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Validity, reliability and dimensionality of the Norwegian version of Wound-QoL

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Abstract

The aim of the study was to explore the psychometric properties of the Norwegian version of the Wound-quality of life (QoL)-17. We included 204 patients with hard-to-heal wounds on the lower extremity. Patients filled out the Wound-QoL-17, SF-36 and Patients' Global Impression of Change at three time points over 14 weeks. Clinical and demographical data were collected at baseline. Wound severity was collected at baseline and 14 weeks follow-up (T2). Confirmatory factor analyses showed acceptable fit of the hypothesised three-factor model (i.e., body, psyche and everyday life) of the Wound-QoL as long as we accepted two correlated error terms within the Body factor ($\chi^2 = 203.14$, $p = 0.000$, $df = 99$, $\chi^2/df = 2.05$, Root Mean Square Error of Approximation = 0.072, Standardised Root Mean Square Residual = 0.059, Comparative Fit Index = 0.943 and Tucker–Lewis Index = 0.930). Correlation showed moderate to strong associations between Wound-QoL and SF-36 (−0.400** to −0.777**), and significant associations between Wound-QoL and Patients' Global Impression of Change (0.199*), general wound pain intensity (0.435**), pain intensity at wound change (0.340**) and infection (0.174*). The intraclass correlations, ranging from 0.578** to 0.782**, suggested strong test–retest reliability. Cronbach's alphas for all subscales and the total score between 0.748 and 0.922, indicated good internal consistency. The Norwegian version of Wound-QoL demonstrates good reliability and construct validity and is suitable for evaluating QoL in patients with hard-to-heal wounds. However, some improvements were performed to achieve an acceptable fit.

KEYWORDS
chronic wounds, hard-to-heal wounds, quality of life, reliability, validity

Key Messages

- Assessing health-related quality of life (HRQoL) in patients with hard-to-heal wounds is essential to promote health and facilitate effective wound management.
- The aim of this study was to test the psychometric properties (i.e., validity, reliability and dimensionality) of the Norwegian Wound-QoL-17.
- The hypothesised three-factor model of the Wound-QoL-17 had an acceptable fit to the observed data, and the dimensionality was quite clear, as long as we accept two correlated error terms within the Body factor.
- The Norwegian Wound-QoL-17 has good internal consistency, acceptable to good test–retest reliability and moderate to strong convergent validity with SF-36.

1 | INTRODUCTION

Health-related quality of life (HRQoL) refers to the degree of well-being, satisfaction and opportunities experienced by an individual, influenced by factors such as disease, accidents or treatment.[1] Quality of life (QoL) is a personal experience, and patient-reported outcome measures (PROMs) are therefore suitable for assessing HRQoL.[2] Wound-specific HRQoL questionnaires are essential tools in clinical care and research to promote health and facilitate effective wound management.[3,4] Clinicians often overlook or underestimate symptoms in routine clinical care. The implementation of PROMs has demonstrated effectiveness in providing clinicians with insights into patients' symptoms from their perspective, thereby enhancing shared decision-making.[5,6] In addition, research indicates that the use of PROMs improves both symptom control and communication between patients and clinicians across various diseases.[7]

Hard-to-heal (HTH) or chronic wounds fail to heal within the expected timeframe despite optimum treatment.[8] These wounds often develop as complications of trauma, diabetes, arterial or venous insufficiency and immobility. Patients with HTH wounds often report a number of symptoms and signs such as pain, odour, drainage and bleeding, recurrent infections, discomfort from dressing materials, limited mobility and sleep disturbances.[9–12] The burdensome symptom profile can be complex and also lead to psychosocial challenges, such as loss of self-esteem, loneliness, hopelessness, frustration, anxiety and depression.[13] The distress from having an HTH wound may be linked to delayed wound healing, and for some patients healing is not obtainable despite optimal treatment.[14,15] Patients with HTH wounds report similar or worse HRQoL compared to patients with for instance pulmonary and cardiovascular diseases.[16] Furthermore, as the population ages, the incidence of HTH wounds rises and results in a significant economic strain on both society and those affected.[16]

Research describes four PROMs for assessing HRQoL in patients with HTH wounds: the Freiburg Life Quality Assessment for Wounds,[17] the Cardiff Wound Impact Schedule,[3] the Würzburg Wound Score[18] and the Wound-QoL. Whilst the former three exclusively calculate a total score, the Wound-QoL is short and permits subscale scores on the three dimensions of body, psyche and everyday life.[6] These features enable clinicians to identify the symptom burden associated with specific dimensions.[7] The choice of PROM should be based on the complexity of the health condition, general health status and age of the patients. Comprehensive questionnaires may be exhaustive for elderly and frail patients, potentially resulting in incomplete answers and poor-quality data.[6]

The Wound-QoL was published in 2013 by the German Center for Health Services Research in Dermatology. This questionnaire consists of 17 items from three other wound-specific QoL PROMs, namely the Freiburg Life Quality Assessment for Wounds, the Cardiff Wound Impact Schedule and the Würzburg Wound Score.[6] The Wound-QoL-17 has been translated and validated into several languages,[6,19–22] has good cross-cultural content validity[20,22–25] and shows acceptable psychometric properties.[6,19,26] Note that, some studies have revealed problems during psychometric testing. One study proposed adjustments to the questionnaire to address limitations in differentiating responses according to Item Response Theory (IRT) (e.g., items 2, 3, 10, 12 and 16), as well as challenges in fully validating the underlying factors of the Wound-QoL.[27] Another study introduced the revised 14-item Wound-QoL, with items 10, 12 and 17 removed based on recommendations from the IRT analyses, clinical practice and construct validity analyses. Item 5 was identified as a stand-alone item not belonging to any of the three dimensions.[28] Based on the results from an

exploratory factor analysis, a third study proposed solving the problems with items 2, 3 and 5 by splitting the 'Body' factor into two factors, namely 'Inner Body' and 'Outer Body' in addition to move item 5 to the Psyche factor. Thus, the three dimensions and the 17-item structure of the Wound-QoL are unclear and debatable.[28]

Currently, there is no validated Wound-specific HRQoL questionnaire available in Norwegian although these tools are recommended in both clinical care and research. Despite some documented challenges in psychometric testing, the Wound-QoL has recently undergone a successful translation with cultural adaptation and linguistic validation into Norwegian following international guidelines.[24] Consequently, the objective of the present study was to assess the psychometric properties, including validity, reliability and dimensionality, of the Norwegian version of the Wound-QoL.

