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## **The need for supportive care among head and neck cancer patients: psychometric assessment of the Dutch version of the Supportive Care Needs Survey Short-Form (SCNS-SF34) and the newly developed Head and Neck Cancer Module (SCNS-HNC)**

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## ABSTRACT

**Background.** In order to provide adequate supportive care tailored to patients' wishes and needs, insight into their perceived need for supportive care is required. A frequently used patient-reported outcome measure on generic cancer-related supportive care needs is the 34-item Short-Form Supportive Care Needs Survey (SCNS-SF34).

**Purpose:** To assess the psychometric properties of the Dutch version of SCNS-SF34 and the newly developed module for head and neck cancer (HNC) patients (SCNS-HNC).

**Methods:** HNC patients were included from two cross-sectional studies. Content validity of the SCNS-HNC was analyzed by examining redundancy and completeness of items. Factor structure was assessed using confirmatory and exploratory factor analyses. Cronbach's alpha, Spearman's correlation, Mann-Whitney U test, Kruskal-Wallis and intraclass correlation coefficients (ICC) were used to assess internal consistency, construct validity and test-retest reliability.

**Results:** Content validity of the SCNS-HNC was good, although some HNC-topics were missing. For the SCNS-SF34 a 4-factor structure was found: physical & daily living, psychological, sexuality and health system, information & patient support (alpha = 0.79 to 0.95). For the SCNS-HNC a 2-factor structure was found: HNC-specific functioning and lifestyle (alpha = 0.89 and 0.60). Respectively 96% and 89% of the hypothesized correlations between the SCNS-SF34 or SCNS-HNC and other patient-reported outcome measures were found; 57% and 67% also showed the hypothesized magnitude of correlation. The SCNS-SF34 domains discriminated between treatment procedure (physical & daily living:  $p = 0.02$  and psychological:  $p = 0.01$ ) and time since treatment (health system, information & patient support:  $p = 0.02$ ). Test-retest reliability of SCNS-SF34 domains and HNC-specific functioning domain were above 0.70 (ICC = 0.74 to 0.83), and ICC = 0.67 for the lifestyle domain. Floor effects ranged 21.1% to 70.9%.

**Conclusion:** The SCNS-SF34 and SCNS-HNC are valid and reliable instruments to evaluate the need for supportive care among (Dutch) HNC patients.

## INTRODUCTION

Head and neck cancer (HNC) patients often experience generic cancer-related problems, such as pain, fatigue<sup>1</sup>, anxiety<sup>2</sup> and depression<sup>3</sup> as well as HNC-specific problems such as dysphagia<sup>4</sup>, or problems with speech<sup>5</sup>, nutrition<sup>6</sup> and hearing<sup>7</sup> influencing their quality of life<sup>1,6</sup>. Supportive care, defined as the prevention and management of adverse effects of cancer and its treatment<sup>8</sup>, can help to improve these problems.

In order to provide adequate supportive care tailored to patients' wishes and needs, insight into their perceived need for supportive care is required. A frequently used patient-reported outcome measure (PROM) on generic cancer-related supportive care needs is the 34-item Short-Form Supportive Care Needs Survey (SCNS-SF34). The SCNS-SF34 measures the need and level of need for supportive care, including physical and daily living, psychological, sexuality, patient care and support and health system and information needs<sup>9,10</sup>.

Currently, the SCNS-SF34 has been translated and validated in English<sup>9,11</sup>, French<sup>12</sup>, German<sup>13</sup>, Italian<sup>14</sup>, Mexican<sup>15</sup>, Chinese<sup>16,17</sup> and Japanese<sup>18</sup> populations, including breast<sup>12,16,18</sup>, colorectal<sup>17</sup>, prostate<sup>11</sup> and mixed<sup>9,13-15</sup> cancer patients. A Dutch translation of the SCNS-SF34 has not been validated so far. In addition, the SCNS-SF34 has not yet been validated among HNC patients. Cross-validation of PROMs when translated into a different language or used in a different cancer population is of importance, since lingual, cultural and population differences may affect psychometric characteristics.

Supplementary modules for use in conjunction with the SCNS-SF34 have been developed to measure supportive care needs specific for breast<sup>19,20</sup>, melanoma<sup>21</sup> and prostate<sup>22</sup> cancer patients. Henry et al.<sup>23</sup> added four items (alcohol cessation, smoking cessation, feeling better about my appearance and finding meaning and purpose in life) to the SCNS-SF34 which were expected to be relevant to HNC patients, however these items were not validated. Therefore, we developed a HNC-specific module (SCNS-HNC) by multidisciplinary team discussions consisting of a physician, speech pathologist, linguist, psychologist, and health scientist, which we previously used to identify cutoff scores on the EORTC HNC-specific quality of life questionnaire (EORTC QLQ-H&N35)<sup>24</sup>.

The aim of this study was to assess the psychometric properties (i.e., internal consistency, validity and test-retest reliability) of the Dutch version of the SCNS-SF34 and SCNS-HNC in HNC patients.

## PATIENTS AND METHODS

### Design and study participants

Patients were included from two cross-sectional studies conducted at the department of Otolaryngology – Head and Neck Surgery of the VU University Medical Center (VUmc), Amsterdam, the Netherlands. The first study included HNC patients who visited the department from April to September 2013 and who participated in an evaluation study of a touch screen computer-assisted PROM system, which is part of standard clinical practice (called OncoQuest)<sup>25</sup>. After completing OncoQuest, all eligible patients were asked to fill in a questionnaire at home using paper and pencil (including the SCNS-SF34 and SCNS-HNC). In addition, all patients who discussed the results of OncoQuest with an oncology nurse (also part of standard clinical practice) were asked whether they agreed to have a researcher present during this nursing consultation. The researcher completed a study-specific report form regarding this consultation.

