**ORIGINAL RESEARCH-BASIC SCIENCE** 

Revised: 3 December 2020

WILEY

# Assessing the quality of life of people with chronic wounds by using the cross-culturally valid and revised Wound-QoL questionnaire

Catharina C. von Stülpnagel MSc<sup>1</sup> | Neuza da Silva PhD<sup>1</sup> | Matthias Augustin MD<sup>1</sup> () | Catherine van Montfrans PhD<sup>2</sup> | Caroline Fife PhD<sup>3,4</sup> T Ann-Mari Fagerdahl PhD<sup>5</sup> | Alexander Gamus PhD<sup>6</sup> | Toni M. Klein  $MSc^1$  | Christine Blome PhD<sup>1</sup> | Rachel Sommer PhD<sup>1</sup>

<sup>1</sup>German Center for Health Services Research in Dermatology (CVderm), Institute for Health Services Research in Dermatology and Nursing (IVDP), University Medical Center Hamburg-Eppendorf (UKE), Hamburg, Germany

<sup>2</sup>Department of Dermatology, Erasmus Medical Center, Rotterdam, The Netherlands <sup>3</sup>Baylor College of Medicine, Houston, Texas

<sup>4</sup>The U.S. Wound Registry, Woodlands, Texas

<sup>5</sup>Department of Clinical Science and Education, Wound Centre, Södersjukhuset, Karolinska Institutet, Stockholm, Sweden

<sup>6</sup>Maccabi Health Services, Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel

#### Correspondence

Catharina C. von Stülpnagel, M.Sc. German Center for Health Services Research in Dermatology (CVderm) Institute for Health Services Research in Dermatology and Nursing (IVDP) University Medical Center Hamburg-Eppendorf (UKE) Martinistraße 52, Hamburg 20246, Germany.

Email: c.stuelpnagel@uke.de

# Abstract

The Wound-QoL is an often used reliable and valid measure, originally developed in Germany. It has been sequentially translated and validated for other languages/countries, for the measurement of health-related quality of life (HRQoL) in patients with chronic wounds. However, a study from the United States postulated its benefits from further adaptations. Furthermore, some patients struggled to provide an answer for some of the items. We aimed to test the cross-cultural structure and psychometric performance of the questionnaire to suggest necessary revisions. This cross-sectional analysis of existing data sets included 1185 patients from Germany, the US, the Netherlands, Spain, Sweden, and Israel. Patients in the U.S. Wound Registry completed the Wound-QoL during routine care. Different studies comprised the data collection in the other countries. Almost half of the patients were women (48.4%). Furthermore, 42.6% were diagnosed with leg ulcers. Their average age was 66 years. We used a confirmatory factor analysis and an unconstrained graded response model. We revised and shortened the Wound-QoL from 17 to 14 items. In addition, we supported the crosscultural metric invariance of the revised Wound-QoL questionnaire. The new version with 14 items and three dimensions revealed good psychometric properties with Cronbach's alpha ( $\alpha$ ) of 0.913 for the total score, and 0.709–0.907 for different dimensions. Furthermore, we provided strict invariance for different clinical variables. In conclusion, the revised Wound-QoL is a reliable and cross-cultural instrument to measure the HRQoL on patients with chronic wounds. Future studies should analyse the revised Wound-QoL for convergent validity with generic HRQoL questionnaires as well as for determining its sensitivity to clinical change.

#### KEYWORDS

item response theory, patient burden, psychometric performance, wound care

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made. © 2021 The Authors. Wound Repair and Regeneration published by Wiley Periodicals LLC on behalf of The Wound Healing Society.

# 

# 1 | INTRODUCTION

Ulcers that do not heal within 30 days are defined as chronic wounds.<sup>1,2</sup> Chronic wounds are reportedly prevalent in 1.04% of the German population.<sup>3</sup> They affect around 20% patients in the United States aged over 75.<sup>4,5</sup> There are limited studies on the prevalence of chronic wounds in Sweden. Nonetheless, older studies reported on a prevalence of at least 0.1-0.6%.<sup>6,7</sup> According to the diabetes registry of the Ministry of Health, the estimated annual prevalence of diabetic foot ulcers was 1.2% in Israel.<sup>8</sup> Elderly people are particularly affected by chronic wounds.<sup>3</sup> Thus, the aging population might lead to an increase in the incidence in near future. Chronic wounds often impair the functioning and wellbeing of the affected people as they are imposed with restrictions on all domains of their health-related quality of life (HRQoL). Physical impairments often include pain, discomfort, itching, involuntary physical inactivity, and exacerbation of other health problems. In addition, the patients have to cope with an impaired social and emotional HRQoL (e.g., worries about wound infection). Some of the commonly described impairments are namely feelings of frustration, anxiety, social isolation, depression and low self-esteem because of a negative self-concept.<sup>9,10</sup> The appearance and odor of the wound leads to embarrassment.<sup>11</sup> Besides that. impairments can result from other factors, such as feeling disheartened about the treatment progress, distrust in healthcare professionals, and frustration about the healthcare system.<sup>12</sup>