Two research questions were explored: (1) How well does the original three-factor measurement model of the Wound-QoL-17 fit the observed data? (2) Does the Wound-QoL-17 reveal good validity and reliability in a Norwegian population with HTH wounds? We expected the Wound-QoL-17 to correlate with other HRQoL measures, global impression of change and wound-related parameters.

2 | MATERIALS AND METHODS

2.1 | Sample and recruitment

This longitudinal cohort study was conducted between March 2021 and August 2023 with approval from the Regional Committee for Medical and Health Research Ethics (REK Midt) (*Date 18.12.2019/No 31816*) and the Data Access Committee at Nord-Trøndelag Health Trust (Date 01.11.2019/No 2019_3394).

Patients with HTH wounds on the lower extremity were recruited using the convenience sampling method. Eligible patients were older than 18 years, had adequate cognitive functioning, and were fluent in Norwegian. Patients with HTH wounds secondary to burns, cancer, radiation, immunological diseases and vasculitis were excluded. The inclusion and exclusion criteria provide a homogenous sample, controlled and precise study conditions and likely more reliable findings. Participants were either recruited by nursing staff at hospital outpatient clinics (95%) or municipal-based home nursing care (5%) in Norway. A researcher (MMS) made follow-up phone calls to the recruited participants at three time points: Baseline (T0), as well as 1–2 weeks (T1) and 8–14 weeks (T2) after inclusion.

2.2 | Demographic and clinical data

Demographic and clinical data were collected from participants and clinical assessments by wound-care clinicians at T0: Gender, age, living arrangement, social intercourse, marital status, education, wound aetiology, wound size (i.e., cm^2), wound exudate (i.e., little/moderate/large), infection (certain = redness, heat, pain, disturbing exudate, likely fever, elevated infection parameters in blood sample and suspected infection = redness, heat, pain and disturbing exudate), pain intensity (0–10 numeric rating scale where 0 is no pain and 10 is the worst pain imaginable) and wound duration (weeks). In addition, information on wound severity was collected from the patients by a researcher (MMS) by phone at T2: wound size change (i.e., much larger/larger/unchanged/little less/much less/healed), wound exudate, infection and pain intensity. Clinical data at T2 was based on the participants' own perceptions (Table 3).

2.3 | Measures

Participants filled out the Norwegian Wound-QoL-17 and the 36-item Short Form Health Survey (SF-36) at T0, T1 and T2. They also filled in the Patients' Global Impression of Change (PGIC) at T1 and T2. The paper-format questionnaires were self-administered. Researchers instructed the patients to fill out the questionnaires on their own.

The Wound-QoL is a multidimensional disease-specific QoL questionnaire for patients with HTH wounds. The 17 items are each scored on a 5-point Likert scale from 0 (not at all) to 4 (very much). Three subscale scores can be calculated by averaging their respective items: body (0–20), psyche (0–20) and everyday life (0–24). A global score can be calculated by averaging items 1 to 16 (0–64). Item 17 concerns economics and is not included in any subscale.[6,29] The Wound-QoL measurement instrument, mean scores, standard deviation, skewness and kurtosis are presented in Appendix A. The English Wound-QoL is a valid and reliable PROM.[27]

The SF-36 is a generic QoL questionnaire with 36 items divided into eight subscales: physical functioning (10 items), bodily pain (two items), role limitations due to physical health problems (four items), role limitations due to personal or emotional problems (three items), emotional well-being (five items), social functioning (two items), energy/fatigue (four items) and general health perceptions (five items). SF-36 also includes a single item that provides an indication of perceived change in health. The items are scored on a 2–6-point Likert

scale. A scoring key is applied to transform pre-assigned numeric values of each item into scores that fall within the 0–100 range. Then, items in the same subscale are averaged together to create the eight subscale scores, where lower scores indicate poorer HRQoL.[30] The Norwegian SF-36 is a valid and reliable PROM.[31]

The PGIC is a single-item tool quantifying the participants' perception of change in their condition following treatment or intervention. Overall health status improvement is scored on a 7-point scale with 1 representing 'no change' and 7 'a great deal better'. The PGIC is used worldwide and all translations are performed with linguistic validations in collaboration with Mapi Research Trust.[32]

2.4 | Statistical analysis

Demographic and clinical data were analysed with descriptive statistics using SPSS version 29.0.1, whilst confirmatory factor analyses (CFA) were performed in Stata version 18.

A sample size of 200 is generally sufficient for ordinary factor analysis, particularly when dealing with no more than 40 items.[33] In this study, 205 participants completed the questionnaires at baseline. To keep the sample size above 200 we decided to allow one missing item within a subscale. Out of 205, one participant was excluded due to several missing items. Twelve respondents had one missing item that was replaced with the mean for the individual's answer on the items represented by the subscale. The final sample sizes were 204 at T0, 180 at T1 and 159 at T2.

C*onstruct validity* is concerned with the underlying theoretical concept or construct that a questionnaire is intended to measure.[34] This was examined with CFA to explore the three-factor model (i.e., body, psyche and everyday life) and observe whether the manifest variables were influenced by the latent factors. The factor loading represents the extent to which the latent factor explains the variance in the observed variable. Factor loadings of $\geq$0.55 are considered to be good.[35] The Robust Maximum Likelihood estimation procedure must be applied in the CFA if the data has skewness and kurtosis (Appendix A). When analysing continuous but non-normal endogenous variables, the Satorra–Bentler corrected χ^2 should be reported.[36,37]

An aspect of construct validity is *convergent validity* which refers to the degree to which two measures that theoretically should measure the same concept (QoL) are observed to be related.[34] The majority of validation studies on Wound-QoL have utilised the generic HRQoL questionnaire EQ-5D-3L in evaluating validity,[20,22,25,38,39] however this questionnaire is not available in Norwegian. We therefore tested convergent validity by correlating the subscales and total score of Wound-QoL and SF-36 at T0 using Spearman's correlation coefficient.

