

**Research Summary – Qualiveen Questionnaire – Quality of Life**

<b>Author Year Research Design Setting (country)</b>	<b>Demographics and Injury Characteristics of Sample</b>	<b>Validity</b>	<b>Reliability</b>	<b>Responsiveness Interpretability</b>
<p><a href="#">Costa et al.</a> 2001</p> <p>Questionnaire</p> <p>France</p>	<p>Questionnaire development: n=9</p> <p>Item reduction: n=281 (218 male, 59 female, 4 missing data) Mean age: 41, range 17-87</p> <p>Reproducibility: n=46</p> <p>Questionnaire development: 4 paraplegic, 3 tetraplegic, 2 conus medullaris syndrome.</p> <p>Item reduction: 155 paraplegia, 90 tetraplegia, 24 conus medullaris syndrome, 12 missing data.</p>	<p>The final decision to reduce the number of items was made by the scientific committee, using their knowledge of the SCI population.</p> <p>Correlations between items in each domain and the domain: Limitations: r=0.52 to 0.65 Constraints: r=0.43 to 0.66 Fears: r=0.39 to 0.60 Feelings: r=0.50 to 0.77</p> <p>Correlations between items in each domain and non-corresponding domains:</p>	<p><b>Internal Consistency:</b> α= 0.80 Limitations: α=0.85 Constraints: α=0.80 Fears: α=0.81 Feelings: α=0.83</p> <p>Item-total correlations:</p> <p><b>Test-retest, Inter-rater, Intra-rater:</b> 15-day test-retest ICC ranged from 0.85 to 0.92 for the 4 subscales</p>	<p><b>Floor/ceiling effect:</b> Floor and ceiling effects were minimal, suggesting that the questionnaire adequately covered the range of patient experiences.</p>

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		<p>Limitations: <math>r=0.29</math> to <math>0.64</math>                      Constraints: <math>r=0.18</math> to <math>0.59</math>                      Fears: <math>r=0.12</math> to <math>0.40</math>                      Feelings: <math>r=0.28</math> to <math>0.57</math></p> <p>The criteria for acceptable discriminant validity is that the “item was more correlated with its own domain than with other domains”</p> <p><i>Clinical:</i>                      Scores from 4 Qualiveen Scales correlated with 3 items from Subjective Quality of Life Profile (SQLP) related to urination (correlation values are not provided):                      How well patients urinate: <math>P=.0001</math></p>		

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		Patient Satisfaction with Urination: P=.0001 Time taken to urinate: P<.05		
Qualiveen MANUAL  N/A  France	N=400 (290M, 104F, 6 missing data) Mean (sd) age: 41.2 (14.0) Mean (sd) DOI: 11.5 (9.6) years  Type of injury: Paraplegia (N=209) Tetraplegia (N=109) Cauda equine (N=56) Missing data (N=26)  Complete lesion: Yes (N=188) No (N=115) Doesn't know (N=74) Missing data (N=23)  Method of urinating:			<b>Interpretability:</b> See table 1.