HRQoL is a relevant and well-accepted patient-reported outcome in medical science; thus, playing an important role in healthcare and health services research.<sup>13</sup> Examples include the clinical testing of drugs, health economic evaluations, evaluation of interventions and care concepts, benchmarking procedures, and identification of care deficits. Several professional societies have also recognised importance.<sup>14</sup> Moreover, the assessment of HRQoL as a central patient-oriented outcome of care and the resulting recommendations for action can be regarded an essential component of internal quality assurance. It is a prerequisite for an adequate provision of care for all health system users.<sup>15</sup>

The above-mentioned impairments in people with chronic wounds and the relevance of assessing HRQoL resulted in the development of the Wound-QoL questionnaire.<sup>16</sup> The questionnaire necessitates the patients to fill out 17 items. Sixteen of these items are assigned to three subscales, namely body, psyche, and everyday life. Item 17 ('... the wound has been a financial burden to me'.) is not categorised to any dimension. Nonetheless, it contributes to the total score calculated from the arithmetic mean of all the items.<sup>16</sup> Researchers have established the reliability and validity of the freguently used Wound-QoL.<sup>17,18</sup> It was sequentially translated and psychometrically validated into different languages, for example, Dutch,<sup>19</sup> U.S. English,<sup>20</sup> Spanish,<sup>21</sup> Swedish,<sup>22</sup> and Hebrew.<sup>8</sup> Alternative subscale structures have been tested in the Hebrew study. The result deviated from the original structure and included the last item (item 17) in the everyday life category.<sup>8</sup> In addition, there were minor changes of item 10 during the translation progress of the Hebrew Wound-QoL version.<sup>8</sup> Furthermore, researchers adapted wording of item 4 in the Dutch version before the study.<sup>19</sup> The validation study in the US recommended additional adaptations based on the failure of some items to show good discrimination in the item response theory (IRT) analysis. In addition, the researchers could not completely confirm the factor structure of the original German version.<sup>20</sup>

The development Wound-QoL was concomitant with difficulties during its application in clinical practice. For example, some patients struggled with answering the items on their ability to move around (item 11), climbing stairs (item 12) or being dependent for help on others (item 16). These items might be misleading for patients with limited mobility through other impairments, such as paraplegia, amputation, or wheelchair use. This can be attributed to their dependence on other people or mobility impairment before having a chronic wound.

Previous validation studies focused on one country at a time. However, cross-cultural psychometric testing facilitates compare or pool data from different countries. No studies have included patients from more than one country to validate the cross-cultural accuracy of the Wound-QoL. Moreover, all Wound-QoL studies, but the one on the U.S. English version used the classical test theory (CTT) to assess psychometric characteristics. IRT evaluates the psychometric properties of an existing scale and its items, thus optimally shortening the scale when necessary. In addition, it enables an evaluation of the performance of the reduced scale.<sup>23</sup> The most important difference between CTT and IRT is that the latter defines the scale for the underlying latent variable. Furthermore, all items are calibrated with respect to this scale. Following the calibration of the IRT parameters for a defined population, researchers can predict the latent score if the participants did not response to every item.<sup>23</sup>

Hence, a cross-cultural validation and revision of the Wound-QoL is necessary for clinical practice as well as research. Therefore, we pooled existing patient data from six different countries (US, Germany, Spain, the Netherlands, Sweden, and Israel) with the aim of testing the dimensional structure of the Wound-QoL<sup>16</sup> within a cross-cultural dataset and revising the questionnaire, if needed.

### 2 | METHODS

#### 2.1 | Study design and participants

We combined data of studies conducted in Germany, the US, Spain, the Netherlands, Sweden, and Israel. This resulted in a total sample of 1185 individuals.

We used three data sets from Germany with a positive local ethic approval that were as follows: (1) data from the validation study, which included patients of the University Medical Center Hamburg-Eppendorf and the military hospital in UIm, collected between February and July 2013<sup>16</sup>; (2) data collected via the mobile nursing service ORGAMed in Dortmund, between July and August 2014, facilitating determination of the test-retest reliability<sup>18</sup>; and (3) data collected by an ambulant medical office in Schleswig-Holstein and North Rhine-Westphalia via supraregional mobile nursing services, between October 2015 and January 2016. This enabled the analysis of

Wound Repair and Regeneration

-WILEY

(dis-)agreement between patient- and proxy-reported HRQoL.<sup>24</sup> All patients were aged 18 years or older.

The Spanish validation study included patients with ulcers of various underlying causes recruited at the dermatology departments across five university hospitals.<sup>21</sup> The inclusion criteria were as follows: an active chronic wound of the lower extremity and aged 18 years or more. The study was approved by the local ethics committee.