The second study included HNC patients who visited the department in February or March 2015. All eligible patients were asked to fill in a questionnaire at home using paper and pencil (including the SCNS-SF34 and SCNS-HNC). In addition, all patients who completed the first questionnaire in this second study were asked to complete the SCNS-SF34 and SCNS-HNC a second time 1 - 2 weeks later (for test-retest analyses).

Completed questionnaires were sent back to VUmc. In case of missing data, clarifications were sought over the telephone. Patients were included in this particular study when they (i) were treated with curative intent for cancer of the oral cavity, pharynx, larynx, nasal cavity or major salivary glands; (ii) were between 3 months and 5 years after last treatment; and (iii) were  $\geq 18$

years. Patients were excluded when they had cognitive impairments or did not understand the Dutch language. According to the Dutch Medical Research Involving Human Subjects Act, ethical approval was not necessary, because patients were not subjected to procedures or required to follow rules of behavior.

### Measures

#### *SCNS-SF34*

The SCNS-SF34 measures the need and level of need for supportive care in the last month on 34 items on a 5-point, two-level response scale<sup>9,10</sup>. The first response scale consists of two broad categories of need, i.e., 'no need' and 'a need'. The 'no need' scale is further

subdivided into ‘not applicable’ for issues that were no problem to the patient and ‘satisfied’ for issues on which a patient needed support but the support was satisfactory. The ‘need’ category has three subcategories indicating the level of need for additional care: ‘low need’, ‘moderate need’ and ‘high need’. According to the original study of Boyes et al. among mixed cancer patients<sup>9</sup> supportive care needs can be subdivided into five underlying domains: physical & daily living, psychological, sexuality, patient care & support and health system & information. An alternative factor structure was suggested by Au et al. among breast cancer patients<sup>16</sup>, who found four underlying domains using 33 items: physical & daily living, psychological, sexuality and health system, information & patient support. A total score per domain can be calculated and converted to a standardized 0 - 100 score, with a higher score indicating a higher level of need<sup>10</sup>.

The SCNS-SF34 was translated into Dutch according to the European Organization for Research and Treatment of Cancer (EORTC) guideline<sup>26</sup>. A translator and a nurse specialist (both Dutch native speakers) translated the SCNS-SF34 into Dutch. The translations were compared by two of the authors (FJ and IV) and slight discrepancies were solved by discussion in order to provide one Dutch version. By means of back-translation the Dutch version was converted into English by two independently working native English-speaking persons and compared by the two authors to the original English version.

### *SCNS-HNC*

The SCNS-HNC measures the need for supportive care concerning eleven HNC-specific issues using the same response scale as the SCNS-SF34. In addition, a single free-text item was added where patients could report any additional needs, which were not yet taken into account in the SCNS-SF34 or SCNS-HNC. This free-text item was added to analyze whether supportive care needs were missing from the patient perspective. Reading age of the SCNS-HNC calculated using the formula of Douma (formula of Flesch–Kincaid Grade adjusted for Dutch situation) was 13 - 15 years<sup>27</sup>.

### Other PROMs and clinical measures

All HNC patients also completed the EORTC generic (EORTC QLQ-C30)<sup>28</sup> and HNC-specific (EORTC QLQ-H&N35)<sup>29</sup> quality of life measure, the Hospital Anxiety and Depression Scale (HADS)<sup>30</sup>, the Speech Handicap Index (SHI)<sup>31</sup> and a PROM evaluating swallowing problems (SWAL-QOL)<sup>32</sup>. In the first study these PROMs were completed using OncoQuest<sup>25</sup>, while in the second study they were assessed concurrently with the SCNS-SF34 and SCNS-HNC. Besides, in the first study a study-specific report form was completed by an observing

researcher who was present during the nursing consultation following OncoQuest. This report form included information on topics, information and supportive care options discussed during the nursing consultation.

Finally, socio-demographic characteristics were patient-reported and clinical characteristics were retrieved from patients' medical records.

### Data analyses

Content validity of the SCNS-HNC was analyzed by examining redundancy and completeness of items. Items were considered redundant if  $< 10\%$  of the patients reported a need (or in case of SCNS-HNC item 6  $< 10\%$  of patients treated with total laryngectomy). Completeness of the SCNS-HNC was examined by analyzing supportive care needs reported on the free-text item of the SCNS-HNC and analyzing needs discussed during the nursing consultation as assessed in the study-specific report form. If  $\geq 5\%$  of patients reported or discussed an additional supportive care need, adding this specific need to the SCNS-HNC should be considered.

Confirmatory factor analysis was used to analyze whether the original 5-factor<sup>9</sup> or alternative 4-factor structure<sup>16</sup> of the SCNS-SF34 could be replicated, as proposed by Terwee et al.<sup>33</sup>. Criteria for an acceptable fit were: 1) Root Mean Square Error of Approximation (RMSEA)  $< 0.06$  and Comparative Fit Index (CFI) and Tucker-Lewis Index-Non-Normed Fit Index  $\geq 0.9$ . Principal component analysis with varimax rotation of factors with eigenvalues  $> 1.0$  was used to analyze the factor structure of the SCNS-HNC. Appropriateness of principal component analysis was examined using Bartlett's test of sphericity ( $p < 0.05$ ) and the Kaiser, Meyer Olkin index of sampling adequacy ( $KMO \geq 0.60$ ). Internal consistency was assessed using Cronbach's alpha coefficient; a value between 0.70 and 0.95 is considered good<sup>33</sup>.

