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Performance of the EORTC questionnaire for the assessment of quality of life in head and neck cancer patients EORTC QLQ-H&N35: a methodological review

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Abstract
Purpose The EORTC QLQ-H&N35 (H&N35) is widely used to measure quality of life in head and neck cancer patients. The aims of this study were to obtain insight into a) the languages in which the H&N35 has been used and the psychometric properties in those languages, b) the study designs, and c) its acceptance by patients and investigators.
Methods A systematic literature review was performed searching for all original papers that had used at least one item of the H&N35. Identified papers were read and the information about methodological issues abstracted statistically analysed.
Results A total of 136 papers were identified. The H&N35 was administered in 19 different languages in 27 countries. The study design was cross-sectional in the majority of studies (53 %), prospective cohort studies (31 %), phase-II-trials (7 %), phase-III-trials (6 %) and case–control studies (1 %). The scales with the highest percentages of missing values were Sexuality (11.5 %) and Speech (7 %). The median Cronbach's alpha of the multi-item scales ranged from 0.61 (Senses) to 0.93 (Sexuality). Construct validity was rarely investigated. On average, 12 scales (range 0-18) of the instrument were used by the investigators. The scale most often used was swallowing (in 85 % of studies) and least often used was Weight Gain (39 %).
Conclusion The H&N35 is widely used throughout the world, mainly in observational studies, and has demonstrated robust psychometric features in different languages.

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However, some methodological problems reported imply that the instrument can be improved in some areas.

Keywords Head and neck cancer · EORTC QLQ-H&N35 · Validation studies · Psychometrics · Reliability

Background

The EORTC Quality of Life Group develops site-specific modules to be used with a core questionnaire, the EORTC QLQ-C30. One of the first was the module for patients with head and neck cancer, the EORTC QLQ-H&N37 [1], later revised and shortened to its final version with 35 items, the H&N35 [2]. This module consists of 7 multi-item scales, measuring pain in the mouth, problems with swallowing, senses, speech, social eating and social contact, and 11 single-item scales, assessing problems with teeth, mouth opening, dry mouth, sticky saliva, coughing, feeling ill, as well as use of analgesics, nutritional supplements, feeding tube and finally weight gain and weight loss.

The module has been translated into 53 languages (February 2012, http://groups.eortc.be) and is in use worldwide as one of the standard instruments for measuring quality of life in head and neck cancer patients [3, 4].

Some issues have been raised that may hamper the use of the H&N35. One criticism occasionally raised is that patients may feel annoyed by some of the items, for example, those enquiring about problems with sexual functioning [5, 6]. A matter of debate is whether this presents difficulty for the researcher who feels uncomfortable in asking such questions or for the patient who feels embarrassed or irritated in answering. Another criticism concerns items that may not be applicable to some of the patients, for example, questions about swallowing solid food administered to patients who are tube fed or about hoarseness when the larynx has been removed [7]. Little is known about the use of the H&N35 in research, on the way the psychometric issues are reflected in different languages, and how well the multi-item scales are accepted by patients and investigators.

The goal of the present study was to review all papers relating to studies that have used the H&N35 module to date, investigating potential methodological problems and benefits. Questions to be answered were as follows:

1. In what languages has the H&N35 been used and validated since it was published (*cross-cultural use*)?
2. How reliable and valid are the multi-item scales of the H&N35? Were any psychometric problems reported (*psychometrics*)?
3. How accepted are the questions by the patients, that is, how frequently did they skip specific items or scales (*acceptance by patients*)?
4. How accepted are the questions and the scales by the investigators, that is, do they omit items or scales (*acceptance by investigators*)?
5. How often is the H&N35 used for what types of studies?

Methods

The H&N35 contains 35 items which can be condensed into seven multi-item and eleven single-item symptom scales. All EORTC QoL questionnaires result in scales that score from 0 to 100. A score of 100 indicates perfect QoL in the functioning scales, whereas for the symptom scales, it indicates heavy burden.

A systematic review was performed, searching for all publications up to August 2011 that reported data using the H&N35. Databases searched were Pubmed, EMBASE and Social Science Citation Index. Original papers written in the following languages were eligible for this review: Bosnian, Croatian, Dutch, English, French, German, Japanese, Russian, Serbian, Spanish and Turkish. Papers written in Japanese were translated by a native speaker. All other non-English papers were read by the first author (SS) in the original version.