Data from the US were collected via the U.S. Wound Registry that routinely uses the U.S. English version of the Wound-QoL. Patients were aged 18 years or older. In addition, they must have had the ability to read and understand English language.<sup>20</sup> Practice improvement or quality reporting are exempted from the institutional review boards within the U.S. Wound Registry projects. This did not necessitate an approval from the institutional review board. This can be accredited to the approval from the centres for Medicare & Medicaid Services for evaluating the Wound-QoL as a quality activity reportable to Medicare.

The study conducted in the Netherlands recruited 120 patients treated at different healthcare centres between August 2018 and May 2019 via a home care organisation.<sup>19</sup> The study was approved by the medical ethic committee.

The Swedish data comprised 92 patients 18 years or older. They were recruited between August 2015 and July 2016 during a scheduled treatment for their hard-to-heal wounds at the lower extremities in a wound clinic at a large city of Sweden.<sup>22</sup> The study was approved by the local ethic committee.

Thirty-two patients with leg ulcers were eventually recruited from Israel between August and September 2017 from outpatient clinics. They received their scheduled treatment for wounds at these clinics. They were aged 18 years or older.<sup>8</sup> The researchers obtained an approval from the local ethics committee.

# 2.2 | Measures

The Wound-QoL is a wound-specific questionnaire containing 17 items from which one can derive three subscales and a total score. The items 1–5, 6–10, and 11–16 belong to the subscale body, psyche, and everyday life, respectively. Each item is scored on a 5-point Likert scale from 0 (not at all) to 4 (very much). On obtaining at least 75% response, we calculated a second-order global score as well as scores for every dimension as the mean of the respective responses. Higher scores indicated greater impairment of the quality of life.

Considering the combination of data sets from different studies with no unified protocol, we could merge the clinical and sociodemographic information for age, sex, and the type of wound.

# 2.3 | Data analyses

We conducted descriptive statistics analyses (absolute and relative frequencies for the categorical variables, and mean and standard deviation for the continuous variables) to characterise the sociodemographic and clinical features of the sample.

A confirmatory factor analysis (CFA) was conducted to test the relevance of the cross-cultural data to the measurement model. We used the maximum likelihood estimator with robust standard errors and a Satorra-Bentler scaled chi-squared test statistic. Therefore, comparative fit index (CFI)  $\geq$ 0.95 and root mean square error of approximation (RMSEA)  $\leq$ 0.06 indicated a good fit. In contrast, a CFI  $\geq$ 0.9<sup>25</sup> and RMSEA  $\leq$ 0.1 indicated an acceptable fit.<sup>26,27</sup>

We tested the cross-cultural invariance with multi-group CFA (mCFA) to check the measurement of the latent variable through equivalent items in different countries. Invariance can be divided into the following four levels: configural, metric, scalar, and strict. While configural invariance describes an equivalent factor structure with no restrictions, metric invariance imposes the restriction of equality on all factor loadings across the groups. Scalar invariance constrains the item intercepts with equal factor loadings. In contrast, strict invariance necessitates equal variances of errors across the groups.<sup>28</sup> We used changes in fit statistic to determine if the sequential constrained model fits the data. This can be associated to the dependence of the chi-squared difference test on the sample size. Both models fit the data equally if changes in CFI and RMSEA are less than 0.02 and 0.015,<sup>29,30</sup> respectively.

Furthermore, we used Cronbach's  $\alpha$  to calculate the reliability. While values >0.9 were considered good, those  $\geq$ 0.7 were considered acceptable.<sup>31</sup>

The CFA tests for unidimensionality, one of the assumptions for IRT analyses. Thus, we used an unconstrained IRT to cross-culturally analyse the difficulty and discrimination of each item within the original German structure. Considering the items of the Wound-OoL are ordinal, we used the graded response model (GRM) of Samejima 1968.<sup>32</sup> Besides unidimensionality, an IRT analysis assumes monotonicity and local independence within the data. Monotonicity is concomitant with a smooth increase of the operating characteristic curves. In addition, residual correlations <0.25 between pairs of items prove local independence.<sup>13</sup> Difficulty and discrimination are properties of the item characteristic curve (ICC). An ICC shows the response probabilities as a function of the latent variable for each category of an item. The difficulty of an item is described through the location of the item function along the impairment of quality of life. In contrast, discrimination describes the capability of the item to categorise people with low and high levels of impairment of HRQoL.<sup>13</sup> An ideal item with a high discrimination is likely to have extremely 'peaky' curves for each category.<sup>13</sup> In addition, an ICC can facilitate the analysis of the order of the categorical thresholds. Categorical thresholds are the crossings where successive categories of an item are equally likely to be answered.<sup>33</sup> In contrast, response thresholds describe the points where the probability to answer in one category is equal to that in the category or even a higher category. These response thresholds are always ordered in a GRM.<sup>33</sup> Furthermore, some authors have described the ordered categorical thresholds as another indicator, besides a high discrimination for ideal items.<sup>13</sup> Nonetheless, disordered crossings should not be considered as a single criterion for the 4 WILEY Wound Repair and Regeneration

removal of items.<sup>33</sup> Despite examining the order of the categorical thresholds we could not make a final decisions to exclude items solely based on this criterion. In addition, the item information curve (IIC) was given for every conducted GRM, therefore for every dimension. The IIC indicates the items that contribute less information to the dimension. This calls for a sample size of approximately 500 participants for IRT models with more than one parameter, which is the case for GRM.<sup>23,34,35</sup>