To analyze construct validity, a priori hypotheses were formulated regarding the correlation between the SCNS-SF34 (31 hypotheses) or SCNS-HNC (9 hypotheses) and other PROMs (EORTC QLQ-C30, EORTC QLQ-H&N35, HADS, SHI and SWAL-QOL) (presented in Table 1), and expected differences between groups of HNC patients (13 hypotheses). Hypotheses were based on previous studies<sup>9,11-13,16,18,34-36</sup> and researchers' expectations. Regarding expected differences, it was expected that: 1) younger patients (18 - 60 years) reported a higher level of need than older patients ( $> 60$  years) on all domains except for physical & daily living<sup>12,13,16,18,35</sup>; 2) females reported a higher level of need on the physical &

daily living and psychological domain<sup>13</sup>, while males reported a higher level of need on the sexuality domain<sup>13,35</sup>; 3) patients with multimodality treatment reported a higher level of need on all domains but sexuality than patients who received single treatment; and 4) patients longer after treatment reported a lower need on the patient care & support and health system & information domains<sup>36</sup>. Correlations were analyzed using Spearman's correlation coefficient, since needs were non-normal distributed. Magnitude of the correlations were defined as moderate ( $r = 0.30$  to  $0.50$ ) or strong ( $r > 0.50$ )<sup>37</sup>. Differences between groups of HNC patients were analyzed using Mann-Whitney U test or Kruskal-Wallis. A  $p$ -value  $< 0.05$  was considered statistically significant. The SCNS-SF34 and/or SCNS-HNC were found to be valid if at least 75% of the hypotheses were in correspondence with the a priori defined hypotheses<sup>33</sup>.

Test-retest reliability was analyzed using intraclass correlation coefficients with absolute agreement (ICC) in patients who completed the second questionnaire within one month after the first. An ICC value  $\geq 0.70$  has been considered good<sup>33</sup>. Finally, floor or ceiling effects ( $> 15\%$  of patients with the lowest or highest possible score) was investigated using frequency tables.

All analyses were performed using the IBM Statistical package for the Social Science (SPSS) version 22 (IBM Corp., Armonk, NY USA) and Mplus version 6.11 (Muthen & Muthen, Los Angeles, CA USA)<sup>38</sup>.

#### Sample size calculation

For this study, at least 170 patients were needed for factor analyses (5 times the number of SCNS-SF34 items), 50 patients per subgroup for construct validity analyses, and 50 patients for test-retest reliability<sup>33</sup>.

**Table 1. A priori defined hypotheses regarding the (magnitude of the) correlation of domains of the SCNS-SF34 and items of the SCNS-HNC with other patient-reported outcome measures and the found correlation**

	SCNS-SF34					SCNS-HNC				
	P&DL	PSY	SEX	PC&S HSI & PS <sup>1</sup>	HS&I <sup>1</sup>	Chewing or swallowing	Dry mouth and/ or sticky mucus	Problems with weight	To be informed on nutrition	Difficulty speaking
<b>HADS</b>										
Anxiety	<u>0.48</u> <sup>+</sup>	<u>0.65</u> <sup>++</sup>	<u>0.34</u> <sup>+</sup>	<u>0.51</u> <sup>+</sup>	+					
Depression	<u>0.61</u> <sup>+</sup>	<u>0.64</u> <sup>++</sup>	<u>0.33</u> <sup>+</sup>	<u>0.57</u> <sup>+</sup>	+					
<b>EORTC QLQ-C30</b>										
Physical functioning	-0.50 <sup>--</sup>									
Role functioning	-0.63 <sup>-</sup>									
Emotional functioning	-0.56 <sup>-</sup>	<u>-0.64</u> <sup>-</sup>		<u>-0.47</u> <sup>-</sup>	-					
Cognitive functioning	<u>-0.43</u> <sup>-</sup>	<u>-0.47</u> <sup>-</sup>								
Social functioning	-0.54 <sup>-</sup>									
Global quality of life	<u>-0.55</u> <sup>--</sup>	-0.51 <sup>-</sup>								
Fatigue	<u>0.64</u> <sup>++</sup>	<u>0.55</u> <sup>+</sup>		<u>0.52</u> <sup>+</sup>						
Pain	<u>0.47</u> <sup>++</sup>			<u>0.42</u> <sup>+</sup>						
Dyspnea				<u>0.19</u> <sup>+</sup>						
Sleep/insomnia	<u>0.42</u> <sup>+</sup>									
Appetite loss		<u>0.44</u> <sup>+</sup>		<u>0.38</u> <sup>+</sup>						



<b>EORTC QLQ-H&amp;N35</b>	
Swallowing	<u>0.62</u> <sup>++</sup>
Dry mouth	0.55 <sup>+</sup>
Sticky saliva	0.57 <sup>+</sup>
Weight loss	<u>0.40</u> <sup>+</sup>
Weight gain	0.08 <sup>+</sup>
Speech	<u>0.61</u> <sup>++</sup>
Sexuality	<u>0.47</u> <sup>+</sup>
<b>SWAL-QOL</b>	
Symptom	<u>0.62</u> <sup>++</sup>
Food selection	<u>0.48</u> <sup>+</sup>
<b>SHI total score</b>	
	<u>0.64</u> <sup>++</sup>

Abbreviations: SCNS-SF34, Supportive Care Needs Survey Short-Form 34; SCNS-HNC, Supportive Care Needs Survey Head and Neck Cancer Module; P&DL, physical & daily living; PSY, psychological; SEX, sexuality; PC&S, patient care & support; HS&I, health system & information; HSI&PS, health system, information & patient support; HADS, Hospital Anxiety and Depression Scale; EORTC QLQ-C30, European Organization for Research and Treatment of Cancer generic health-related quality of life module; EORTC QLQ-H&N35, European Organization for Research and Treatment of Cancer Head and Neck Cancer Module; SWALQOL, swallowing quality of life; SHI, Speech Handicap Index.