Search terms entered for title, abstract or key words were "H?N35" and "head and neck module", respectively. The question mark is used for the search electronic in databases to indicate that any single character or none at all is considered correct. For example, a paper using the abbreviation "HN35" as well as a paper using "H&N35" would be included in the search. The results of that search were presented to a group of health care professionals experienced in the treatment of head and neck cancer within the EORTC Quality of Life Group with the opportunity to add papers that had not been detected by the criteria used in the initial search.

All reviews were excluded; only original papers were analysed. Several papers on the same study population were considered eligible for inclusion as long as different data were presented. It was not always possible to determine exactly whether data from the same population were reported or not. Therefore, all papers from the same author or study group were included even if the presented data came presumably from the same patient sample. Duplicate hits, that is, the same article found in different search engines, were removed.

If no access to the full text was available, the paper's corresponding author was contacted and asked to send a PDF file or a printed copy of the manuscript.

The following details were documented for each paper: the number of patients assessed with the H&N35, cancer site, language in which the H&N35 was administered, information about compliance and missing values, information on or discussion of methodological problems, challenges or advantages, number of H&N35 scales used, estimates of internal consistency (Cronbach's alpha), construct validity, study design and topic. These details were entered into a database for statistical analysis, using STATA 11 [8]. The analysis included computation of frequencies, percentages and averages (mean, median) as well as testing differences between groups using Kruskal–Wallis tests.

Results

A total of 136 original papers were found that had used the H&N35 (see Fig. 1). Access to the full text was available for 125, with access to the abstract for the remaining 11. A detailed description of the studies can be found in the supplementary material. Considering all papers together, the H&N35 had been completed by 13,969 patients (subject to the assumption that each paper reported on a different study population). Most often, the H&N35 was used in observational studies; 53 % of the studies had a cross-sectional design, 31 % were prospective cohort studies, 7 % phase-II-trials, 6 % phase-III-trials, 1 % case–control studies, and one study reported on a case series.

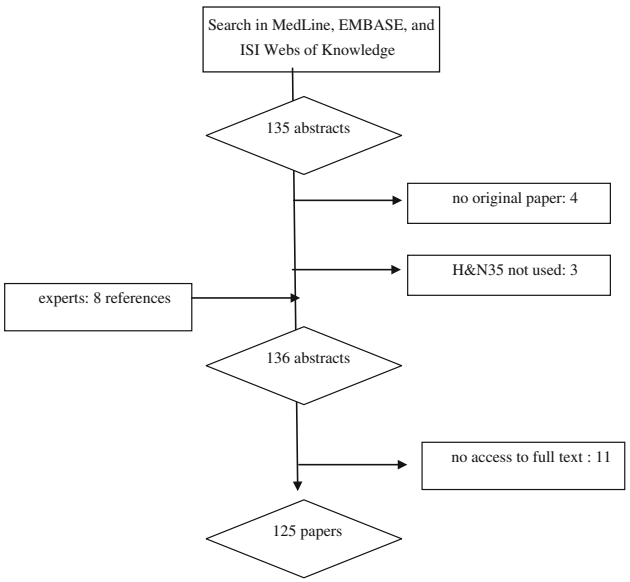

Fig. 1 Flow diagram of literature search

Cross-Cultural Use: The H&N35 was administered in 19 different languages: German (29 papers), Dutch (26), Swedish (15), English (11), French (8), Norwegian (7), Mandarin (7), Cantonese (6), Danish (4), Spanish (5), Polish (3), Portuguese (3), Japanese (3), Czech (1), Greek (1), Italian (1), Korean (1), Sinhala (1) and Turkish (1). Studies were performed in 26 different countries: The Netherlands (25 studies), Germany (22), Sweden (15), Taiwan (9), Norway (7), France (6), Switzerland (6), United Kingdom (6), Denmark (4), Hong Kong (4), Spain (5), Japan (3), Poland (3), Portugal (2), Canada (2), United States (2), Australia (2), and 1 study each in Austria, Belgium, Brazil, Czech Republic, Greece, Italy, Korea, New Zealand, Sri Lanka and Turkey. A breakdown of studies from the different world regions is displayed in Fig. 2.