We excluded an item while revising the Wound-QoL if the following criteria were met: (1) the item has one of the lowest IIC in the GRM for that dimension and (2) the item content was identified potentially problematic in expert meetings between researchers, psychologists, statisticians, and physicians. This dual approach prevented the exclusion of items, important for clinical practice.

After reducing the number of items, we checked the modification indices of the CFA to determine the impact loading items to different factors or adding correlations on the structure.

We confirmed the structure of the revised questionnaire using CFA. We again tested for the invariance with mCFA across the countries and different clinical variables. Furthermore, we used Cronbach's  $\alpha$  to calculate the internal consistency.

We eventually calculated the pairwise Pearson correlation between the Wound-QoL scores of the original structure and the newly revised structure. Values above 0.9 were considered extremely strong correlation.<sup>36</sup>

We used the Statistical Package for Social Science v.25.0 (IBM, Armonk, NY) and R version 3.6.0 (R Foundation for Statistical Computing, Vienna, Austria) for statistical analyses. While the 'lavaan' package was used to calculate the CFA within R, the 'ltm' package was used to conduct the GRM.

# 3 | RESULTS

### 3.1 | Participants

Our data set included 1185 participants from distinct studies. Of these patients, 599 came from the US (50.5%), 227 from Germany (19.2%), 115 from Spain (9.7%), 120 from the Netherlands (10.1%), 92 from Sweden (7.8%), and 32 from Israel (2.7%). Table 1 summarises the sociodemographic and clinical characteristics of the sample. Overall, 574 patients were women (48.4%) with an average age of 65.99 years (SD = 15.28). More than 42% of them had a leg ulcer.

# 3.2 | Factor structure based on the original version

Unidimensionality was proved via CFA with CFI = 0.905 and RMSEA = 0.089, which indicated an acceptable fit. Furthermore, mCFA confirmed the metric invariance of the Wound-QoL across different countries with  $\Delta$ CFI = 0.012,  $\Delta$ RMSEA = 0.001. Considering the metric invariance, we could calculate the reliability for the entire

#### TABLE 1 Characteristics of the 1185 participants

Characteristic	n (%)			
Country				
United States	599 (50.5)			
Germany	227 (19.2)			
Spain	115 (9.7)			
The Netherlands	120 (10.1)			
Sweden	92 (7.8)			
Israel	32 (2.7)			
Sex				
Female	574 (48.4)			
Male	611 (51.6)			
Age				
Below 30 years	37 (3.12)			
30-65 years	444 (37.47)			
Above 65 years	704 (59.41)			
Diagnosis				
Pressure ulcer	92 (7.76)			
Leg ulcer, not specified	47 (3.97)			
Arterial leg ulcer	93 (7.85)			
Venous leg ulcer	271 (22.87)			
Diabetic foot ulcer	107 (9.03)			
Postsurgical	215 (18.14)			
Other wounds	139 (11.73)			
Wound, not specified	221 (18.65)			

sample by examining Cronbach's  $\alpha$ . The body and psyche subscale had acceptable values of  $\alpha = 0.75$  and 0.87, respectively. In contrast, everyday life and the total score had good reliability with  $\alpha = 0.91$  and 0.92, respectively. However, the average variance extracted (AVE) of the body dimension (0.41) and psyche dimension (0.59) was lower than the squared intra-factor correlation between the body and psyche dimension (0.60). Thus, the above mentioned two dimensions measured the same construct. Analysis of the modification indices indicated an improvement of the model fit while loading the item 5 ('... the treatment of the wound has been a burden to me'.) not only on the body dimension, but also on the other two dimensions.

In addition, we used IRT to check for further indicators, for example item information. The unconstrained GRM for each dimension of the original German structure provided ICCs for every item belonging to one dimension. The ICCs showed disordered categorical thresholds for items 2 and 16 (Figure 1), with discrimination values of 0.806 and 1.639 (Table 2), respectively. The ICC of item 3 showed ordered categorical thresholds; however, it had a low discrimination value of 0.998. These items were not able to completely discriminate between the patients. Moreover, item information functions (Figure 2) identified similar items as problematic. In addition, item 10 and 12 had low information in relation to the impairment of HRQoL within their respective dimension.



FIGURE 1 Item characteristic curve for every item of the graded response model for every dimension with the original Wound-QoL structure [Color figure can be viewed at wileyonlinelibrary.com]

We decided to remove or retain items 2, 3, 10, 12, 16, 17 ('... the wound has been a financial burden to me'.) and 5 ('... the treatment of the wound has been a burden to me'.) in the expert meetings.