\*: a positive moderate ( $r = 0.30 - 0.50$ ) association was expected;

\*\* : a positive strong ( $r > 0.50$ ) association was expected;

† : a negative moderate ( $r = -0.30 - -0.50$ ) association was expected;

†† : a negative strong ( $r < -0.50$ ) association was expected.

If the a priori defined hypothesis was supported, the coefficient was underlined.

<sup>1</sup> Since a 4-factor structure was found, we only present correlations of the combined HIS & PS domain.

## RESULTS

### Study sample

In total, 201 patients were included for content analyses, factor analyses and construct validity analyses; 110 patients for test-retest analyses; and 69 patients for content analysis using the study-specific report forms. Socio-demographic and clinical characteristics are presented in Table 2.

**Table 2. Characteristics of the study samples**

Characteristics	Factor analyses and construct validity n = 201	Test-retest reliability n = 110	Content validity (study specific report form) n = 69
	%	%	%
<b>Age</b>			
- 18 – 60 years	31.3%	25.5%	46.4%
- > 60 years	68.7%	74.5%	53.6%
<b>Sex</b>			
- Male	66.7%	72.7%	63.8%
- Female	33.3%	27.3%	36.2%
<b>Living arrangements</b>			
- Living alone	24.4%	30.0%	14.3% <sup>1</sup>
- Living with partner	58.7%	59.1%	59.2%
- Living with partner and children	15.4%	10.0%	22.4%
- Other (e.g., with children)	1.5%	0.9%	4.1%
<b>Education</b>			
- Elementary education	6.5%	3.6%	5.8% <sup>1</sup>
- Lower education	37.8%	40.0%	24.6%
- Secondary education	26.9%	25.5%	23.2%
- Higher education	28.9%	30.9%	17.4%
<b>Employment status</b>			
- Employed (paid/unpaid)	35.8%	30.9%	42.9% <sup>1</sup>
- Unemployed	12.5%	11.8%	16.3%
- Housewife/houseman	3.5%	3.6%	4.1%
- Retired	48.3%	53.6%	36.7%

**Table 2. Continued**

Characteristics	Factor analyses and construct validity	Test-retest reliability	Content validity (study specific report form)
	n = 201	n = 110	n = 69
	%	%	%
Tumor site			
- Oral cavity	31.3%	33.6%	30.4%
- Pharynx	36.8%	35.5%	36.2%
- Larynx	19.9%	20.9%	17.4%
- Nasal cavity	6.0%	4.5%	8.7%
- Major salivary glands	6.0%	5.5%	7.2%
Disease stage (UICC)			
- Stage I	27.9%	30.9%	23.2%
- Stage II	13.4%	10.0%	21.7%
- Stage III	16.4%	16.4%	18.8%
- Stage IV	36.8%	34.5%	34.8%
- Unknown	5.5%	8.2%	1.4%
Type of treatment			
- Surgery	25.4%	25.5%	27.5%
- Radiotherapy	20.4%	21.8%	23.2%
- Surgery and chemoradiation	8.5%	7.3%	5.8%
- Surgery and radiation	22.4%	22.7%	23.2%
- Chemoradiation	23.4%	22.7%	20.3%
Time since last treatment			
- < 1 year	38.8%	34.5%	44.9%
- 1 - 2 year	29.9%	31.8%	26.1%
- > 2 year	31.3%	33.6%	29.0%

Abbreviations: UICC, International Union Against Cancer.

<sup>1</sup> Living arrangement, education and employment status is missing in 20 patients.

### Content validity of the SCNS-HNC

On all SCNS-HNC items,  $\geq 10\%$  of the patients reported a need, indicating there were no redundant items. Regarding completeness, two of the 201 patients who filled in the SCNS-HNC reported on the free-text item that they had an additional need not yet taken into account in the questionnaire, one indicated to have needs regarding pain and one regarding psychological distress. The study-specific report form of the nursing consultation following OncoQuest revealed some frequently discussed HNC-specific issues not yet included in the SCNS-HNC: coughing and breathlessness (23%), difficulty eating or eating in company (19%), taste and olfaction (16%), changes in appetite (9%), and mobility of the tongue (6%).