Psychometrics: Sixty-one papers explicitly or implicitly discussed methodological issues of the H&N35. Internal consistency was investigated in 18 papers by means of Cronbach's alpha and in general appeared to be high, that is

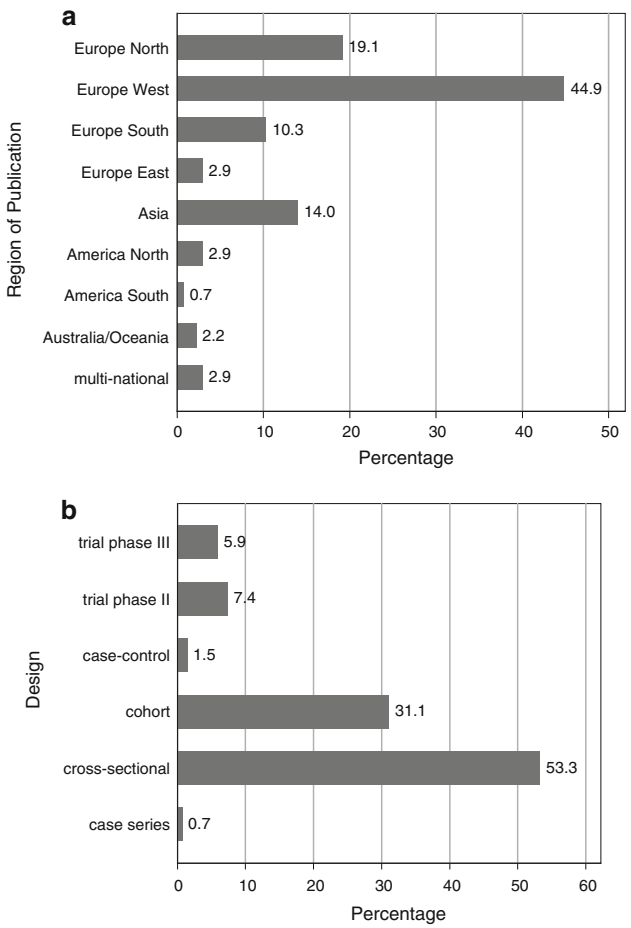

Fig. 2 Description of papers analysed. *Panel a* proportion of studies performed in different world regions. *Panel b* proportion of study designs used in the studies. *Note* region is defined as being the region where the study was primarily performed not as the region where the paper was published

Table 1 Internal consistency of EORTC QLQ-H&N35 multi-item scales, sorted by language

Reference	Language	Author	Years	Pain in the mouth	Swallowing	Senses	Speech	Social eating	Social contact	Sexuality
[37]	Mandarin	Chie	2003	0.83	0.78	0.78	0.75	0.89	0.84	0.92
[38]	Cantonese (?)	Ng	2006	Combined H&N scale only: 0.79						
[39]	Cantonese	Bower	2009	0.80	0.84	**0.35**	0.77	0.93	0.87	0.96
[17]	Danish	Jensen	2006	0.84	0.82	0.83	0.82	0.92	0.89	0.93
[11]	English	Sherman	2000	0.88	0.92	**0.54**	0.75	0.89	0.84	0.93
[7]	German	Singer	2009	0.73	0.81	0.70	**0.55**	0.86	0.80	0.90
[40]	Greek	Nalbadian	2010	0.76	0.73	**0.23**	0.88	0.88	0.81	0.99
[8]	Italian	Zotti	2000			**0.53**	**0.58**			
[15]	Japanese	Toth	2005	**0.64**	0.72	0.70	0.79	0.74	0.75	0.93
[41]	Mandarin	Lue	2008	Ranged from 0.75 to 0.85						
[6]	Multiple	Bjordal	1999	min. 0.78*	min. 0.78*	**0.10**	**0.10–** 0.87*	0.82	0.79	No information
[2]	Multiple	Bjordal	2000	0.81	0.82	0.72	0.74	0.87	0.83	0.95
[42]	Norwegian	Aarstad	2007			**<0.70**				
[10]	Norwegian	Aarstad	2008			**<0.70**				
[43]	Norwegian	Aarstad	2011	>0.70	**<0.70**	**<0.70**	>0.70	>0.70	>0.70	>0.70
[9]	Portuguese	Silveira	2010	0.72	0.90	0.70	**0.46**	0.92	0.86	0.99
[16]	Sinhala	Jayasekara	2009	0.73	0.82	**0.61**	0.81	0.82	0.89	**0.60**
[12]	Spanish	Arraras	2001	0.68	0.76	**0.43**	0.82	0.83	0.80	0.85
		Median		*0.77*	*0.82*	***0.61***	*0.76*	*0.88*	*0.84*	*0.93*