Item 2 ('... my wound had a bad smell'.) and 3 ('... the discharge from the wound has upset me'.) were considered the most substantial impairments in people with chronic wounds. Considering their external appearance, we recognised odor and discharge as significant items. The aforementioned aspects can not only be recognised by the patient, but also other people, thus leading to unpleasant situations. In addition, the wound-experts highlighted the significance of item 16 ('... I have felt dependent on help from others because of the wound'.). This can be attributed to the dependence of a majority of patients, which needs to be taken into account in a people-centred approach. Moreover, the importance of item 5 on the treatment burden was acknowledged. However, the participants of the expert meetings identified it to be a generic question, rather than being specific for one dimension. This in turn can be associated to the influence of the burden on all areas of a patient's life, including the physical dimension. We included item 5 in the total score; nonetheless, we did not assign it to any specific dimension, thus increasing the fit indices in the CFA. Therefore, we decided to keep these four items in the questionnaire.

Item 10 ('... I have been afraid of hitting the wound against something'.) covered the emotional (focusing on the anticipatory anxiety/ fear) and physical (pain patients will feel when they hit the wound) aspects. Thus, it may refer to a psychological or a physical dimension. The physical component of this item was partially covered by item 1 ('... my wound hurt'.). In addition, the former contributed the least information to the psyche dimension in the GRM models. Hence, we decided to exclude item 10 based on its content and the statistical performance criterion.

Item 12 ('... climbing stairs has been difficult because of the wound'.) had a low discrimination value of 1.986. However, it had ordered categorical thresholds and was the lowest item information function in the everyday life scale, apart from item 16. Item 12 also caused the previously mentioned difficulties in clinical practice, particularly in patients in a wheelchair, for whom it is not applicable. In addition, item 11 already covered the ability to move around ('... I have had trouble moving around because of the wound'.). Therefore, we removed item 12 from the guestionnaire.

Despite its inclusion under the everyday life dimension in the Hebrew analysis, item 17 is the only one in the original structure that is not ordered to one dimension. Considering its financial burden, the relevance of the aspect to HRQoL construct in a narrow sense is questionable.37 Furthermore, country-specific health systems might influence the attitude of patients towards financial impact. This particular item did not belong to any of the subscales. Thus, we could not determine the discrimination values or item information function, which could have been used to decide its inclusion. Hence, item 17 was removed from the questionnaire as well.

#### 3.3 Factor structure based on the revised version

Following the exclusion of items 10, 12 and 17, and eliminating item 5 out of any dimension, we reconducted a CFA. The acceptable fit parameters were namely CFI = 0.936 and RMSEA = 0.084. In addition, mCFA confirmed metric invariance across the different countries for the revised structure with  $\Delta$ CFI = 0.008 and  $\Delta$ RMSEA = 0.001. Furthermore, the AVE was lower than the squared intra-factor correlation in every dimension, thus indicating the three dimensions of the revised structure measured different constructs.

**TABLE 2** U.S. English Wound-QoL item wordings with discrimination values of the graded response model for every dimension

	In th Bod	ne last seven days Y	Discriminatio	on value	
	1	my wound hurt.	2.309		
	2	my wound had a bad smell.	0.806		
	3	the discharge from the wound has upset me.	0.998		
	4	the wound has affected my sleep.	2.868		
	5	the treatment of the wound has been a burden to me. <sup>a</sup>	1.423		
	Psy	che			
	6	the wound has made me unhappy.		2.316	
	7	I have felt frustrated because the wound so long to heal.	is taking	2.503	
	8	I have worried about my wound.		4.294	
	9	I have been afraid of the wound getting v getting new wounds.	vorse or of	2.769	
	10	I have been afraid of hitting the wound a something. <sup>b</sup>	gainst	1.555	
	Eve	ryday life			
	11	I have had trouble moving around becaus wound.	e of the	2.754	
	12	climbing stairs has been difficult because wound. <sup>b</sup>	of the	1.986	
	13	I have had trouble with everyday activitie of the wound.	es because	4.126	
	14	the wound has limited my recreational ac	tivities.	3.508	
	15	the wound has forced me to limit my con other people.	tact with	3.492	
	16	I have felt dependent on help from other of the wound.	s because	1.639	
Not categorized					
	17	the wound has been a financial burd	en to me. <sup>b</sup>	-	

<sup>a</sup>ltem without any dimension after revision of the Wound-QoL. <sup>b</sup>Items exulted after revision of the Wound-QoL. While the internal consistency was good in terms of the Wound-QoL total score ( $\alpha = 0.913$ ) and the everyday life dimension ( $\alpha = 0.907$ ), it was acceptable with regard to the dimensions body ( $\alpha = 0.709$ ) and psyche ( $\alpha = 0.877$ ).