### Factor analysis and internal consistency

The 5-factor structure as well as the 4-factor structure of the SCNS-SF34 could not be replicated in our study sample using confirmatory factor analysis (Table 3). Under either the assumption of correlated factors or of uncorrelated factors, both factor structures had a negative residual variance on item 16 “Changes in your sexual relationships”. Therefore, we also performed an analysis in which item 16 was deleted. In that case, both factor models could not be estimated when assuming correlated factors. When assuming uncorrelated factors, both factor models showed inadequate RMSEA-scores. Therefore, an exploratory principal component analysis was performed to investigate the factor structure for use in HNC patients. At first a new 5-factor structure was generated (Table 4), replicating the physical & daily living and sexuality domains and almost replicating the psychological needs and health system, information & patient support domain as reported in Au et al.<sup>16</sup>. However, the fifth factor comprised 4 items (item 17 - 19 and 24) without clear cohesion. Since 3 out of these 4 items had high cross-loadings (cross loadings 0.34 to 0.51), a second principal component analysis was performed without item 19 (which did not have any cross-loadings) and forced into 4 factors, resulting in the same factor structure as in Au et al. [16]. Although this 4-factor structure (Bartlett’s test of sphericity ( $p < 0.001$ ) and KMO = 0.93) did not have a good fit of the model using confirmatory factor analyses, this model is nevertheless proposed to be the best model for use in HNC patients with good internal consistency (Cronbach’s alpha ranging from 0.79 (sexuality domain) to 0.95 (psychological)) (Table 5).

Principal component analysis of the SCNS-HNC showed two underlying constructs, namely HNC-specific functioning and lifestyle (Bartlett’s test of sphericity ( $p < 0.001$ ) and KMO = 0.88) (Table 6). Item 6 was not included in the principal component analysis, since it was not correlated ( $r < 0.30$ ) with the other items. Internal consistency of HNC-specific functioning domain was good (Cronbach’s alpha = 0.89), while below 0.70 for the two-item lifestyle domain (Cronbach’s alpha = 0.60).

### Construct validity

In total, 27 of the 28 (96%) hypothesized correlations (seven hypotheses on health system, information & patient support were investigated instead of 11 hypotheses when the 5-factor structure would have been replicated) between the SCNS-SF34 and other PROMs, were found (Table 1). Sixteen correlations (57%) also supported the a priori hypothesized magnitude of correlation. Regarding expected differences, three of the ten hypotheses were confirmed (30%) (Table 7). Patients treated with multi-modality treatment reported

a higher need on the physical & daily living ( $p = 0.015$ ) and psychological domain ( $p = 0.009$ ), while no difference was found for health system, information & patient support ( $p = 0.070$ ). Patients longer after treatment reported less need for health system, information & patient support than patients shorter after treatment ( $p = 0.015$ ). No significant differences were found regarding gender or age.

Of the SCNS-HNC, 8 of the 9 (89%) hypothesized correlations were found (Table 1). Six correlations (67%) also supported the a priori hypothesized magnitude of correlation.

#### Test-retest reliability

Test-retest reliability of the SCNS-SF34 domains was good (ICC ranged from 0.74 (sexuality) to 0.83 (physical & daily living)). Test-retest reliability for HNC-specific functioning was also good (ICC = 0.83), while it was slightly lower than 0.70 for the lifestyle domain (ICC = 0.67).

#### Presence of floor and/or ceiling effects

On all SCNS-SF34 and SCNS-HNC domains floor effects were present (Table 5 and 6). Floor effects (no need for care) ranged from 21.1% (health system, information & patient support) to 70.9% (lifestyle). No ceiling effects were present.

**Table 3: Goodness-of-fit indices for the Supportive Care Needs Survey Short-Form 34 (SCNS-SF34) using confirmatory factor analysis (n = 201)**

Model		$\chi^2$ statistic	Df	p-value	RMSEA	CFI	TLI
<b>5 factor model</b>	uncorrelated factors <sup>1</sup>	10017.44	527	$\leq 0.001$	0.299	0.476	0.442
	uncorrelated factors without item 16	Model could not be estimated					
	correlated factors <sup>1</sup>	901.112	517	$\leq 0.001$	0.061	0.979	0.977
	correlated factors without item 16	867.861	485	$\leq 0.001$	0.063	0.978	0.976
<b>4 factor model</b>	uncorrelated factors <sup>1</sup>	8210.269	495	$\leq 0.001$	0.278	0.567	0.538
	uncorrelated factors without item 16	Model could not be estimated					
	correlated factors <sup>1</sup>	854.928	489	$\leq 0.001$	0.061	0.979	0.978
	correlated factors without item 16	823.389	458	$\leq 0.001$	0.063	0.979	0.977

Abbreviations:  $\chi^2$ , Chi-Square Df, degrees of freedom; RMSEA, Root Mean Square Error of Approximation; CFI, Comparative Fit Index; TLI, Tucker-Lewis Index-Non-Normed Fit Index.

<sup>1</sup> Model in which item 16 had a negative residual variance

**Table 4: First factor structure generated for the SCNS-SF34 in head and neck cancer patients using principal component analysis (n = 201)**

Item	Factor Loadings <sup>1</sup>				
	1	2	3	4	5
1. Pain		0.38	0.39	<u>0.48</u>	
2. Lack of energy/tiredness	0.30	0.52		<u>0.58</u>	
3. Feelings unwell a lot of the time		0.55		<u>0.65</u>	
4. Work around the home				<u>0.75</u>	
5. Not being able to do the things you used to do	0.38	0.41		<u>0.69</u>	
6. Anxiety		<u>0.79</u>		0.30	
7. Feeling down or depressed	0.30	<u>0.78</u>			
8. Feelings of sadness		<u>0.81</u>			
9. Fears about the cancer spreading		<u>0.84</u>			
10. Worry that the results of treatment are beyond your control		<u>0.73</u>			
11. Uncertainty about the future		<u>0.82</u>			
12. Learning to feel in control of your situation	0.31	<u>0.68</u>		0.39	
13. Keeping a positive look		<u>0.52</u>		0.41	
14. Feelings about death and dying		<u>0.78</u>			
15. Changes in sexual feelings		0.47			<u>0.73</u>
16. Changes in your sexual relationships		0.35			<u>0.83</u>
17. Concerns about the worries of those close to you		0.37	<u>0.51</u>		
18. More choice about which cancer specialists you see		0.34	<u>0.73</u>		
19. More choice about which hospital you attend			<u>0.74</u>		
20. Reassurance by medical staff that the way you feel is normal	<u>0.55</u>	0.32	0.35		
21. Hospital staff attending promptly to your physical needs	<u>0.63</u>		0.44		
22. Hospital staff acknowledging, and showing sensitivity to, your feelings and emotional needs	<u>0.68</u>		0.35		
23. Being given written information about the important aspects of your care	<u>0.64</u>		0.50		
24. Being given information (written, diagrams, drawings) about aspects of managing your illness and side-effects at home	0.51		<u>0.58</u>		

Table 4: Continued.