Bold printing indicates Cronbach's alpha below 0.70. * Denotes a range of alpha coefficients by different tumour sub-samples

Alpha $\geq$ 70 (Table 1). Moderate or low internal consistency, that is, Alpha $<$ 70, was reported on the Speech [6–9] and Senses [6–8, 10–12] scales. Consequently, the items of the Senses scale were treated as single items in two studies [13, 14]. One study [15] reported a moderate Cronbach's alpha (0.64) regarding the Pain in the Mouth scale. The average Cronbach's alpha (computed as the median alpha per scale of all papers where coefficients were reported) ranged from 0.61 (Senses) to 0.93 (Sexuality).

Construct validity was evaluated less frequently. Jayasekara [16] reported overall good construct validity with 87 % scaling successes though the Senses scale exhibited scaling failure, that is, the items were more highly correlated with other scales than with its own scale. Jensen [17] criticised high interscale correlations ($>$ 0.7) as an "indication of overlapping constructs" (p. 35) and, therefore, considered the Social Eating and Social Contact scales to be difficult to differentiate psychometrically and conceptually [17]. On the other hand, he argued that the categorisation of items and scales was sensible because the entire range of the items and scales were covered by the patients' responses. In a study in laryngeal cancer patients after surgery, items of the Speech scale had scaling failure in 24 %, 1.4 % occurred with Pain in the Mouth and Swallowing, and 0 % in all other multi-item scales [7]. Arraras et al. reported good evidence for sensitivity to change in all scales [12]. Silveira et al. investigated the module's ability to differentiate symptomatic vs. asymptomatic patients and found good performance except in the following scales: senses, dry mouth, weight gain and weight loss [9]. In three studies, a total H&N35 scale value was calculated based on all head and neck scales [18–20].

Acceptance by patients (*missing values*): 23 papers reported on percentages of missing values with varying results. The completeness of the questionnaire varied from 66 % [17] to 99 % [21], both studies including patients

Table 2 Missing values information per scale with reported missing values

Scale	Mean (range) percentage of missing values	Number of studies reporting on missing values	References
Sexuality	11.5 % (0–29.0 %)	11	[5, 6, 8, 15, 16, 22–24, 40, 44, 45]
Speech	7.0 % (0–19.0 %)	3	[8, 40, 46]
Teeth	2.7 % (0–5.0 %)	3	[40, 44, 45]
Weight Gain	2.0 % (0–4.0 %)	2	[40, 45]

from Denmark. Scales with missing values included Sexuality, Speech, Teeth and Weight Gain with average percentages of missing values of 11.5, 7.0, 2.7 and 2.0 %, respectively (Table 2). Some authors reported that, regarding the Teeth and Sexuality scales [16, 17, 22], it may remain unclear whether a non-answer was due to the patient being unwilling to answer or because the item did not apply to their status.

The percentage of missing data was unrelated to the region where the study had been performed (P = 0.26 to 0.99).

Acceptance by investigators: The H&N35 consists of 7 multi-item scales and 11 single-item scales. The number of scales reported on in the reviewed studies varied considerably (range: 0 to 18 scales; mean: 12 scales; see Table 3). The use of the scales ranged from 39 % (Weight Gain)—that means that 61 % of the studies did not use or did not report on this scale – to 85 % (Swallowing). Usually, no rationale was given why specific scales were omitted. From the pattern of use, we can see that the scales used least frequently were those where only yes/no answers were possible. These items were reported in less than half of the papers (39 % Weight Gain to 45 % Pain Killers; see Table 3). The Sexuality scale was relatively often (27 %) omitted; however, there were also studies which only used that scale [23, 24]. The number of scales differed significantly between the regions where the study was performed (P = 0.01, see Fig. 3): Whereas in Northern America and in multi-national studies usually all 18 scales were used, on average 12 scales were used in studies performed in Western Europe. No differences were observed according to study designs (P = 0.78).