Criterion validity refers to the extent to which the results from a measurement instrument are related to an external criterion measure or standard.[34] We tested criterion validity by correlating Wound-QoL with PGIC, wound size (cm^2), infection, wound exudate, general wound pain intensity and pain intensity at wound change at T0 (T2 for PGIC) using Spearman's correlation coefficient.

Test–retest reliability assesses the consistency and stability of a questionnaire.[34] In this study, the purpose was to evaluate the consistency of Wound-QoL between T0 and T1, considering the presumption of minimal changes in participants' wound status over a 1–2 week period. Test–retest was evaluated by the intraclass correlation coefficient (ICC) where an ICC >0.70 was considered good.[40]

Internal consistency estimates to which degree the items in the questionnaire are interrelated and measure the same concept.[34] This study assessed internal consistency by the reliability coefficients Cronbach's alpha (α). Cronbach's α estimated to what extent the items were correlated with each other, where α of >0.70 was considered acceptable.[34]

Internal responsiveness assesses the questionnaire's capacity to detect change within a specific predetermined timeframe.[41] Standard response mean (SRM) was used to calculate the mean change by the standard deviation of the change. SRM of <0.50 is considered a small change, 0.50–0.80 a moderate change and >0.80 a large change.[41]

External responsiveness assesses how well changes in a measure over a specified time period correspond to changes in a reference measure of health status or condition.[41] Spearman's correlation coefficient was used to estimate to what extent the change in all subscales and total score corresponded with change in wound size, infection, wound exudate, general wound pain intensity and pain intensity at wound change (T0–T2). Values >0.40 were considered acceptable.[34]

Floor and ceiling effect occurs when <15% of a group scores the minimum or maximum possible score, indicating that the questionnaire may have limited ability to differentiate between individuals at the higher and lower end of the score.[34] Descriptive analyses were performed on baseline data.

Dimensionality refers to the homogeneity of items included in a factor. When a questionnaire is multidimensional (i.e., has more than one factor), items often tap into more than one single domain or factor. A multidimensional questionnaire is specified when any item

loads on ≥2 factors or if its error term is assumed to covariate with that of another indicator.[42] However, a questionnaire must also exhibit its theoretical dimensionality and show evidence of reliability. In the present study, dimensionality was examined with CFA. How well the observed data fits the hypothesised model is assessed with fit index measures: Chi-square, Test of close fit, Root Mean Square Error of Approximation (RMSEA), Comparative Fit Index (CFI), Tucker–Lewis Index (TLI) and Standardised Root Mean Square Residual (SRMR)[43] (see Table 1 for recommended values of fit measures).

If the initial model does not fit the data well, modification indices (MI) and standardised residuals may be explored to identify potential improvements to the model.[35]

3 | RESULTS

3.1 | Demographic and clinical data

Of the total sample, 134 (65.7%) were men. The average age was 69.5 years (SD = 13.64). The wounds had different aetiology (i.e., diabetic foot ulcer, venous and/or arterial leg ulcer, traumatic ulcer, pressure injury and neuropathic ulcer), and the majority of participants suffered from diabetic foot ulcers (29.4%). Demographic characteristics of the study participants from T0 are presented in Table 2. Clinical characteristics from T0 and T2 are shown in Table 3.

3.2 | Validity

Construct validity was tested with CFA and correlation analyses. In CFA covariances between the subscales were desirable since previous research shown that the three subscales are correlated.[43] The CFA gave significant *t*-values for all factor loadings ($p < 0.01$), ranging between 0.38 and 0.88.

Tabachnick and Fidell[44] consider loadings ≥0.55 to be good. This was the fact for 14 of the 16 items in the current study. Two loadings were considered poor (item 2 = 0.38 '...my wound had a bad smell' and item 3 = 0.52 '...there was a disturbing discharge from the wound'). Ideally, the standardised factor loadings should be 0.7 or higher[45]; this was the fact for six out of the 16 items.

Together with the factor loadings, the square of a standardised factor loading (R^2) is used to assess the

TABLE 1 Recommendations for model evaluation in fit measures of dimensionality.[35]

	Good fit	Acceptable fit
Chi-square (χ^2)	$0 \leq \chi^2 \leq 2df$	$2df < \chi^2 \leq 3df$
RMSEA	≤0 to ≤0.05	<0.05 to ≤0.08
CFI	≤0.97 to ≤1.00	≤0.95 to <0.97
TLI	1.00 to <0.90	≤0.90
SRMR	0≤ to ≤0.05	<0.05 to ≤0.10

Abbreviations: CFI, Comparative Fit Index; df, degrees of freedom; RMSEA, Root Mean Square Error of Approximation; SRMR, Standardised Root Mean Square Residual; TLI, Tucker–Lewis Index.

TABLE 2 Demographic characteristics.

	T0 (baseline) $n = 204$ (%)
Gender	
Male	134 (65.7)
Living alone	92 (45.1)
Social intercourse family/friends	
Daily	110 (53.9)
Once a week	67 (32.8)
Once a month	14 (6.9)
<Once a month	12 (5.9)
Missing	1 (0.5)
Marital status	
Unmarried	30 (14.7)
Married/registered partnership	107 (52.5)
Divorced/separated	29 (14.2)
Widow(er)	37 (18.1)
Missing	1 (0.5)
Education	
Primary school	46 (22.5)
High school	92 (45.1)
<4 year college/university	29 (14.2)
>4 year college/university	36 (17.6)
Missing	1 (0.5)
Occupational status	
Employed	42 (20.6)
Unemployed	161 (78.9)
Missing	1 (0.5)
Age (years)	
Mean (±SD)	69.5 (13.64)
Median	72
Range	24–95

TABLE 3 Clinical characteristics.