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	Self-catheterization (N=165) Catheterized by someone else (N=22) Percussion (N=111) Abdom or manual pressure (N=90) Derivation (N=7) Indwelling catheter (N=10) Other (N=44)  Family situation: Single (N=78) Has a partner (N=236) Other (N=70) Missing data (N=16)																					
	Table 1. Mean (SD) Reference scores for Qualiveen domains and overall Index score for different groups:																					
	<table border="1"> <thead> <tr> <th data-bbox="474 1174 732 1276">Group:</th> <th data-bbox="732 1174 997 1276">Inconvenience domain (0-4):</th> <th data-bbox="997 1174 1241 1276">Restrictions domain (0-4):</th> <th data-bbox="1241 1174 1411 1276">Fears domain (0-4):</th> <th data-bbox="1411 1174 1654 1276">Impact on daily life domain (0-4):</th> <th data-bbox="1654 1174 1860 1276">Overall index: (0-4)</th> </tr> </thead> <tbody> <tr> <td data-bbox="474 1276 732 1312"><b>Men (N=290)</b></td> <td data-bbox="732 1276 997 1312">1.36 (0.91)</td> <td data-bbox="997 1276 1241 1312">1.79 (0.87)</td> <td data-bbox="1241 1276 1411 1312">1.72 (0.96)</td> <td data-bbox="1411 1276 1654 1312">1.16 (1.01)</td> <td data-bbox="1654 1276 1860 1312">1.51 (0.77)</td> </tr> <tr> <td data-bbox="474 1312 732 1383"><b>Women (N=104)</b></td> <td data-bbox="732 1312 997 1383">1.50 (0.96)</td> <td data-bbox="997 1312 1241 1383">1.79 (0.87)</td> <td data-bbox="1241 1312 1411 1383">1.54 (0.89)</td> <td data-bbox="1411 1312 1654 1383">1.42 (1.24)</td> <td data-bbox="1654 1312 1860 1383">1.64 (0.87)</td> </tr> </tbody> </table>				Group:	Inconvenience domain (0-4):	Restrictions domain (0-4):	Fears domain (0-4):	Impact on daily life domain (0-4):	Overall index: (0-4)	<b>Men (N=290)</b>	1.36 (0.91)	1.79 (0.87)	1.72 (0.96)	1.16 (1.01)	1.51 (0.77)	<b>Women (N=104)</b>	1.50 (0.96)	1.79 (0.87)	1.54 (0.89)	1.42 (1.24)	1.64 (0.87)
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	<b>Age &lt; 30 yrs (N=92)</b>	1.42 (0.90)	1.58 (0.78)	1.61 (0.94)	1.17 (1.05)	1.44 (0.76)	
	<b>Age 30-39 yrs (N=96)</b>	1.42 (0.93)	1.8 (0.8)	1.72 (1.03)	1.2 (1.01)	1.54 (0.77)	
	<b>Age 40-50 yrs (N=100)</b>	1.41 (0.99)	1.58 (0.78)	1.72 (0.94)	1.19 (1.14)	1.55 (0.84)	
	<b>Age &gt; 50 yrs (N=103)</b>	1.32 (0.89)	2.10 (1.04)	1.62 (0.89)	1.35 (1.12)	1.62 (0.81)	
	<b>Paraplegia (N=208)</b>	1.46 (0.89)	1.81 (0.85)	1.07 (0.85)	1.03 (1.31)	1.55 (0.76)	
	<b>Tetraplegia (N=107)</b>	1.34 (0.95)	2.04 (0.90)	1.80 (0.88)	1.15 (0.97)	1.59 (0.73)	
	<b>Cauda equina syndrome (N=56)</b>	1.51 (1.05)	1.81 (1.20)	1.62 (0.97)	1.56 (1.23)	1.60 (0.97)	

**Research Summary – Qualiveen Questionnaire – Quality of Life – Cross-cultural Validation Studies**

<b>Author Year Research Design Setting (country)</b>	<b>Demographics and Injury Characteristics of Sample</b>	<b>Validity</b>	<b>Reliability</b>	<b>Responsiveness Interpretability</b>
<p><a href="#">Khadour et al.</a> 2024</p> <p>Questionnaire Arabic Version (short form)</p> <p>Four neurorehabilitat ion centers in the Syrian Provinces of Damascus and Latakia</p>	<p>108 participants with SCI Mean (<math>\pm</math> SD) age 39.54 (<math>\pm</math> 11.34) years 77M, 31F Mean (<math>\pm</math> SD) time since injury 31.22 (<math>\pm</math> 11.6) months Level of injury: Cervical (n = 39), thoracic (n = 36), lumbar/sacral (n = 33) ASIA grade: A (n = 20), B (n = 54), C (n = 34)</p>	<p><b>Content validity (n = 30):</b> Most patients agreed that all items were necessary to examine the wide range of bladder problems that patients encounter. The questionnaires were typically accessible, simple to comprehend, and quick to complete for the participating patients, and no changes were required.</p> <p><b>Construct validity:</b></p> <ul style="list-style-type: none"> <li>- A significant strong association was observed between the QoL item of the NBSS-SF and the SF-Qualiveen overall score</li> </ul>	<p><b>Internal consistency:</b> The overall SF- Qualiveen showed a good internal consistency (Cronbach’s alpha of &gt;0.8). The domains “Bother with limitations,” “Fear,” “Feeling,” and “Frequency of limitations” also demonstrated good internal consistency, with a Cronbach’s alpha of &gt; 0.7: See table 1.</p> <p><b>Reproducibility:</b> The overall SF Qualiveen reproducibility was good, with ICCs of 0.90. The ICC value for every SF-</p>	

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		<p>(<math>r=0.82, p 0.003</math>) and bother with limitations domain of the SF-Qualiveen (<math>r=0.76, p 0.004</math>).</p> <ul style="list-style-type: none"> <li>- There was a substantial moderate positive association between the overall scores on the NBSS-SF and the domains of the SF-Qualiveen, involving bother with limitations (<math>r=0.53, p=0.02</math>), fears (<math>r=0.44, p=0.03</math>), feelings (<math>r=0.49, p=0.04</math>), and frequency of limitations (<math>r=0.46, p=0.02</math>).</li> <li>- The majority of the SF-Qualiveen domain demonstrated a</li> </ul>	<p>Qualiveen domain was higher than 0.7 (0.83 for the bother with limitations, 0.80 for fears, 0.84 for feeling, and 0.82 for frequency of limitations).</p>	