One study group had developed an alternative head and neck module (EORTC QLQ-H&N17) for surgically treated patients [25].

Discussion

This review describes the use of the EORTC module for the measurement of quality of life in head and neck cancer patients, the H&N35. Major objectives were to find out in what languages it has been used and validated, what psychometric properties in the different language versions have been reported, and how well accepted the module is by patients and investigators.

Based on the 136 papers identified and assessed as part of this evaluation, we can conclude that the H&N35 is used by many investigators throughout the world. As many authors investigated or commented on methodological issues of the H&N35, this information could be collated.

Use of the H&N35 in 26 countries and 19 languages to date indicates broad cross-cultural acceptance. It is, however, interesting to note that it had been translated into 53 languages altogether, leaving 34 translations "unused". Presumably, these translations were requested for trials performed by pharmaceutical companies without publication in academic journals. Most publications came from Western and Northern European Countries and Asia. Although many studies investigating quality of life in head and neck cancer patients are performed in Northern America [26, 27], relatively few have used the H&N35. This can be explained by the fact that, traditionally, Northern American studies make more use of other well-validated instruments such as the Functional Assessment of Cancer Therapy–Head Neck scale [28–31], the University of Washington Quality of Life Questionnaire, or the Performance Status Scales–Head and Neck cancer [32].

Relatively few studies have reported on construct validity. Those that did mainly confirmed the proposed scale structure, though some concerns have been expressed regarding the high interscale correlation, indicating overlapping constructs. Similarly, some authors computed total scores although this was not intended by the developers of the H&N35. Reliability was mainly evaluated using the concept of internal consistency which was satisfactory overall. The only scale with a median Cronbach's alpha beneath the threshold of 0.70 was Senses. Reasons for this moderate internal consistency may be that smell and taste are different functions, and patients may have problems with the one without difficulties in the other domain. Moderate internal consistency of this scale was found in different languages and study populations; therefore, the two items should perhaps better be handled separately.

All other scales exhibited good to very good consistency coefficients with Sexuality having the highest scores in all but one language. Sensitivity to change was not frequently explicitly investigated, though the H&N35 was used in many prospective studies and changes over time were observed, providing indirect evidence for sensitivity to change. However, explicit investigation of sensitivity to change would be desirable.

Although the H&N35 is relatively long compared to other EORTC quality of life modules, it proved to be well accepted by patients. The reported frequency of missing values was generally low. Only areas where patients might feel that this domain is not applicable to them, for example, problems with teeth when they have dentures, were left out more frequently. Good acceptance of the H&N35 was also found by other authors who compared different QoL measures in head and neck cancer patients [3, 4, 33].

The acceptance by investigators was also high, considering the number of studies using this instrument, although the entire H&N35 was not always used. Items where only a yes/no response format is provided were frequently either not administered to the patients or not reported by the

Table 3 Use of sales as reported in the publications (sorted by number of scales used)

Ref	Author	Years	Scales used	PA	SW	SE	SP	SO	SC	SX	TE	OM	DR	SS	CO	FI	PK	NS	FT	WL	WG
[39]	Bower	2009	18	x	x	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[47]	Infante-Cossio	2009	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[16]	Jayasekara	2009	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[48]	Keereweer	2010	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[49]	Lee	2010	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[40]	Nalbadian	2010	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[50]	Schiefke	2009	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[51]	van den Berg	2008	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[52]	Yoshimura	2009	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[53]	Arraras	2005	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[12]	Arraras	2001	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[54]	van Herpen	2010	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[55]	Aplak	2007	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[56]	Baumann	2006	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[57]	Beutner	2006	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[14]	Bindewald	2007	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[2]	Bjordal	2000	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[6]	Bjordal	1999	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[58]	Braz	2005	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[59]	Breil	2006	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[37]	Chie	2003	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[60]	Guntinas-Lichius	2006	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[61]	Guntinas-Lichius	2007	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[62]	Guntinas-Lichius	2009	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[63]	Hanna	2004	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[22]	Harding	2008	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[17]	Jensen	2006	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[21]	Jensen	2007	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[64]	Jensen	2006	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[65]	McMillan	2006	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[66]	Müller	2001	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[38]	Ng	2006	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[67]	Nijdam	2008	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[68]	Op de Coul	2005	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[69]	Pow	2006	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Table 3 continued