	T0 (baseline) $n = 204$ n (%)	T2 (week 8–14)[a] $n = 159$ n (%)
Wound aetiology		
Diabetic foot ulcer	60 (29.4)	
Venous leg ulcer	30 (14.7)	
Arterial leg ulcer	22 (10.8)	
Mixed ulcer	4 (2)	
Traumatic ulcer	36 (17.6)	
Pressure injury	19 (9.3)	
Neuropathic ulcer[b]	11 (5.4)	
Unknown	19 (9.3)	
Wound size (cm^2)		
Mean (±SD)	15.33 (49.68)	
Median	2.04	
Range	0–600	
Wound size change last 2 weeks[c]		
Much larger		4 (2.5)
Larger		18 (11.3)
Unchanged		20 (12.6)
Little less		35 (22)
Much less		37 (23.3)
Healed		39 (24.5)
Missing		6 (3.8)
Wound exudate[d]		
Little	89 (43.6)	82 (51.6)
Moderate	87 (42.6)	24 (15.1)
Large	26 (12.7)	10 (6.3)
Not applicable		37 (23.3)
Missing		6 (3.8)
Wound infection[e]		
Diagnosed	35 (17.2)	11 (6.9)
Suspected	29 (14.2)	9 (5.7)
None	138 (67.6)	95 (59.7)
Not applicable		39 (24.5)
Missing		5 (3.1)
General wound pain intensity (NRS 0–10)		
Mild (NRS 0–3)	135 (66.2)	84 (52.8)
Moderate (NRS 4–7)	51 (25)	24 (15.1)
Severe (NRS 8–10)	16 (7.8)	8 (5)
Not applicable		43 (27)
Pain intensity at wound treatment (NRS 0–10)		
Mild (NRS 0–3)	127 (62.3)	83 (52.2)
Moderate (NRS 4–7)	56 (27.5)	25 (15.7)
Severe (NRS 8–10)	19 (9.3)	8 (5)
Not applicable		43 (27)
Wound duration		
<6 weeks	25 (12.3)	
≥6 weeks	175 (85.8)	
Unknown	1 (0.5)	
PGIC		
Very much improved		12 (7.5)
Much improved		41 (25.8)
Minimally improved		30 (18.9)
No change		47 (29.5)
Minimally worse		14 (8.8)
Much worse		4 (2.5)
Very much worse		3 (1.9)
Missing		8 (5)

Abbreviations: NRS, numeric rating scale; PGIC, patients global impression of change.

[a]Clinical data at T2 was based on the participants' own perceptions.

[b]Neuropathic ulcer with absence of diabetes.

[c]Wound size last 2 weeks was based on the participant's own evaluation.

[d]Little wound exudate = little or no fluid in the dressing, moderate wound exudate = fluid wets the dressing without completely soaking it and large wound exudate = fluid soaks the dressing and requires frequent changes.

[e]Certain wound infections = redness, heat, pain, disturbing exudate, likely fever and elevated infection parameters in blood samples. Suspected infection = redness, heat, pain and disturbing exudate.

degree to which an item is a good measure of the factor and represents how much variation in an item is explained by the latent factor.[43,45] In this study, R^2 values ranged between 0.13 to 0.78. Kline (2011) suggests that the shared variance with the factor should be greater than 0.50.[37] In this regard, 10 out of 16 items in Model-1b did not fulfil this criterion (Figure 1). Factor loadings, t-values and R^2 are presented in Table 4.

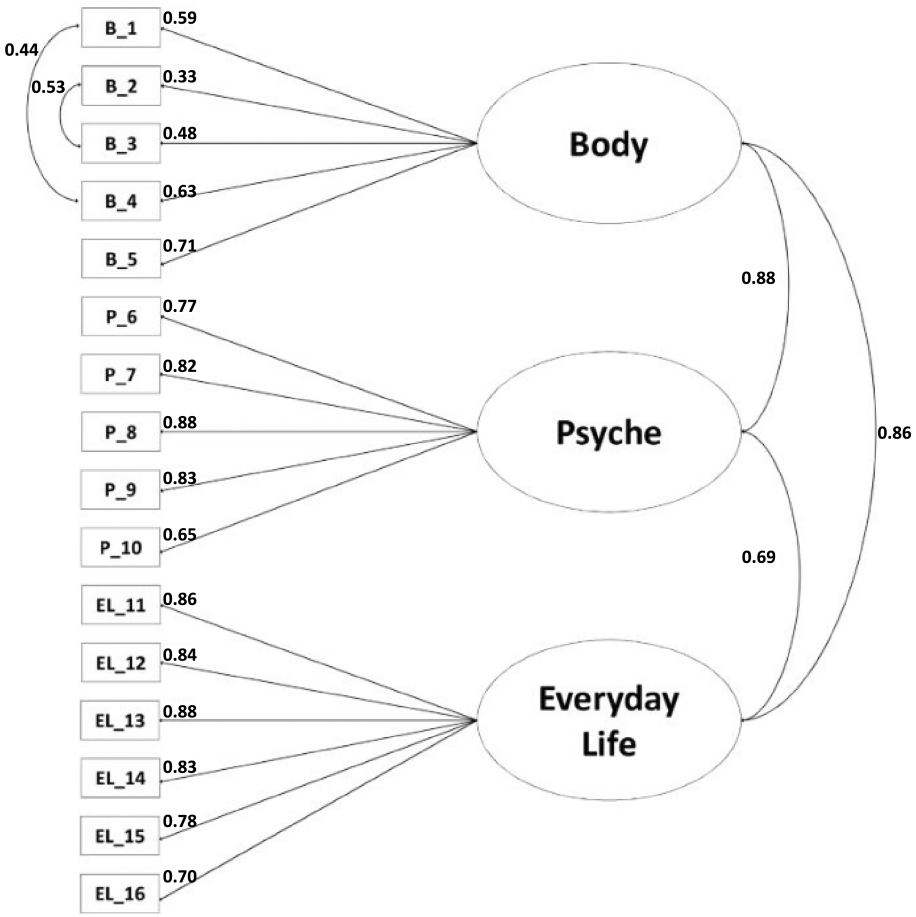

FIGURE 1 The 16-item factor model (Model 1b).

The correlations between the three factors were high (0.69, 0.86 and 0.88), indicating that the factors are closely related and that the belonging items measure the same underlying concept of QoL.

