses. Results of the multi-group confirmatory factor analysis demonstrate that all of the goodness of fit indices supported the one-factor model for SONG-HD Fatigue with variance of fatigue and thresholds constrained to be equal across countries: ratio of chi square to degrees of freedom = 1.89, $P=0.02$, root mean square error of approximation = 0.07, standardized root mean square residual = 0.04, and comparative fit index = 0.99. Thus, we conclude that measurement of SONG-HD Fatigue is invariant across countries. Factor loadings were high for each item, ranging from 0.82 to 0.91 (Supplemental Table 2).

Discussion

Fatigue is a critically important outcome for patients receiving hemodialysis. The SONG-HD Fatigue instrument is intended to facilitate consistent, meaningful, and feasible

Table 2. Mean scores for Standardized Outcomes in Nephrology-Hemodialysis Fatigue, the 12-Item Short Form Survey, Functional Assessment Chronic Illness Therapy–Fatigue, and the Visual Analog Scale by country at baseline

Country	Mean Scores (SD)			Standardized Outcomes in Nephrology-Hemodialysis Fatigue, <i>n</i> =485 ^d
	12-Item Short Form Survey, <i>n</i> =240 ^a	Functional Assessment Chronic Illness Therapy–Fatigue, <i>n</i> =245 ^b	Visual Analog Scale, <i>n</i> =485 ^c	
	Mental Composite Score	Physical Composite Score		
United Kingdom, <i>n</i> =303	46.41 (11.71)	36.65 (9.19)	4.83 (2.68)	5.22 (2.54)
Australia, <i>n</i> =106	48.33 (12.84)	41.53 (9.88)	4.90 (2.70)	4.29 (2.23)
Romania, <i>n</i> =76	51.69 (10.21)	41.90 (8.20)	3.86 (2.67)	3.84 (2.37)

^aThe 12-Item Short Form Survey (mental composite score and physical composite score) scores range from zero to 100, where higher scores indicate better functioning.

^bFunctional Assessment Chronic Illness Therapy–Fatigue scores range from zero to 52, where higher scores indicate better functioning/less fatigue.

^cThe Visual Analog Scale scores range from zero to ten, where higher scores indicate higher fatigue.

^dStandardized Outcomes in Nephrology-Hemodialysis Fatigue scores range from zero to nine, where higher scores indicate higher worse functioning/greater fatigue.

assessment of fatigue in trials involving patients receiving hemodialysis. The instrument includes three items that address the severity of the effect of fatigue on life participation, tiredness, and energy—which are the three most important content dimensions of fatigue as indicated by patients receiving hemodialysis. The measure was developed through a multiphase, patient-centered approach that allowed for extensive input from patients, caregivers, and health professionals to ensure content validity. The psychometric evaluation found that the SONG-HD Fatigue measure satisfies criteria for reliability and validity in accordance with the recommended US Food and Drug Administration guidelines for measurement (24).

The psychometric properties were assessed by country because of the differences in means between the United Kingdom, Australia, and Romania. However, similar patterns of correlation (intraclass correlation coefficient and Spearman rho), equal factor loadings across countries, and the good model fit indicate similar measurement properties across countries. There are several possible explanations for these differences in mean scores. Cultural differences in the way patients respond to questions about fatigue are possible, as has been identified for other patient-reported outcomes, such as quality of life, symptoms, and functional outcomes, in oncology and cardiology (25–27). It may also be related to differences in health care systems and practices or the population that completed the survey. We note that the majority of the participants in the United Kingdom had been on hemodialysis for <1 year, which may contribute to the higher mean score observed. Furthermore, the generalizability of our results beyond the English-speaking population is unknown. SONG-HD Fatigue was developed in English, and thus, we were able to recruit only patients who were able to read, speak, and understand English.

Fatigue in the hemodialysis population is complex, and the many possible causes are difficult to delineate. For this reason, it was difficult to identify definitive known groups *a priori* for comparison. However, we identified a grouping variable through the exploratory known-group analysis conducted with dialysis vintage to assess whether patients reported less fatigue the longer they were on hemodialysis (4,5,20). Similar to previous work, we found that patients who had been on hemodialysis for a shorter period of time had higher mean scores for fatigue. Also, our findings suggest that perhaps there may be a nonlinear relationship between dialysis vintage and fatigue. Although the limited data collection did not permit further investigation of this relationship, we will aim to include it in future work building on the findings of this study.