We performed further analyses to check for the invariance across the sociodemographic and clinical variables. We found strict invariance for the continent of origin  $\Delta$ CFI = 0.013 and  $\Delta$ RMSEA = 0.004, age ( $\leq$  30; > 30 and < 65;  $\geq$  65)  $\Delta$ CFI = 0.003 and  $\Delta$ RMSEA = 0.002, sex  $\Delta$ CFI = 0.002 and  $\Delta$ RMSEA = 0.003, and wound type (leg ulcer vs. other;  $\Delta$ CFI = 0.001 and  $\Delta$ RMSEA = 0.003).

Correlations between the scores of the original and the revised structure were: 0.992, 0.965, 0.979, and 0.989 for the global scores, body, psyche, and everyday life, respectively.

# 4 | DISCUSSION

This study was the first to examine psychometric performance of the Wound-QoL in a dataset, including several countries. This study was strengthened by the combined use of CTT and IRT analyses. Despite the good cross-cultural and psychometric properties of the original Wound-QoL, we provided a revised and shortened instrument to determine the wound-specific HRQoL across countries. Our results were based on IRT analyses, clinical practice, and the construct similarity between the original body and psyche dimension.

The revised version includes 14 of the original 17 items with items 1–4, 6–9, 11, and 13–16 belonging to body, psyche, and everyday life. Item 5 does not specifically refer to one dimension; therefore, it is used as a stand-alone item in the revised version. This adaptation shed light on the acceptable (body dimension) and good (total score) internal consistencies and good fit indices regarding the CFA. Furthermore, the correlations between the original and revised scores were above 0.95. Thus, it highlighted the reliability of the revised version to measure the HRQoL in patients with chronic wounds with 14 items. In addition, these correlations indicated a high overlap. Therefore, we can use the revised Wound-QoL as an alternative to the original Wound-QoL, which includes items that might not be applicable for every patient. The revised



**FIGURE 2** Item information curve of every dimension and item with the original Wound-QoL structure [Color figure can be viewed at wileyonlinelibrary.com]

version has the advantage of being shorter, therefore reducing the burden of the patients, while answering the questionnaire.

The combination of data from different countries was the strength of our study. This allowed us to prove the invariance across the countries. However, merging of different data sets led to some issues. The combination of existing data from previous studies, resulted in an unequal sample size, ranging from 32 patients in Israel to 599 patients in the US. This might have led to the presence of a metric instead of strict invariance across the countries.<sup>38,39</sup> Furthermore, the questionnaire underwent minor changes during the translation and validation process, particularly in the Hebrew Wound-QoL version and before the Dutch study. Thus, an identical questionnaire could not be used across all countries. In addition, the original studies comprised few clinical and sociodemographic variables.

In addition, there was a difference in data quality of the combined studies. Most of the patients included in the German studies and in Spain had leg ulcers even though the prevalence rate in Germany indicated pressure ulcers as the majority.<sup>3</sup> In the US, the real-life data was collected through the U.S. Wound Registry and only routinely collected data was available.<sup>20</sup> As mentioned before, small changes in the Wound-QoL questionnaire were made in Israel and the Netherlands, which implicated a lower quality of the used data. Additionally, the validation studies conducted in Germany and Sweden included patients from specialist centres with expertise in wound management. This could limit the generalisability of the results.

Further analyses should test for the psychometric properties for the same sample size of patients across countries and continents. They should ascertain the invariance of the questionnaire's structure for the sociodemographic and clinical variables. In addition, researchers should also consider the variations across cultures and medical systems. For instance, differences in the statutory and private health insurances or ethnicity might lead to variations in wound care.<sup>40</sup> In addition, it is necessary to evaluate the revised Wound-QoL for its convergent validity and responsiveness using a generic HRQoL measure as criterion. It might be also necessary to evaluate the revised questionnaire in another study. The amount and order of the items could lead to a different response behaviour.

In conclusion, the revised Wound-QoL is a reliable and valid instrument to measure HRQoL of patients with chronic wounds across countries. Its application in clinical practice might improve the health care of patients with chronic wounds.

#### ACKNOWLEDGEMENTS

The authors would like to thank Elena Conde Montero for collecting and providing the data from Spain. The authors would also like to thank the Scientific Communication Team of the IVDP, in particular Mathilda Meyer and Mario Gehoff, for copy editing. Open Access funding enabled and organized by Projekt DEAL.

#### CONFLICT OF INTEREST

Catharina C. von Stülpnagel, Neuza da Silva, Toni M. Klein, Ann-Mari Fagerdahl, Caroline Fife, Catherine van Montfrans and Alexander Gamus declare no conflict of interest. Matthias Augustin has served as consultant, and/or a paid speaker. Matthias Augustin has received research grants, honoraria, and/or travel expenses reimbursed for consulting; scientific lectures, and/or participated in clinical trials sponsored by companies that manufacture drugs used for the treatment of Psoriasis, including AbbVie, Almirall, Amgen, Biogen (Biogen Idec), Boehringer Ingelheim, Celgene, Centocor, Eli Lilly, Galderma, Janssen-Cilag, Leo Pharma, medac, MSD, Mundipharma, Novartis, Pfizer, Sandoz and XenoPort. Christine Blome has received the speaker honoraria, research grants, awards and/or travel expenses from Celgene, Janssen-Cilag, Kreussler Pharma, Lilly, Mapi Group, medi, Stiefel Laboratories, EuroQol Group and Urgo. R. Sommer has received the speaker, research honoraria and/or travel expenses by Janssen-Cilag, Leo Pharma, Novartis and Beiersdorf.