Ref	Author	Years	Scales used	PA	SW	SE	SP	SO	SC	SX	TE	OM	DR	SS	CO	FI	PK	NS	FT	WL	WG
[70]	Rogers	1999	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[44]	Rogers	1998	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[71]	Shepherd	2004	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[11]	Sherman	2000	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[7]	Singer	2009	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[9]	Silveira	2010	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[72]	Silveira	2011	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[19]	Smadja	2005	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[73]	Stoeckli	2001	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[15]	Toth	2005	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[74]	Tschudi	2003	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[75]	Wojtowicz	2001	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[8]	Zotti	2000	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[76]	Zwahlen	2008	18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
[77]	Salas	2009	17	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	–	x	x
[78]	Al Nawas	2006	17	x	x	x	x	x	x	–	x	x	x	x	x	x	x	x	x	x	x
[79]	Björdal	2001	17	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	–
[80]	Ciuman	2007	17	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	–
[81]	Finizia	1998	17	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	–
[82]	Hammerlid	2001	17	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	–
[83]	Infante-Cossio	2009	14	x	x	x	x	x	x	x	–	x	x	x	x	x	x	–	–	x	–
[84]	Verdonck-de Leeuw	2010	14	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	x	–	–
[85]	Bahannan	2007	14	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[86]	Borggreven	2007	14	x	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–
[87]	Roh	2007	14	x	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–
[43]	Aarstad AK	2011	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[88]	Alicikus	2009	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[89]	Huang	2010	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[90]	Verdonck-de Leeuw	2009	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[91]	Leung	2011	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[92]	Lundstrom	2009	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[93]	Oates	2008	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[10]	Aarstad AK	2008	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[18]	Aarstad HJ	2006	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[94]	Abendstein	2005	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–

Table 3 continued

Ref	Author	Years	Scales used	PA	SW	SE	SP	SO	SC	SX	TE	OM	DR	SS	CO	FI	PK	NS	FT	WL	WG
[95]	Allison	2002	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[86]	Borggreven	2007	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[96]	Bozec	2007	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[97]	De Graeff	2001	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[98]	Evensen	2002	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[99]	Fang	2004	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[100]	Fang	2004	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[101]	Fang	2008	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[102]	Fang	2005	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[103]	Hammerlid	2001	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[41]	Lue	2008	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[104]	Nordgren	2006	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[105]	Nordgren	2008	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[106]	Nordgren	2003	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[107]	Oates	2007	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[108]	Öhrn	2001	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[109]	Petruson	2003	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[110]	Petruson	2005	13	x	x	x	x	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[111]	Birkhaug	2002	12	x	x	x	–	x	x	x	x	x	x	x	x	x	–	–	–	–	–
[112]	Derks	2003	12	x	x	x	x	x	x	–	x	x	x	x	x	x	–	–	–	–	–
[113]	Finizia	2002	11	x	x	x	x	x	x	x	–	–	x	x	x	x	–	–	–	–	–
[114]	Johansson	2008	11	x	x	x	x	x	x	x	–	–	x	x	x	x	–	–	–	–	–
[115]	Schliephake	2002	11	x	x	–	x	–	x	–	–	–	–	–	x	x	x	x	x	x	x
[116]	Schliephake	2002	11	x	x	–	x	–	x	–	–	–	–	–	x	x	x	x	x	x	x
[117]	Hammerlid	2001	10	x	x	x	–	x	–	–	x	x	x	x	x	x	–	–	–	–	–
[21]	Jensen	2007	9	x	x	x	–	x	–	–	–	–	x	–	x	–	–	x	x	x	–
[118]	Ackerstaff	2009	8	x	x	x	x	x	x	–	–	–	x	x	–	–	–	–	–	–	–
[119]	Pourel	2002	8	x	x	x	x	x	x	–	–	x	x	–	–	–	–	–	–	–	–
[120]	Curran	2007	7	x	x	x	x	x	x	x	–	–	–	–	–	–	–	–	–	–	–
[121]	Jenewein	2008	7	x	x	x	x	x	x	x	–	–	–	–	–	–	–	–	–	–	–
[122]	Singer	2007	7	–	–	–	x	–	x	x	–	–	x	x	x	–	–	–	–	x	–
[123]	Ho	2010	6	x	x	–	–	–	–	–	x	x	x	–	–	–	x	–	–	–	–
[124]	Derks	2005	6	x	x	x	x	x	x	–	–	–	–	–	–	–	–	–	–	–	–
[125]	Gryczynski	2003	6	x	x	x	x	x	x	–	–	–	–	–	–	–	–	–	–	–	–
[126]	Jellema	2001	6	–	x	x	x	x	–	–	–	–	x	x	–	–	–	–	–	–	–