Item	Factor Loadings <sup>1</sup>				
	1	2	3	4	5
25. Being given explanations of those tests for which you would like explanations	<u>0.67</u>	0.31	0.31		
26. Being adequately informed about the benefits and side-effects of treatments before you choose to have them	<u>0.74</u>		0.30		
27. Being informed about your test results as soon as feasible	<u>0.76</u>	0.31			
28. Being informed about cancer which is under control or diminishing (that is, remission)	<u>0.78</u>	0.36			
29. Being informed about things you can do to help yourself to get well	<u>0.74</u>				
30. Having access to professional counselling (e.g., psychologist, social worker, counsellor, nurse specialist) if you, family or friends need it	<u>0.65</u>	0.34			
31. To be given information about sexual relationships					<u>0.77</u>
32. Being treated like a person not just another case	<u>0.82</u>				
33. Being treated in a hospital or clinic that is as physically pleasant as possible	<u>0.74</u>				
34. Having one member of hospital staff with whom you can talk to about all aspects of you condition, treatment and follow-up	<u>0.77</u>			0.31	

<sup>1</sup> loadings > 0.3 are presented, and main (i.e., highest) loading is underlined.

**Table 5. Floor and ceiling effects of the SCNS-SF34 and suggested factor structure in head and neck cancer patients (n = 201)**

Item	% Lowest score	% Highest score	Factor Loadings <sup>1</sup>			
			1	2	3	4
<i>Physical &amp; daily living</i>	38.8%	0%				
1. Pain	70.9%	2.5%		0.39	<u>0.54</u>	
2. Lack of energy/tiredness	51.0%	4.5%	0.33	0.51	<u>0.60</u>	
3. Feelings unwell a lot of the time	74.6%	1.0%		0.53	<u>0.67</u>	
4. Work around the home	58.4%	3.0%			<u>0.76</u>	
5. Not being able to do the things you used to do	57.7%	7.5%	0.39	0.39	<u>0.69</u>	
<i>Psychological</i>	29.7%	0%				
6. Anxiety	68.0%	2.5%		<u>0.78</u>	0.31	
7. Feeling down or depressed	67.7%	1.0%	0.32	<u>0.78</u>		
8. Feelings of sadness	66.7%	2.0%		<u>0.81</u>		
9. Fears about the cancer spreading	51.5%	8.5%		<u>0.85</u>		
10. Worry that the results of treatment are beyond your control	59.7%	3.5%	0.34	<u>0.74</u>		
11. Uncertainty about the future	50.0%	5.5%	0.33	<u>0.82</u>		
12. Learning to feel in control of your situation	58.0%	1.5%	0.35	<u>0.68</u>	0.41	
13. Keeping a positive look	54.2%	3.5%	0.31	<u>0.52</u>	0.42	
14. Feelings about death and dying	65.0%	4.5%		<u>0.79</u>		
17. Concerns about the worries of those close to you	60.5%	2.5%	0.38	<u>0.42</u>	0.30	
<i>Sexuality</i>	69.9%	0.5%				
15. Changes in sexual feelings	75.3%	3.0%		0.48		<u>0.74</u>
16. Changes in your sexual relationships	77.8%	2.5%		0.36		<u>0.84</u>
31. To be given information about sexual relationships	85.4%	0.5%				<u>0.76</u>
<i>Health system, information &amp; patient support</i>	21.1%	0%				
18. More choice about which cancer specialists you see	67.5%	1.5%	<u>0.47</u>	0.41		
20. Reassurance by medical staff that the way you feel is normal	43.5%	2.5%	<u>0.62</u>	0.34	0.31	
21. Hospital staff attending promptly to your physical needs	57.5%	2.0%	<u>0.73</u>			



Table 5. Continued

Item	% Lowest score	% Highest score	Factor Loadings <sup>1</sup>			
			1	2	3	4
22. Hospital staff acknowledging, and showing sensitivity to, your feelings and emotional needs	55.0%	1.5%	<u>0.75</u>			
23. Being given written information about the important aspects of you care	58.0%	2.0%	<u>0.75</u>			
24. Being given information (written, diagrams, drawings) about aspects of managing your illness and side-effects at home	61.5%	4.0%	<u>0.65</u>		0.30	
25. Being given explanations of those tests for which you would like explanations	46.2%	2.5%	<u>0.72</u>	0.31		
26. Being adequately informed about the benefits and side-effects of treatments before you choose to have them	47.2%	4.5%	<u>0.79</u>			
27. Being informed about your test results as soon as feasible	43.3%	11.9%	<u>0.74</u>	0.31		
28. Being informed about cancer which is under control or diminishing (that is, remission)	38.3%	10.4%	<u>0.77</u>	0.37		
29. Being informed about things you can do to help yourself to get well	50.2%	8.5%	<u>0.78</u>	0.30		
30. Having access to professional counselling (e.g., psychologist, social worker, counsellor, nurse specialist) if you, family or friends need it	66.7%	4.5%	<u>0.67</u>	0.35		
32. Being treated like a person not just another case	53.2%	9.5%	<u>0.79</u>			
33. Being treated in a hospital or clinic that is as physically pleasant as possible	44.3%	6.5%	<u>0.72</u>			
34. Having one member of hospital staff with whom you can talk to about all aspects of you condition, treatment and follow-up	47.3%	6.5%	<u>0.78</u>			
19. More choice about which hospital you attend	68.5%	2.0%	-	-	-	-
Eigenvalue			16.69	3.34	1.67	1.23
Variance			50.58	10.11	5.05	3.71
Cronbach's alpha			0.95	0.95	0.89	0.79