## ORCID

Catharina C. von Stülpnagel D https://orcid.org/0000-0001-6269-5125

Matthias Augustin b https://orcid.org/0000-0002-4026-8728 Christine Blome b https://orcid.org/0000-0002-1163-1639 Rachel Sommer b https://orcid.org/0000-0002-3080-497X

#### REFERENCES

- Center for Medicare and Medicaid Services (CMS). Decision memo for electrostimulation for wounds (CAG-00068R). Medicare Coverage Database. Baltimore, MD: CMS; 2003.
- Järbrink K, Ni G, Sönnergren H, et al. The humanistic and economic burden of chronic wounds: a protocol for a systematic review. Syst Rev. 2017;6:15. https://doi.org/10.1186/s13643-016-0400-8.
- Heyer K, Herberger K, Protz K, Glaeske G, Augustin M. Epidemiology of chronic wounds in Germany: Analysis of statutory health insurance data. Wound Repair Regen. 2016;24(2):434-442. https://doi.org/10. 1111/wrr.12387.
- Graham ID, Harrison MB, Nelson EA, Lorimer K, Fisher A. Prevalence of lower-limb ulceration: a systematic review of prevalence studies. *Adv Skin Wound Care*. 2003;16(6):305-316. https://doi.org/10.1097/ 00129334-200311000-00013.
- Nussbaum SR, Carter MJ, Fife CE, Haught R, Nusgart M, Cartwright D. An Economic evaluation of the impact, cost, and medicare policy implications of chronic nonhealing wounds. *Value Health*. 2018;21(1):27-32. https://doi.org/10.1016/j.jval.2017.07.007.
- Lindholm C, Bjellerup M, Christensen OB. Zederfeldt B. A demographic survey of leg and foot ulcer patients in a defined population. *Acta Derm Venereol*. 1992;72(3):227-230.
- Nelzen O, Bergqvist D, Lindhagen A. The prevalence of chronic lower-limb ulceration has been underestimated: results of a validated population questionnaire. *Br J Surg.* 1996;83(2):255-258.
- Gamus A, Kaufman H, Keren E, Brandin G, Peles D, Chodick G. Validation of "Wound QoL" Hebrew version disease-specific questionnaire for patients with lower extremity ulcerations. *Int Wound J.* 2018;15 (4):600-604. https://doi.org/10.1111/iwj.12903.
- Cole-King A, Harding KG. Psychological factors and delayed healing in chronic wounds. *Psychosom Med.* 2001;63(2):216-220. https://doi. org/10.1097/00006842-200103000-00004.
- Flett R, Harcourt B, Alpass F. Psychosocial aspects of chronic lower leg ulceration in the elderly. West J Nursing Res. 1994;16(2):183-192. https://doi.org/10.1177/019394599401600205.
- Augustin M. Cumulative life course impairment in chronic wounds. *Curr Probl Dermatol.* 2013;44:125-129. https://doi.org/10.1159/ 000350789.