Convergent validity was good amongst subscales and the total scores of Wound-QoL and SF-36 showed moderate to strong correlations (−0.397 to −0.777). All correlations were significant ($p < 0.01$) (Table 5). Wound-QoL showed significant positive correlations with PGIC (0.199*), general wound pain intensity (0.435**), pain intensity at wound change (0.340**) and infection (0.174*), but not with wound size (0.108) and wound exudate (0.030). Except for pain intensity, correlations indicated a low *criterion validity*.

3.3 | Reliability

Internal consistency was good for the Body subscale ($\alpha = 0.75$), very good for Psyche ($\alpha = 0.89$) and excellent for Everyday life ($\alpha = 0.92$) and Total score ($\alpha = 0.78$).

Test–retest reliability between subscales and total score of Wound-QoL at T0 and T1 showed acceptable to good estimates (ICC = 0.578–0.782). All correlations were statistically significant ($p < 0.01$) (Table 6).

Internal responsiveness for T0–T1 was small for all subscales and total score (0.137–0.389) of the Wound-QoL. For T0–T2 internal responsiveness was small for Body and Everyday life, however moderate for Psyche and Total score (0.393–0.551) (Appendix B).

External responsiveness of the Wound-QoL was evaluated as weak due to correlations of change in all subscales and total score with change in PGIC, wound exudate, infection, general wound pain intensity, pain intensity at wound treatment and wound size (−0.003 to –0.193*) (Appendix C).

The ceiling effect ranged between 0 and 1.47, with Everyday life being the worst-performing subscale. Floor effects ranged between 0.49 and 10.78, with Psyche being the worst-performing subscale. The Wound-QoL did not show any signs of problematic floor or ceiling effects according to the set criteria 15% limit of maximum or minimum score (Appendix D).

3.4 | Dimensionality

We tested the original three-factor model comprising 16 items (Model 1a where item 17 is excluded). Model 1a demonstrated a modest fit with the observed data:

TABLE 4 Standardised factor loadings, *t*-values, squared multiple correlations (R^2) in the measurement Model 1a and 1b (Model 1b in parenthesis).

Items	Standardised estimate	*t*-values	R^2
Body_1	0.69 (0.59)	17.76** (12.44**)	0.47 (0.35)
Body_2	0.38 (0.33)	6.79** (5.20**)	0.13 (0.11)
Body_3	0.52 (0.48)	11.30** (8.77**)	0.28 (0.23)
Body_4	0.71 (0.63)	20.52** (13.64**)	0.51 (0.40)
Body_5	0.68 (0.71)	17.58** (17.87**)	0.47 (0.51)
Psyche_6	0.77 (0.77)	24.89** (26.28**)	0.59 (0.60)
Psyche_7	0.82 (0.82)	29.84** (29.73**)	0.67 (0.67)
Psyche_8	0.88 (0.88)	45.31** (45.86**)	0.77 (0.78)
Psyche_9	0.84 (0.83)	38.59** (37.73**)	0.70 (0.70)
Psyche_10	0.65 (0.65)	17.24** (17.09**)	0.42 (0.42)
Everyday life_11	0.86 (0.86)	38.20** (37.07**)	0.74 (0.74)
Everyday life_12	0.84 (0.84)	28.06** (27.84**)	0.71 (0.71)
Everyday life_13	0.88 (0.88)	42.23** (43.45**)	0.78 (0.78)
Everyday life_14	0.83 (0.83)	33.11** (33.01**)	0.68 (0.68)
Everyday life_15	0.78 (0.78)	24.77** (23.80**)	0.61 (0.61)
Everyday life_16	0.69 (0.70)	17.14** (17.25**)	0.48 (0.48)

*$p < 0.05$, **$p < 0.01$.

$\chi^2 = 282.93$, $p = 0.001$, df = 101, $\chi^2/df = 2.97$, RMSEA = 0.094, SRMR = 0.072, CFI = 0.900, TLI = 0.881 (Table 7). We scrutinised the MI, expected change and standardised residuals, which showed a high MI for error variance for item 2 and item 3 (58.07), as well as item 1 and item 4 (36.55). The first pair of items concerned the experience of having a bad-smelling wound (item 2) and a disturbing discharge from the wound (item 3). Furthermore, my wound hurt (item 1) seemed to be closely related to the wound affected my sleep (item 4). Accordingly, correlating error terms between those pairs of variables seems theoretically sound. A nested version of the original three-factor model that includes those two error terms within the Body factor, was named Model-1b and revealed an acceptable to good fit ($\chi^2 = 203.14$, $p = 0.000$, df = 99, $\chi^2/df = 2.05$, RMSEA = 0.072, SRMR = 0.059, CFI = 0.943 and TLI = 0.930). In this stage of the process, we also revealed high MI for the error variance between item 5 and the Psyche factor (MI = 23.29) and between item 10 and the Body factor (MI = 27.89) and Everyday life factor (MI = 17.68), respectively. Thus, we tested the revised and validated 14-item version of the Wound-QoL, a three-factor model comprising 13 items[28,46] (Model-2a items 5, 10 and 12 are excluded). The model fit was improved compared to the original three-factor model (Model-1a) but the challenge with the two pairs of items (item 2 and item 3/item 1 and item 4) within the Body factor remains. By including two error terms within the Body factor, the revised three factors model revealed a good model fit (Model-2b). To deal with the problems with the closely interrelated pairs of items, we estimated the four-factor model suggested by Liu and colleagues[21] dividing the 'Body' factor into 'Inner body' and 'Outer body' (Model 3). This model reveals a better fit than the original 16-item model (1a) and the revised 13-item model (2a), but a weaker fit than Model 2b with two correlated error terms within the Body factor. Compared to the original three-factor model with correlated error terms (Model 1b), Model 3 revealed approximately similar fit. A comparison of the estimated models and their fit indices is presented in Table 7.

4 | DISCUSSION

The aim of this study was to investigate the psychometric properties of the Wound-QoL in a Norwegian population with HTH wounds on the lower extremity. The testing revealed good validity and reliability, however, we did discover issues with the factor structure and some of the items in the questionnaire.