<sup>1</sup> loadings > 0.3 are presented, and main (i.e., highest) loading is underlined.

**Table 6. Floor and ceiling effects of the SCNS-HNC and suggested factor structure in head and neck cancer patients (n = 201)**

Item	% Lowest score	% Highest score	Factor loadings <sup>1</sup>	
			1	2
<i>HNC-specific functioning</i>	21.3%	1.0%		
1. Problems with chewing and or swallowing	47.0%	8.0%	<u>0.84</u>	
2. Problems with dry mouth and/or sticky mucus	36.0%	10.0%	<u>0.85</u>	
3. Problems with weight (underweight or overweight)	47.0%	6.5%	<u>0.74</u>	
4. To be informed on nutrition	57.5%	5.0%	<u>0.78</u>	
5. Difficulty speaking	54.8%	5.0%	<u>0.77</u>	
7. Problems with hearing	71.5%	2.5%	<u>0.59</u>	
8. Oral hygiene	56.6%	4.5%	<u>0.75</u>	
9. Problems with mobility of neck or shoulders	58.8%	7.0%	<u>0.70</u>	
<i>Lifestyle</i>	70.9%	0.5%		
10. Quit smoking	81.4%	5.0%		<u>0.84</u>
11. Quit drinking	78.5%	0.5%		<u>0.85</u>
6. Care of your stoma and/or voice prosthesis <sup>2</sup>	20.0%	30.0%	-	-
Eigenvalue			4.76	1.39
Variance			47.63	13.94
Cronbach's alpha			0.89	0.60

Abbreviations: HNC, head and neck cancer.

<sup>1</sup> loadings > 0.3 are presented, and main (i.e., highest) loading is underlined.

<sup>2</sup> Percentage lowest score and percentage highest score calculated for patients treated with total laryngectomy only.

Table 7. Differences in SCNS-SF34 domain scores between different patient groups

Characteristics	N	SCNS domain			
		Physical & daily living n = 196	Psychological n = 195	Sexuality n = 196	Health system, information & patient support n = 199
		Median [range]	p	Median [range]	p
Age			0.67		0.31
18 - 60 years	63		7.5 [0 - 92.5]	0 [0 - 75.0]	13.3 [0 - 83.3]
> 60 years	138		10.0 [0 - 85.0]	0 [0 - 100.0]	15.0 [0 - 91.7]
Gender			0.11		0.55
Male	134	10.0 [0 - 95.0]		0 [0 - 100.0]	
Female	67	12.5 [0 - 95.0]		0 [0 - 66.7]	
Treatment procedure			0.02		0.07
Single treatment	92	5.0 [0 - 95.0]		5.0 [0 - 85.0]	11.7 [0 - 85.0]
Multi modality treatment	109	10.0 [0 - 95.0]		15.0 [0 - 92.5]	18.3 [0 - 91.7]
Time since last treatment					0.02
0 - 1 year	78				19.2 [0 - 91.7]
1 - 2 years	60				13.3 [0 - 81.7]
> 2 years	63				7.5 [0 - 76.7]

Abbreviations: SCNS, Supportive Care Needs Survey.

## DISCUSSION

This study is the first study that investigated the psychometric properties of the Dutch version of the SCNS-SF34 and newly developed SCNS-HNC among HNC patients. Psychometric properties assessed were content validity, factor structure, internal consistency, construct validity and test-retest reliability.

Content validity analyses of the SCNS-HNC showed that there were no redundant items, but that some HNC issues may need to be added: taste and olfaction, difficulty eating, eating in company and changes in appetite, coughing and breathlessness, and mobility of the tongue. For some of these problems the need for supportive care was already addressed indirectly, e.g., the problems on difficulty eating, eating in company and changes in appetite were addressed partly by the question on being informed about nutrition, and the problems on mobility of the tongue is addressed by the question on chewing and swallowing, and speech. For the other problems/needs (taste and olfaction, and coughing and breathlessness), multidisciplinary discussions are needed on the necessity to update the SCNS-HNC. In the present study we aimed to include only those problems/needs for which supportive care is available. However, we realize that this aim is not consistent with the tenets of supportive care needs assessment. One of the purposes is to assist in identifying, guiding and designing the range of services that ought to be available to patients<sup>39</sup>. Although an item on taste and olfaction, and on coughing and breathlessness may be added, the SCNS-HNC is a comprehensive PROM.