- B WILEY Wound Repair and Regeneration
- Kapp S, Miller C, Santamaria N. The quality of life of people who have chronic wounds and who self-treat. J Clin Nurs. 2018;27(1-2):182-192. https://doi.org/10.1111/jocn.13870.
- Fayers PM, Machin D. Quality of life. The assessment, analysis, and reporting of patient-reported outcomes. 3rd ed. Chichester, West Sussex, UK, Hoboken, NJ: John Wiley & Sons Inc.; 2016.
- Koller M, Neugebauer EAM, Augustin M, et al. Die Erfassung von Lebensqualität in der Versorgungsforschung - konzeptuelle, methodische und strukturelle Voraussetzungen. Gesundheitswesen. 2009;71 (12):864-872. https://doi.org/10.1055/s-0029-1239516.
- Cella D, Riley W, Stone A, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. J Clin Epidemiol. 2010;63(11):1179-1194. https://doi. org/10.1016/j.jclinepi.2010.04.011.
- Blome C, Baade K, Debus ES, Price P, Augustin M. The "Wound-QoL": a short questionnaire measuring quality of life in patients with chronic wounds based on three established disease-specific instruments. *Wound Repair Regen*. 2014;22(4):504-514. https://doi.org/10. 1111/wrr.12193.
- Augustin M, Conde Montero E, Zander N, et al. Validity and feasibility of the wound-QoL questionnaire on health-related quality of life in chronic wounds. *Wound Repair Regen*. 2017;25(5):852-857. https:// doi.org/10.1111/wrr.12583.
- Sommer R, Augustin M, Hampel-Kalthoff C, Blome C. The Wound-QoL questionnaire on quality of life in chronic wounds is highly reliable. *Wound Repair Regen*. 2017;25(4):730-732. https://doi.org/10. 1111/wrr.12578.
- Amesz SF, Klein TM, Meulendijks AM, et al. A translation and preliminary validation of the Dutch Wound-QoL questionnaire. *BMC Dermatology*. 2020;20(1):5. https://doi.org/10.1186/s12895-020-00101-2.
- Sommer R, von Stülpnagel CC, Fife CE, et al. Development and psychometric evaluation of the U.S. English Wound-QoL questionnaire to assess health-related quality of life in people with chronic wounds. *Wound Repair Regen.* 2020;28:609-616. https://doi.org/10.1111/wrr. 12837.
- Conde Montero E, Sommer R, Augustin M, et al. Validation of the Spanish Wound-QoL Questionnaire. *Actas Dermo-Sifiliográficas*. 2021; 112(1):44–51. https://doi.org/10.1016/j.ad.2020.09.007.
- Fagerdahl A-M, Bergstrom G. Translation and validation of a woundspecific, quality-of-life instrument (The Wound-QoL) in a Swedish population. Ostomy Wound Manage. 2018;64(5):40-46.
- Edelen MO, Reeve BB. Applying item response theory (IRT) modeling to questionnaire development, evaluation and refinement. *Qual Life Res.* 2007;16(1 Suppl):5-18. https://doi.org/10.1007/s11136-007-9198-0.
- Sommer R, Hampel-Kalthoff C, Kalthoff B, et al. Differences between patient- and proxy-reported HRQoL using the Wound-QoL. Wound Repair Regen. 2018;26(3):293-296. https://doi.org/10.1111/wrr.12662.
- 25. Kline RB. *Principles and practice of structural equation modeling.* 4th ed. New York, London: Guilford Press; 2016.

- Schermelleh-Engel K, Moosbrugger H, Müller H. Evaluation the fit of structural equation models: test of significange and descriptive goodness-of-fit measures. *Meth Psychol Res.* 2003;8(2):23-74.
- Hu L-t, Bentler PM. Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. *Struct Equ Modeling*. 1999;6(1):1-55.
- Fischer R, Karl JAA. Primer to (Cross-Cultural) Multi-Group Invariance Testing Possibilities in R. Front Psychol. 2019;10:1507. https://doi. org/10.3389/fpsyg.2019.01507.
- 29. Chen FF. Sensitivity of goodness of fit indexes to lack of measurement invariance. *Struc Equ Modeling*. 2007;14(3):464-504.
- Cheung GW, Rensvold RB. Evaluating goodness-of-fit indexes for testing measurement invariance. *Struc Equ Modeling*. 2002;9(2): 233-255.
- Cronbach LJ. Coefficient alpha and the internal structure of tests. Psychometrika. 1951;16(3):297-334.
- Samejima F. Estimation of latent ability using a response pattern of graded scores. ETS Res Bull Ser. 1968;1968(1):i-169.
- García-Pérez MA. An analysis of (dis)ordered categories, thresholds, and crossings in difference and divide-by-total irt models for ordered responses. *Span J Psychol.* 2017;20:E10. https://doi.org/10.1017/sjp. 2017.11.
- Tsutakawa RK, Johnson JC. The effect of uncertainty of item parameter estimation on ability estimates. *Psychometrika*. 1990;55(2):371-390.
- 35. Reise SP, Yu J. Parameter recovery in the graded response model using multilog. *J Educ Meas*. 1990;27(2):133-144.
- Weber JC, Lamb DR. Statistics and research in physical education. Saint Louis, MO: C.V. Mosby, Inc.; 1970.
- Torrance GW. Utility approach to measuring health-related quality of life. J Chron Dis. 1987;40(6):593-600. https://doi.org/10.1016/0021-9681(87)90019-1.
- Yoon M, Lai MHC. Testing factorial invariance with unbalanced samples. Struc Equ Modeling. 2018;25(2):201-213.
- Hox JJ, Maas CJM. The accuracy of multilevel structural equation modeling with pseudobalanced groups and small samples. *Struc Equ Modeling*. 2001;8(2):157-174.
- Fiscella K, Franks P, Doescher MP, Saver BG. Disparities in health care by race, ethnicity, and language among the insured: findings from a national sample. *Med Care*. 2002;40(1):52-59. https://doi.org/10. 1097/00005650-200201000-00007.

How to cite this article: von Stülpnagel CC, da Silva N, Augustin M, et al. Assessing the quality of life of people with chronic wounds by using the cross-culturally valid and revised Wound-QoL questionnaire. *Wound Rep Reg.* 2021;1–8. https://doi.org/10.1111/wrr.12901