The hypothesised original three-factor model (i.e., body, psyche and everyday life) of the Wound-QoL-17 showed an acceptable fit to the observed data. The dimensionality was quite clear, as long as we accepted two correlated error terms within the Body factor. However, the CFA revealed some problems with shared error variances between items 1 (pain) and 4 (sleep), as well as items 2 (bad smell) and 3 (disturbing discharge). Research, literature and clinical practice experience indicate that these items are closely related but represent separate concepts. For instance, persons with moderate to severe pain often have trouble with sleeping,[47] but pain and sleep impairment are different symptoms. Likewise, the amount of wound exudate increases with a high bacterial burden, and often causes an unpleasant odour[48] but exudate and odour are different signs. In fact, the same challenges with items 1 and 4 are described in the Chinese validation of Wound-QoL. This study suggests solving the problem by splitting the Body factor into 'Inner' and 'Outer' body.[21] Nevertheless, this splitting results in a two-item factor which is not recommended and violates the principles of comprehensive and robust

TABLE 5 Wound-quality of life (QoL) in relation to selected measures: Cronbach's α and correlation coefficients.

	Wound-QoL body	Wound-QoL psyche	Wound-QoL everyday life	Wound-QoL total score
SF-36 PF	−0.445**	−0.412**	−0.569**	−0.546**
SF-36 RP	−0.400**	−0.457**	−0.519**	−0.523**
SF-36 P	−0.641**	−0.526**	−0.629**	−0.671**
SF-36 GH	−0.397**	−0.455**	−0.380**	−0.457**
SF-36 EW	−0.455**	−0.555**	−0.476**	−0.562**
SF-36 RE	−0.532**	−0.639**	−0.498**	−0.625**
SF-36 SF	−0.536**	−0.565**	−0.702**	−0.693**
SF-36 E	−0.547**	−0.625**	−0.587**	−0.664**
SF-36 total	−0.635**	−0.706**	−0.712**	−0.777**
PGIC				0.199*
Wound size				0.108
General wound pain intensity				0.435**
Pain intensity at wound treatment				0.340**
Infection				0.174*
Wound exudate				0.030
Cronbach's α	0.748	0.889	0.922	0.780

Abbreviations: E, energy/fatigue; EW: emotional well-being; GH, general health; P, pain; PF, physical function; PGIC, patient global impression of change; RE, role limitations due to emotional problems; RP, role limitations due to physical health; SF, social functioning.
*$p < 0.05$, **$p < 0.01$.

TABLE 6 Intraclass correlations within the subscales and total score in Wound-quality of life (QoL) T0 and T1.

Wound-QoL	*r*
Body	0.711**
Psyche	0.725**
Everyday life	0.778**
Total score	0.782**

**$p < 0.01$.

presentation of the underlying constructs in measurements.[43] The present study's analyses showed that the 4-factor model (i.e., inner body, outer body, psyche and everyday life) had a weaker model fit compared to the three-factor model 2b, and approximately similar fit to model 1b.

Moreover, several studies report problems with instability and low factor relation for item 5 (...the treatment of the wound has been a burden to me).[21,27,28] In the present study, the factor loading is good, but the MI indicated that relocating item 5 to the Psyche factor is a potential adjustment. However, this alteration did not improve the model fit. The challenges within the Body factor may be related to the inductive rather than theoretical development of Wound-QoL-17, that is, it was not defined in advance which dimension each item should address.[6] This feature may reduce the questionnaire's ability to accurately measure distinct constructs. Further, in Norwegian, item 5 may be conceptually more related to the Psyche factor due to the term 'burden' which implies that wound treatment can have a negative impact on a persons' psychological well-being. Although items 1–5 show some problems due to the model-fit, these items regarding pain, sleep, smell, wound exudate and treatment burden have high clinical relevance. Therefore, we believe that these five questions should remain in the Wound-QoL questionnaire to provide a sound assessment tool for holistic wound care. This assumption is supported in the study of the revised Wound-QoL where items 2 and 3 were retained due to their high relevance although they were relatively unstable and not closely related to the Body factor.[28]

The CFA also revealed complexities associated with item 10 (...I have been afraid of knocking the wound against something). The MI reveals that this item shares variance with all three factors. In Norwegian, item 10 may be interpreted as addressing the patient's worst-case scenario regarding fear or pain (i.e., Psyche factor), but may also address the patient's physical activity

TABLE 7 Goodness-of-fit measures for Model-1a, Model-1b, Model-2a, Model-2b and Model-3.

Fit measure	Model-1a 3-factor, 16 variables	Model-1b 3-factor, 16 variables	Model-2a 3-factor, 13 variables	Model-2b 3-factor, 13 variables	Model-3 4-factor, 16 variables
χ^2 *Satorra Bentler*	282.93	203.14	158.54	90.01	205.60
p-value	<0.001	<0.000	<0.001	<0.000	<0.001
χ^2/df *Satorra Bentler*	2.97 df = 101	2.05 df = 99	2.56 df = 62	1.50 df = 60	2.09 df = 98
RMSEA	0.094	0.072	0.088	0.053	0.074
p-value (close fit test)	0.000	0.000	0.000	0.145	0.000
SRMR	0.072	0.059	0.064	0.041	0.059
CFI	0.900	0.943	0.933	0.976	0.941
TLI	0.881	0.930	0.916	0.969	0.927

Note: Model-1a = The original 3-factor model comprising 16 items. Model-1b = Model-1a with two error terms within the Body factor. Model-2a = 3-factor-model comprising 13 items; 5, 10 and 12 are dismissed. Model-2b = Model-2a with two error terms within the Body factor. Model-3 = 4-factor-model comprising 16 items dividing the Body factor into the inner and outer body and moving item 5 to the Psyche factor. Everyday Life is kept as an origin (Liu).
Abbreviations: CFI, Comparative Fit Index; RMSEA, Root Mean Square Error of Approximation; SRMR, Standardised Root Mean Square Residual; TLI, Tucker–Lewis Index.