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		<p>moderate association with the quality of life and the storage and voiding domains.</p> <ul style="list-style-type: none"> <li>- The results of SF-Qualiveen showed weak correlation scores for the consequences domains of NBSS-SF.</li> </ul> <p><b>Factorial validity:</b> The best-fit four-factor model for confirming overall item communalities ranged from 0.552 to 0.814, which indicates moderate to high communalities, and confirms the homogeneity of the SF-Qualiveen using principal component analysis.</p>		



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<p><a href="#">Khadour et al.</a> 2023</p> <p>Psychometric study to provide the translation, cultural adaptation, and validation of the <b>Arabic NBSS-SF</b> in patients with multiple sclerosis and SCI</p> <p>Four neurorehabilitat</p>	<p>N = 136 (n = 97 SCI and N = 39 MS) 101M 35F Mean (SD) age 38.7 (11.4) years Mean (SD) injury time 29.7 (12.3) months Level of injury: Cervical (n = 37), Thoracic (n = 31), Lumbar/sacral (n = 29) ASIA Grade: A (n = 18), B (n = 49), C (N = 30)</p>	<p><b>Construct Validity:</b> The correlation analysis showed a significantly strong correlation between the QoL item of NBSS-SF and the Qualiveen total score (r=0.72, p&lt; 0.000). There was a significant moderate positive correlation between the total scores on the Arabic version of the NBSS-SF and the subdomains of the Qualiveen, including</p>																							

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<p>ion centers in two Syrian provinces (Damascus and Lattakia)</p>		<p>limitations (r=0.51, p=0.04), fears (r=0.57, p=0.04), feelings (r=0.46, p=0.01), and constraints (r= 0.59, p=0.03)</p>		
<p><a href="#">Khadour et al.</a> 2023</p> <p>Psychometric study to translate and validate the Arabic NBSS-SF in Syria and evaluate its characteristics among Arabic-speaking SCI patients</p> <p>Four neurorehabilitation centers in the Syrian Provinces of</p>	<p>N = 101 73M 28F Mean (SD) age 38.4 (11.2) years Mean (SD) injury time 30.4 (12.8) months Level of injury: Cervical (n = 38), Thoracic (n = 33), Lumbar/sacral (n = 30) ASIA Grade: A (n = 19), B (n = 51), C (N = 31)</p>	<p><b>Construct validity:</b> There was a significant strong positive correlation between question 2 of NBSS-SF and the Qualiveen (r = 0.73, p &lt; 0.001).</p>		

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Damascus and Latakia				
<p><a href="#">Krebs et al.</a> 2021</p> <p>Prospective validation study to validate and evaluate the measurement properties of the <b>German</b> Qualiveen short-form (SF) questionnaire in individuals with chronic neurogenic lower urinary tract dysfunction (NLUTD) resulting from SCI</p> <p>Tertiary neuro-urologic referral</p>	<p>N = 50 Mean (SD) age 53 (14) years 35M, 15F Etiology: Traumatic (n = 38), non-traumatic (n = 12) Level of SCI: Cervical (n = 13), thoracic (n = 25), lumbo-sacral (n = 12) Completeness of SCI: Motor complete (n = 28), motor incomplete (n = 22) Chronic (&gt; 12 months)</p>	<p><b>Criterion validity:</b></p> <ul style="list-style-type: none"> <li>- The criterion validity for the overall score at the two evaluation time points were (ICC 95% CI) 0.91 (0.62-0.97) and 0.93 (0.64-0.98), respectively.</li> <li>- The criterion validity for the different domain scores at the two evaluation time points were all greater than 0.8</li> </ul> <p><b>Cross-sectional construct validity</b> ranged from moderate to excellent (0.60–0.97)</p>	<p><b>Internal consistency:</b></p> <p>The SF-Qualiveen overall and the domains “bother with limitations” as well as “feelings” showed good internal consistency (Cronbach’s alpha &gt;0.75) at both evaluation time points. However, the internal consistency of the domains “frequency of limitations” and “fears” was moderate (Cronbach’s alpha 0.65/0.59) and moderate-poor (Cronbach’s alpha 0.68/0.37), respectively.</p>	