Appropriateness of the SCNS-HNC was further supported by the identified 2-factor structure: HNC-specific functioning which comprises of 8 items on needs related to HNC-specific functioning and problems, and a lifestyle domain which comprises of 2 items related to quitting smoking and drinking. Internal consistency of HNC-specific functioning was good (Cronbach's alpha = 0.89), while somewhat low for the lifestyle domain (Cronbach's alpha = 0.60), which can be explained by the fact that this domain includes only two items. We acknowledge that a domain with two items is generally recognized as less stable and thereby less reliable and less construct valid than a domain with more items<sup>40</sup>.

Regarding the SCNS-SF34, confirmatory factor analyses showed that the 5-factor structure of Boyes et al.<sup>9</sup> and the 4-factor structure of Au et al.<sup>16</sup> could not be replicated in this study. Nevertheless, exploratory factor analyses showed that the 4-factor structure in

which item 19 is deleted and the domains on health systems & information and patient care & support were combined in one domain (i.e., health system, information & patient support)<sup>16</sup> was the best model for use in HNC patients with good internal consistency (Cronbach's alpha ranged from 0.79 to 0.95). Up till now, this 4-factor structure has only been proposed by Au et al.<sup>16</sup>. Other validation studies proposed the (slightly-adjusted) 5-factor structure of Boyes et al.<sup>9</sup>, although these studies also acknowledged some difficulties or inconsistencies when replicating the 5-factor structure<sup>11-13,15,17,18</sup>. Okuyama et al.<sup>18</sup> for instance showed that items 21 and 22 had stronger cross loadings on the health system & information domain, while originally allocated to the patient care & support domain. The same holds for Lehmann et al.<sup>13</sup> who found that item 30 had stronger cross loadings on the psychological domain, while originally allocated to the health care & information domain. In addition, Schofield et al.<sup>11</sup> reported that items 18 and 19 originally allocated to the patient care & support domain did not load (loading < 0.30) to one of the domains at all and Doubova et al.<sup>15</sup> excluded item 31 due to high cross loadings. Finally, Brédart et al.<sup>12</sup> and Li et al.<sup>17</sup>, the only two studies that performed confirmatory factor analyses, reported that residuals were correlated indicating redundancy among items. Based on these validation studies and our results, as already hypothesized by Li et al.<sup>17</sup>, it can be assumed that one universal factor structure for the SCNS-SF34 is unlikely. The factor structure of the SCNS-SF34 may potentially differ regarding for example age, gender or cancer diagnosis.

To assess construct validity of both the SCNS-SF34 and SCNS-HNC, we defined clear a priori hypotheses regarding the (magnitude of) correlation with other PROMs and expected differences between groups of HNC patients. In our study 96% and 89% of the hypothesized correlations were found for the SCNS-SF34 and SCNS-HNC respectively, however, only 57% and 67% (respectively) showed the hypothesized magnitude of correlation. In 11 of the 16 cases in which the correlation as such was supported but not the magnitude of correlation, a stronger correlation was found than a priori hypothesized based on previous validation studies<sup>9,11-13,16,18</sup> and researchers' expectations. Regarding discriminative construct validity, patients treated with multi-modality treatment in our study reported higher levels of physical & daily living and psychological needs and patients longer after treatment reported less health system, information & patient support needs. No significant differences in supportive care needs were found between different gender and age groups. This is in contrast to previous studies which have repeatedly shown such differences<sup>12,13,16-18,35</sup>.

A possible explanation for the stronger correlations and absence of differences in supportive care needs regarding age and gender is that all patients included in our study were at least 3 months after treatment and in general had low levels of supportive care needs, as shown by the high floor effects of 21.1% to 70.9%. These high floor effects may have resulted in limited variation in outcomes and consequently in higher correlations and the absence of differences between groups. Another explanation may be that supportive care needs are different in HNC patients compared to other cancer populations (i.e., breast, prostate and mixed cancer populations) on which our hypotheses were mainly based<sup>9,11-13,16,18,34,35</sup>. Our results are in line with the results of Henry et al. which was published after our hypotheses formulation<sup>23</sup>, who found relatively high correlations between total SCNS-SF34 score and HADS-D and HADS-A of  $r = 0.44$  and  $0.53$  and no association with gender and age in HNC patients.

Finally, test-retest reliability of the SCNS-SF34 and SCNS-HNC was overall shown to be good (ICC ranged from 0.67 to 0.83). Only two previous validation studies<sup>12,15</sup> also assessed test-retest reliability of the SCNS-SF34. They also showed good test-retest reliability, except for the physical & daily living domain in breast cancer patients<sup>12</sup>.

A limitation of this study is that we included HNC patients after treatment limiting generalizability to HNC patients undergoing treatment or other Dutch cancer populations. Therefore we encourage the validation of the SCNS-SF34 and SCNS-HNC in patients during treatment and other Dutch cancer populations. Another limitation of this study is that although patients were asked to report any additional needs not yet included in the SCNS-HNC, patients did not participate in the developmental stage by interview or focus group. Also, critically reviewing to assess whether all of the items were relevant for the construct being measured and cognitive interviews to determine how the items were perceived or understood by HNC patients were not performed. Main strengths of this study are the development of the SCNS-HNC which can be used in conjunction with the SCNS-SF34, and the assessment of a wide range of psychometric characteristics including content validity, factor structure, internal consistency, construct validity and test-retest reliability. In conclusion, in this study, a module was developed for use in conjunction with the SCNS-SF34 that measures supportive care needs specific for HNC patients (i.e., SCNS-HNC). The SCNS-SF34 and SCNS-HNC are valid and reliable PROMs to evaluate the need for supportive care among HNC patients. More research on the validation of the SCNS-SF34 and SCNS-HNC in other populations, including HNC patients undergoing treatment is, however, warranted.

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