(i.e., Body factor) and daily activities (i.e., Body and Daily life factors). The US English validation study also confirmed the three-factor model of Wound-QoL, and IRT indicated that item 10, provided minimal information in its original dimension (Psyche factor).[27] It is worth noting that item 10 is omitted in the revised Wound-QoL-14 due to content overlap, low information value in its dimension and statistical performance criteria.[28] We hypothesise that the divergent factor loading of item 10 could stem from cultural and linguistic disparities amongst different language versions of the Wound-QoL. Moreover, the information conveyed by item 10 partially overlaps with items 1, 8, 11 and 13. Given the challenges observed in overall model fit in the current and prior studies, we propose to exclude item 10 from a future short-form version of the Norwegian Wound-QoL.

Reliability tests showed that the Norwegian version of the Wound-QoL had good internal consistency, test–retest stability, as well as no floor or ceiling effects. Cronbach's alpha values ($\alpha = 0.75$–0.92) were good to excellent, indicating that the questionnaire items to measure the QoL and that there is in fact little redundancy amongst the items. These findings are similar to other validation studies,[20,21,23,25,27,38] and the values are acceptable compared with the original German study ($\alpha = 0.85$–0.92).[6] In addition, *test–retest* reliability for the subscales and total score at T0 and T1 indicated good stability of the Norwegian Wound-QoL (ICC = 0.711–0.782). This finding was similar to the European, Swedish, Hebrew, Danish and Persian validation studies of Wound-QoL showing somewhat slightly higher values of ICC in test–retest reliability than the present study.[20,23,38,46]

The Wound-QoL did not have any signs of *ceiling or floor effects* (0%–1.47% and 0.49%–10.78%), indicating that the Norwegian Wound-QoL is a highly reliable questionnaire for detecting true change that is clinically important. Similar results were found in the Swedish, U.S. English, Danish and Persian validation studies.[20,25,27,38] Floor effects were on the other hand found in both the Hebrew and Dutch validation studies.[23,39]

The convergent validity was good in the Norwegian Wound-QoL. Moderate to strong correlations were found between the Wound-QoL and SF-36 (−0.397 to −0.777). Although some of the correlations amongst the subscales were quite high (e.g., −0.702, −0.706, −0.712 and −0.777), we believe that a disease-specific PROM reveals unique and valuable information that cannot be measured by a generic PROM alone. Indeed, literature recommends complementing generic with disease-specific PROMS, as the generic ones may not adequately capture the full extent of a specific disease's burden.[49] The Chinese study is the only Wound-QoL validation study that also employs the SF-36 as a validation criterion for assessing convergent validity. Note that, the current study reveals higher correlations than the Chinese study.[21] Although we have observed very strong correlations between the items, subscales and total scores in Wound-QoL and SF-36 one of these questionnaires cannot substitute the other. Wound-QoL focuses specifically on wound-related aspects, which SF-36 does not address. Therefore, despite their similarities, each questionnaire

uniquely contributes to a comprehensive understanding of the patient's QoL, with Wound-QoL filling the gap in wound-specific domains.

The Wound-QoL showed good criterion validity with a significant and moderate correlation to general wound pain intensity ($r = 0.435$**) and pain intensity at wound change (0.340**). The high correlations between QoL and pain may be explained by the fact that pain has a multifaceted impact on various QoL domains such as physical, psychological and social well-being.[50] Unfortunately, we find there is poor competence in pain management within Norwegian wound care service, which may lead to poor pain and HRQoL scores. Note that we found weaker correlations of Wound-QoL to criterion measures such as wound size, wound exudate and infection ($r = 0.030$–0.199*). Note that the majority of participants were recruited from wound clinics where clinicians have high expertise in wound care and are effective in reducing wound size, wound exudate and infection. This may explain why Wound-QoL is not highly correlated with wound-specific parameters, as these are effectively treated.

The Norwegian Wound-QoL showed a minimal to moderate degree of *internal responsiveness* as the subscales and total score changed little to moderately over 2 and 14 weeks. In addition, the *external responsiveness* was deemed to be weak due to the reference measures in this study. Due to the relatively low responsiveness of the Wound-QoL, we recommend collecting and comparing clinical data regularly (i.e., PGIC, wound exudate, infection, general wound pain intensity, pain intensity at wound treatment and wound size) to assess changes in wound status. In comparison, previous studies found that the responsiveness of Wound-QoL ranges from weak to strong.[20,22,38,39] It is however difficult to compare results of internal and external responsiveness amongst studies due to methodological heterogeneity when it comes to follow-up time, reference measures and psychometric testing methods. In addition, there are great variations in the disease trajectory as some patients with HTH wounds have a chronic condition that changes little over time, whilst other patients' wounds actually heal, have less exudate or cause less pain. Interestingly, literature reviews show that there is no consensus on what constitutes a responsive measure or how it should be quantified.[41] Therefore, further studies should look more closely into the responsiveness of Wound-QoL in larger and more homogenous samples of patients with HTH wounds that improve on relevant disease measures.

The Norwegian Wound-QoL-17's three-factor *dimensionality* initially showed an acceptable model fit after introducing two correlated error terms within the Body factor. The same result proved to be applicable to the revised Wound-QoL-14, where items 10, 12 and 17 are removed.[28] We agree that items 10 and 12 (i.e., fear of knocking the wound and trouble climbing stairs) may have limited clinical relevance since they are less applicable for patients with impaired mobility. However, item 17 is highly relevant in a Norwegian setting due to economic challenges in healthcare and social service. Patients with HTH wounds have low status and are not a prioritised patient group. Resources in terms of specialised wound treatment and reimbursements are accessible to patients in outpatient clinics, nursing homes and community nursing services, however not to patients treated in their GP-s office. Item 17 is therefore highly relevant in Norway in order assess HRQoL and detect economic inequalities and burdens amongst patients with HTH wounds. In addition, it is crucial to retain the original questionnaire (17- or 14-item) as alterations will make it impossible to compare results from Norwegian and international studies.

4.1 | Strengths and limitations

A major strength of this study is the large sample size at baseline ($n = 204$) as well as three measurement points over a time period of 8–14 weeks. These features, provide sufficient and robust data for psychometric testing.[51] In fact, the sample size is larger than the majority of validation studies conducted on Wound-QoL.[21–23,25,38,39,52] Note that the dropout rate was 11.3% at T1 and 21.7% at T2 probably due to high age and frailty amongst the study participants. Follow-up at T1 and T2 by phone rather than the presence at the clinic may also have affected the response rate.