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center in Switzerland			<p><b>Test-retest reliability:</b> The test-retest reliability for the different SF-36 domain scores and the overall score was greater than 0.9 and ranged from 0.91 to 0.94 (overall score: 0.94 [0.89-0.97]), similarly to the reliability of the SF-36, which ranged from 0.92–0.96 (overall score: 0.96 [0.93-0.98]).</p>	
<p><a href="#">Konstantinidis et al.</a> 2021</p> <p>Observational cohort study of the <b>Greek version</b> of the Qualiveen</p>	<p>A total of 124 patients with SCI or multiple sclerosis:</p> <p>55 patients with paraplegia: Mean (<math>\pm</math> SD) age 50.69 <math>\pm</math> 13.78 years 38M, 17F</p>	<p><b>Construct and criterion validity</b> were satisfactory and CFA found that the model had good fit [<math>\chi^2</math> (14)=19.133, GFI=0.964, NFI=0.954, RMSEA=0.055, CFI=0.987].</p>	<p><b>Internal consistency:</b> Cronbach's <math>\alpha</math> &gt;0.70 for the total score and most of the four subscales for the test and retest.</p>	

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questionnaire short-form  The outpatient clinic of the Unit of Neuro-urology of the National Rehabilitation Center in Athens	16 patients with tetraplegia: Mean ( $\pm$ SD) age 51.06 $\pm$ 10.47 years 14M, 2F  53 patients with multiple sclerosis: Mean ( $\pm$ SD) age 51.15 $\pm$ 13.32 years 16M, 37F		<b>Test-retest and cross-scale correlations:</b> All domains of the SF-Qualiveen (test) were correlated with the SF-Qualiveen total score (test) and the same applies to the SF-Qualiveen (retest). Domains of the SF-Qualiveen (test) were mediocorely correlated with the domains of the SF-Qualiveen (retest).	
<a href="#">Przydacz et al.</a> 2021  Prospective cross-sectional (validation) study to validate the <b>Polish version</b> of the Qualiveen	The proper translations of the Qualiveen and SF-Qualiveen to Polish language were evaluated by 40 individuals with SCI (and 20 patients who had other neurological	<b>Construct/criterion validity:</b> A significant positive association was found between the total scores of the Qualiveen/SF-Qualiveen and the total score of the ICIQ-SF (Qualiveen: $r = 0.693$ and $P < 0.001$ ;	<b>Internal consistency:</b> For the total Qualiveen and SF-Qualiveen, Cronbach's alpha coefficients were 0.87 and 0.84, respectively.	<b>Floor/ceiling effects:</b> Neither floor or ceiling effects were identified.

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<p>questionnaire short-form</p> <p>Department of Urology of the University Hospital in Krakow, Poland</p>	<p>disorders) during direct interviews.</p> <p>Then, other individuals with SCI (n = 126) completed the Polish versions of Qualiveen, SF-Qualiveen, and International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) at the outpatient department (test) and 2 weeks later at home (re-test).</p> <p>Median age (interquartile range) 46 (32-59) years 87M, 39F Median (interquartile range) time since injury 10 (5-14) years AIS A (n = 55) AIS B (n = 6), AIS C (n = 16), and AIS D (n = 49) Level of SCI: Cervical</p>	<p>SF-Qualiveen: <math>r = 0.611</math> and <math>P &lt; 0.001</math>).</p>	<p><b>Reproducibility:</b> ICCs for the total Qualiveen and SF-Qualiveen were 0.92 and 0.93, respectively.</p>	

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	(n = 26), Thoracic (n = 78), Lumbar (n = 22)			
<p><a href="#">Moreno-Palacios et al.</a> 2021</p> <p>Psychometric study to perform a cross-cultural adaptation and validation of the NBSS to <b>Spanish</b> in patients with neurogenic lower urinary tract dysfunction</p> <p>Three different centers (one in Mexico and two in Argentina)</p>	<p>N = 82 (multiple sclerosis, n = 29; SCI, n = 22; others, n = 31) 37M, 45F Mean (range) age 43.9 (18-78) years</p>	<p><b>Construct Validity:</b> The construct validity was tested by Pearson correlation between NBSS and Qualiveen-SF, which showed a moderate correlation with a result of 0.57 (p &lt; 0.0001).</p>		
<p><a href="#">Cintra et al.</a> 2019</p>	<p>N = 68 (SCI, n = 66; multiple sclerosis, n = 1; did not answer, n = 1)</p>	<p><b>Construct Validity:</b> Pearson Correlation revealed a moderate</p>		