We acknowledge that we were unable to demonstrate the responsiveness of SONG-HD Fatigue due to the uncertainty around time points at which we could be certain that a clinically meaningful change in fatigue had occurred and the lack of an intervention expected to change fatigue. The SONG-HD Fatigue scores were similar between time point 1 and time point 3 (results are presented in Supplemental Table 3), and this was not unexpected. The measure asks the patients to report on the overall fatigue they experienced in the past week. As a result, the similar scores between two time points may be attributed to patients responding to the questions as instructed (to report overall

Table 3. Reliability for the Standardized Outcomes in Nephrology-Hemodialysis Fatigue and Spearman rho correlations between Standardized Outcomes in Nephrology-Hemodialysis Fatigue and the 12-Item Short Form Survey, Functional Assessment Chronic Illness Therapy–Fatigue, and the Visual Analog Scale

Country	Cronbach α for Standardized Outcomes in Nephrology-Hemodialysis Fatigue	Intraclass Correlation ^a (95% Confidence Interval)	Spearman Correlation ^b			
			12-Item Short Form Survey	Functional Assessment Chronic Illness Therapy–Fatigue	Visual Analog Scale	Visual Analog Scale
			Mental Composite Score	Physical Composite Score		
United Kingdom, <i>n</i> = 303	0.86	0.68 (0.61 to 0.73)	-0.53 (-0.64 to -0.40)	-0.45 (-0.57 to -0.31)	-0.83 (-0.87 to -0.77)	0.61 (0.54 to 0.68)
Australia, <i>n</i> = 106	0.81	0.74 (0.63 to 0.82)	-0.30 (-0.64 to 0.14)	-0.46 (-0.74 to -0.05)	-0.75 (-0.85 to -0.60)	0.67 (0.55 to 0.76)
Romania, <i>n</i> = 76	0.83	0.72 (0.57 to 0.82)	-0.52 (-0.72 to -0.25)	-0.53 (-0.72 to -0.26)	-0.72 (-0.88 to -0.43)	0.65 (0.50 to 0.76)

^aIntraclass correlation for time point 1 and time point 2. Standardized Outcomes in Nephrology-Hemodialysis Fatigue was recorded in two different time points (time point 1 and time point 2), 1 week apart, prior to commencing the second dialysis session of the week.

^bThe 95% confidence intervals are in parentheses.

fatigue in the past week), rather than focusing on fluctuations in fatigue. For the same reason, we were unable to use pre- and postdialysis as time points to assess responsiveness in this study, as responses to a measure with a recall period of 1 week are not expected to change from before to after one hemodialysis session. We will conduct further studies to assess responsiveness in a clinical trial for an intervention designed to improve fatigue. Further work will also be done to determine a minimally clinically significant difference, and to assess other psychometric properties, including crosscultural validity.

The SONG-HD Fatigue measure was developed to assess the average fatigue over a period of 1 week. Patients give higher priority to overall fatigue that can limit their day-to-day functioning and social roles (17,19). However, we recognize that postdialysis fatigue has been identified as an important symptom among patients receiving hemodialysis. Trials investigating the effects of an intervention on postdialysis fatigue may need to consider other measures. The Post-Dialysis Fatigue Index (28) was developed for this purpose, but a comprehensive psychometric evaluation has not yet been conducted. Ecologic momentary assessment of fatigue can provide a way to assess postdialysis fatigue with minimal risk of recall bias (1,29). Our future work may also examine the suitability of SONG-HD Fatigue for assessing postdialysis fatigue by testing an adjusted recall period.

SONG-HD Fatigue is a PROM that demonstrates evidence for validity for use in patients receiving hemodialysis. SONG-HD Fatigue is a three-item measure intended for patients to self-report fatigue in the past week and is suitable for use as a core outcome measure in hemodialysis trials. Items are summed to produce a total fatigue score. Implementing this short, validated, and relevant core outcome measure in all trials involving patients on hemodialysis will enable the standardized and consistent assessment of fatigue in a way that is meaningful for patients. This will contribute to the generation of evidence that will better support patients and caregivers in decision making by providing information about the effect of interventions on this critically important outcome of fatigue.

Disclosures

S. Anumudu reports other as medical director at DaVita home unit as part of employment at BCM, outside the submitted work. S. Jassal reports that she participated in a patiomer/hyperkalemia consultative meeting run by Otsuka on April 22, 2020. All remaining authors have nothing to disclose.

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Supplemental Material

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Supplemental Table 1. Data completeness and targeting.

Supplemental Table 2. Standardized estimates of factor loadings and thresholds for SONG-HD Fatigue items.

Supplemental Table 3. Correlation between SONG-HD Fatigue and VAS scores at time points 1 and 3.

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