Table 3 continued

Ref	Author	Years	Scales used	PA	SW	SE	SP	SO	SC	SX	TE	OM	DR	SS	CO	FI	PK	NS	FT	WL	WG
[127]	Riechelmann	2006	6	–	x	x	x	x	x	x	–	–	–	–	–	–	–	–	–	–	–
[13]	Risberg-Berlin	2007	6	–	–	x	–	x	–	x	x	–	x	–	x	–	–	–	–	–	–
[128]	Roberge	2000	6	x	x	–	x	–	–	x	–	–	–	–	x	x	–	–	–	–	–
[129]	Van der Schroeff	2007	6	x	x	x	x	x	x	–	–	–	–	–	–	–	–	–	–	–	–
[110]	Petruson	2005	5	x	x	–	x	–	–	–	x	–	x	–	–	–	–	–	–	–	–
[130]	Rhemrev	2007	5	–	x	x	x	–	–	–	–	–	x	x	–	–	–	–	–	–	–
[131]	Olthoff	2009	4	–	x	–	x	x	–	–	–	–	–	–	–	–	–	–	x	–	–
[132]	Baumann	2005	4	x	–	–	–	x	–	x	–	–	–	–	–	–	x	–	–	–	–
[133]	Harnisch	2008	4	x	–	–	x	x	–	–	–	x	–	–	–	–	–	–	–	–	–
[134]	Dirix	2009	3	x	x	–	–	x	–	–	–	–	–	–	–	–	–	–	–	–	–
[135]	Teguh	2009	3	–	x	–	–	–	–	–	–	–	x	x	–	–	–	–	–	–	–
[136]	Bindewald	2007	3	–	–	x	–	–	–	–	–	–	–	–	–	–	–	x	–	–	x
[137]	Teguh	2008	3	–	x	–	–	–	–	–	–	–	x	x	–	–	–	–	–	–	–
[138]	Schneider	2000	3	–	–	–	x	–	x	–	–	–	x	–	–	–	–	–	–	–	–
[139]	Beetz	2010	2	–	–	–	–	–	–	–	–	–	x	x	–	–	–	–	–	–	–
[140]	Rinkel	2009	2	–	x	–	–	x	–	–	–	–	–	–	–	–	–	–	–	–	–
[141]	Jellema	2005	2	–	–	–	–	–	–	–	–	–	x	x	–	–	–	–	–	–	–
[142]	Jellema	2007	2	–	–	–	–	–	–	–	–	–	x	x	–	–	–	–	–	–	–
[143]	Roesink	2005	2	–	–	–	–	–	–	–	–	–	x	x	–	–	–	–	–	–	–
[23]	Low	2009	1	–	–	–	–	–	–	x	–	–	–	–	–	–	–	–	–	–	–
[144]	Levendag	2007	1	–	x	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
[46]	Rinkel	2008	1	–	–	–	x	–	–	–	–	–	–	–	–	–	–	–	–	–	–
[145]	Risberg-Berlin	2006	1	–	–	x	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
[24]	Singer	2008	1	–	–	–	–	–	–	x	–	–	–	–	–	–	–	–	–	–	–
[146]	Teguh	2008	1	–	x	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
[147]	Wittekindt	2006	1	x	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
[148]	Zumtobel	2006	1	–	–	–	x	–	–	–	–	–	–	–	–	–	–	–	–	–	–
[25]	Maune	2002	0	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
[3]	Mehanna	2006	0	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
[20]	Starska	2003	0	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
[42]	Aarstad AK	2007	mean	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total times used			109	115	106	110	108	103	98	92	93	108	102	98	95	61	58	58	59	53
	Percentage of times used			80.7	85.2	78.5	81.5	80.0	76.3	72.6	68.1	68.9	80.0	75.6	72.6	70.4	45.2	43.0	43.0	43.7	39.3