A possible limitation of this study is the generalizability of findings to the population of patients with HTH wounds since study participants were recruited from outpatient clinics (95.5%) and municipal healthcare facilities (4.5%) with clinicians specialised in wound management. First of all, these patients may have more severe diseases and wounds, and are more challenging to treat. Secondly, these patients also receive more specialised care from clinicians with extensive knowledge of wound and symptom management. This can in turn probably lead to higher healing rates of wounds and reduced symptom burden.

Another limitation of the study worth noting is that clinical data at T2 are assessed by the participants and not researchers or healthcare workers. Whilst the patients' insights can provide valuable information, it is inherently subjective and may be influenced by personal biases, perspectives and interpretation, as well as memory recall issues. Participants' assessment can introduce

variability into the data that might affect the accuracy of the findings and limit the generalizability of the results.

5 | CONCLUSION

The Norwegian Wound-QoL shows acceptable reliability and validity, as well as an acceptable fit to the original three dimensions model. As such, the questionnaire can be used to assess HRQoL in Norwegian patients with HTH wounds. Like several previous validation studies of the Wound-QoL, the present study also found challenges concerning the questionnaire's model fit. However, we will promote the successfully validated Wound-QoL-17 in Norway. The Wound-QoL is short and user-friendly making it effective in capturing the patients' perspective on the wound symptom burdens and HRQoL. When clinicians can collect this information from their patients, they can improve wound management and promote health. We believe that the Norwegian version of Wound-QoL will be a valuable tool in both clinic and future research.

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CONFLICT OF INTEREST STATEMENT

The authors declare that there is no conflict of interest.

DATA AVAILABILITY STATEMENT

Data available on request due to privacy/ethical restrictions. However, data beyond those provided in the article cannot be released until the first author has completed her doctoral degree.

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APPENDIX A: Norwegian Wound-quality of life scores at baseline (T0)

Item	Mean	SD	Skewness	Kurtosis
1 ...my wound hurt	1.46	1.293	0.443**	−0.965
2 ...my wound had a bad smell	0.62	0.922	1.667**	2.464**
3 ...there was a disturbing discharge from the wound	1.14	1.201	0.808**	−0.429
4 ...the wound has affected my sleep	1.32	1.208	0.652**	−0.626
5 ...the treatment of the wound has been a burden to me	1.34	1.324	0.658**	−0.722*
6 ...the wound has made me unhappy	1.48	1.247	0.502**	−0.843*
7 ...I have felt frustrated because the wound is taking so long to heal	2.30	1.334	−0.207	−1.123**
8 ...I have worried about my wound	2.17	1.269	−0.069	−1.130**
9 ...I have been afraid of the wound getting worse or of new wounds appearing	2.13	1.362	−0.068	−1.247**
10 ...I have been afraid of knocking the wound	1.62	1.336	0.428*	−1.075**
11 ...I have had trouble moving about because of the wound	1.29	1.277	0.668**	−0.716*
12 ...climbing stairs has been difficult because of the wound	1.39	1.428	0.665**	−0.947**
13 ...I have had trouble with day-to-day activities because of the wound	1.57	1.320	0.410**	−0.986**
14 ...the wound has limited my leisure activities	2.04	1.470	−0.087	−1.397**
15 ...the wound has forced me to limit my activities with others	1.21	1.289	0.752**	−0.676*
16 ...I have felt dependent on help from others because of the wound	1.41	1.308	0.640**	−0.752**
17 ...the wound has been a financial burden to me	0.73	1.107	1.471**	1.288**
Body	1.16	0.837	0.452**	−0.657*
Psyche	1.95	1.946	0.024	−1.020**
Everyday life	1.47	1.127	0.466**	−0.801
Total score	1.51	0.892	0.237	−0.959**

Note: Skewness divided by SE of Skewness <1.96 = 5% level of significance*, <2.58 = 1% level of significance**. Kurtosis divided by SE of Kurtosis <1.96 = 5% level of significance*, <2.58 = 1% level of significance**.

APPENDIX B: Internal responsiveness of the Norwegian Wound-quality of life

	Subscale	Mean change	SD	SRM
T0–T1 ($n = 180$)	Body	0.171	0.616	0.278
	Psyche	0.283	0.727	0.389
	Everyday life	0.099	0.721	0.137
	Total score	0.179	0.531	0.337
T0–T2 ($n = 159$)	Body	0.351	0.757	0.464
	Psyche	0.493	0.923	0.534
	Everyday life	0.331	0.843	0.393
	Total score	0.388	0.704	0.551

Note: None of the change scores were statistically significant.
Abbreviation: SRM, Standardised Response Mean.

APPENDIX C: External responsiveness of the Norwegian Wound-quality of life (Spearman's correlations)

	Change between	Body	Psyche	Everyday life	Total score
PGIC	T1 and T2	0.127	0.171*	0.046	0.121
Wound exudate	T0 and T2	0.019	−0.054	0.073	0.053
Infection	T0 and T2	−0.003	−0.083	0.004	−0.008
NRS general wound pain intensity	T0 and T2	−0.020	−0.065	0.046	0.010
NRS pain intensity at wound treatment	T0 and T2	0.027	−0.075	0.030	0.014
Wound size	T0 and T2	0.193*	0.180*	0.099	0.156

Abbrevaitions: NRS, Numeric Rating Scale; PGIC, Patient Global Impression of Change.
*$p < 0.05$ level (2-tailed).

APPENDIX D: Ceiling and floor effect of the Norwegian Wound-quality of life at baseline (T0) ($n = 204$)

	Body	Psyche	Everyday life	Total score
Mean; median (range)	1.18; 1.10 (0–3.5)	1.95; 2.0 (0–4)	1.49; 1.33 (0–4)	1.54; 1.50 (0–3.72)
Floor effect % (n)	9.8 (20)	3.43 (7)	10.78 (22)	0.49 (1)
Ceiling effect % (n)	0 (0)	1.47 (3)	0.49 (1)	0 (0)