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<p>Psychometric study to cross-culturally adapt and check for the reliability and validity of the NBSS to <b>Brazilian portuguese</b>, in patients with SCI and multiple sclerosis</p>	<p>57M, 11F Mean (SD) age 38.9 (14.7) years Mean (SD) time since injury 41 (42.6) months Injury level: Cervical (n = 34), Thoracic (n = 28), low back (n = 3), sacral (n = 1), NA (n = 2) ASIA Grade: A (n = 42), B, C, D, or E (n = 22)</p>	<p>correlation between NBSS with the Qualiveen-SF with a finding of 0.66 ([0.40-0.82]; p &lt; 0.0001).</p>		
<p><a href="#">Reuvers et al.</a> 2017  Questionnaire <b>Dutch Version (short form)</b>  Erasmus Medical Centre and Rehabilitation at Rijndam Revalidation</p>	<p>N= 57 patients Mean age: 53.2±14.6 years 37 Male, 20 Female Injury Level: 15 Cervical, 31 Thoracic, 11 Lumbar AIS Score: 23 A, 5 B, 7C, 20 D</p>	<p>Correlation between SF-Qualiveen and UDI-6 (urinary tract symptom inventory) r=0.632, P&lt;0.001</p>	<p><b>Internal Consistency:</b> Cronbach's alpha: 0.89 (Test), 0.92 (Re-test)  <b>Test-retest, Inter-rater, Intra-rater:</b> SF-Qualiveen total score ICC=0.94 Bother with Limitations ICC=0.90 Fears ICC=0.92 Feeling ICC=0.87</p>	



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			Frequency of Limitations ICC=0.79	
<p><a href="#">Nikfallah et al.</a> 2015</p> <p>Cross-sectional prospective validation study of Persian Qualiveen-30</p> <p>A clinic</p>	<p>N=154, 89M 65F Mean age 35.55±9.8 80 SCI, 74 Multiple Sclerosis Iranian SCI &amp; MS patients &gt;=6 mth lower urinary tract symptoms Outpatient</p>	<p>Pearson’s r (p&lt;0.05): Qualiveen (Persian) total with Short Form- 12 (SF-12) Health Survey - Physical Component Summary: -0.29 Qualiveen (Persian) total with SF-12 Mental Component Summary: -0.32</p> <p>Qualiveen and its domains had a moderate to high correlation with the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) (0.36&lt;r&lt;0.57) and SF- 12 MCS (-0.51&lt;r&lt;-0.11) and SF-12 PCS (-</p>	<p><b>Internal Consistency:</b> Cronbach’s alpha: 0.95 (overall); 0.82~0.93 (subdomains)</p> <p><b>Test-retest, Inter- rater, Intra-rater:</b> 3 week test-retest ICC = 0.97 (overall); 0.94~0.97 (subdomains)</p>	<p><b>Responsiveness:</b> The non-overlap measure for overall Qualiveen score based on ICIQ-UI SF and SF-12 were 65.3 and 27.4%, respectively.</p> <p><b>Floor/ceiling effect:</b> 0% floor &amp; ceiling for overall score 0.7~1.3% floor &amp; 0.7~3.5% ceiling for “Bother with Limitations”, “Frequency of limitations”, “Fears” subdomains 8.5~10.5% floor &amp; 2.0~2.8% ceiling for “Feelings” subdomain</p>

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		<p>0.29 &lt; r &lt; -0.19), indicating good convergent validity.</p> <p>Discriminant validity: “patients with higher levels of education had significantly better urinary disorder specific quality of life (P&lt;0.001)” “patients with good income had better urinary quality of life compared to low and moderate income patients (P&lt;0.05)” “Participants with normal voiding had significantly lower values for Qualiveen and all its domains (P&lt;0.05)” *lower Qualiveen scores = better quality of life</p>		

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<p><a href="#">D'Ancona et al.</a> 2009</p> <p>Cross-sectional questionnaire <b>Portuguese version</b></p> <p>State University of Campinas, Rehabilitation Center of Goia ^nia, Prevention and Treatment Center of Voiding Dysfunctions of Jau ^ and Integrated Urology of Piracicaba</p>	<p>N=51 40 Male, 11 Female Mean age: 36.33±12.2 years Age range: 14-64 years 33 SCI patients, 8 multiple sclerosis (MS), 10 myelomeningocele (MMC)</p>	<p>Pearson's correlation coefficient between Qualiveen and International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF):</p> <p>Inconvenience: r=0.62075 Restrictions: r=0.41529 Fears: r=0.64355 Impact: r=0.11956 QoL Index: r=-0.39606 SIUP: r=0.52846</p>	<p><b>Internal Consistency:</b> Cronbach's alpha: 0.75-0.90</p> <p><b>Test-retest, Inter- rater, Intra-rater:</b> Test-retest reliability: ICC: 0.62-0.86</p>	