Ref Reference, *PA* pain in the mouth, *SW* swallowing, *SE* senses, *SO* social eating, *SC* social contact, *SX* sexuality, *TE* problems with teeth, *OP* problems in opening mouth, *DR* dry mouth, *SS* sticky saliva, *CO* coughed, *FI* felt ill, *PK* use of pain killers, *NS* nutritional supplements, *FT* feeding tube, *WL* weight loss, *WG* weight gain

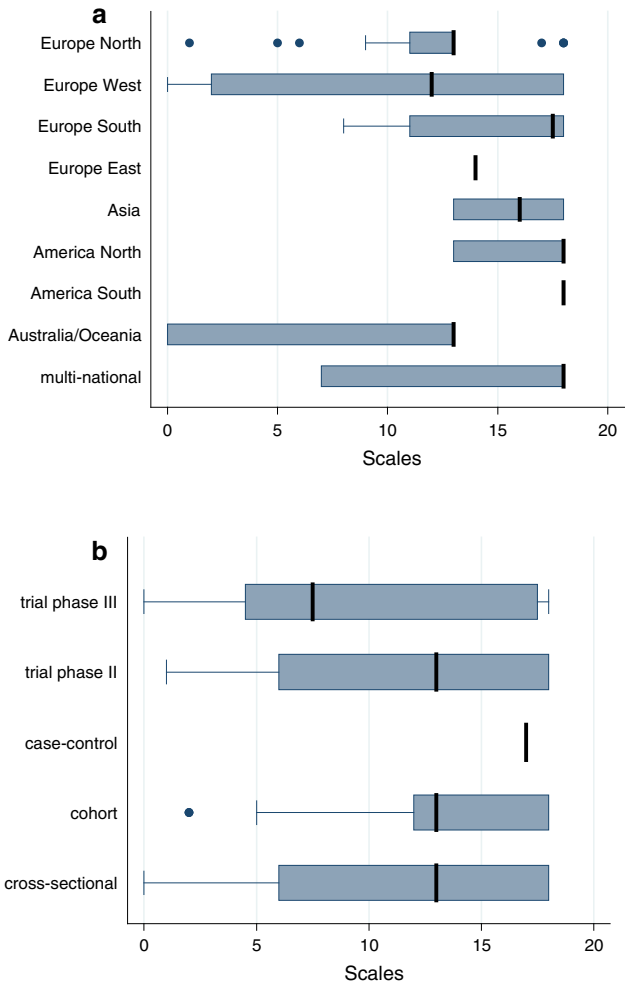

Fig. 3 Number of scales used **a** per region where the study was performed and **b** per study design applied. *Note* displayed are the medians and quartiles. The H&N35 consists of 18 scales

authors. We can only speculate about the reasons for this. One option is that investigators feel that the psychometric properties of Likert scaled response formats are better. Another explanation would be that issues such as weight gain, use of analgesics or feeding tube are considered to be more reliably measured with objective measures instead of patient reported.

In conclusion, the H&N35 is used by many investigators throughout the world. Some methodological problems (e. g. low internal consistency of some multi-item scales, at times poor compliance of investigators with no/yes scales) have been reported and could be solved, for example, by exchanging problematic items. Although the H&N35 was initially developed for clinical trials, it has been used mainly in observational studies and proved well accepted and feasible in that setting. It has also successfully been implemented in clinical practice [34, 35].

In general, we believe that systematic methodological reviews of frequently used instruments can help to improve existing measures and increase our knowledge on how to develop and improve questionnaires that are psychometrically sound and well accepted by patients and clinicians alike. In addition, it could be useful to collect the raw data of all studies in a central data base, so that direct comparisons between different languages and cultures are possible. This has been done with the EORTC QLQ-C30 [36], but not with the EORTC modules. We recommend that it would be worthwhile to undertake such a task.

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