Development of the hearing-related quality of life questionnaire for Auditory-VIsual, COgnitive and Psychosocial functioning (hAVICOP)

1. Introduction

Hearing loss is one of the most common disabilities in the human population (Vos et al., 2016). As stated by the International Classification of Functioning, Disability and Health (ICF), speech understanding difficulties due to hearing loss can negatively impact daily activities and participation in society, and consequently quality of life (World Health Organization, 2018). Currently, hearing rehabilitation is primarily focused on restoring the peripheral auditory function with a hearing aid (HA) and/or cochlear implant (CI). However, a large variation in the degree of benefit obtained from HA's and CI's has been reported (Lopez-Poveda et al., 2017; Moberly et al., 2016), especially pertaining to speech understanding (in noise). Interindividual differences in speech understanding occur even across individuals with similar pure-tone audiometry results (Anderson et al., 2011; Divenyi et al., 2005). Hence, peripheral hearing sensitivity does not fully account for speech understanding outcome with HA and/or CI and the associated impact of hearing loss on quality of life.

It is known that cognitive functions play a role in the process of speech understanding (Stenfelt & Rönnberg, 2009). Over the last decades, speech understanding has been considered a bi-directional process involving both bottom-up and top-down processes (Moberly et al., 2016; Pichora-Fuller et al., 2016). Generally, it is assumed that the transmission of an undistorted speech signal leads primarily to a bottom-up hearing strategy with fast and implicit decoding of the spoken message. However, a distorted speech signal, whether due to the presence of background noise, a hearing impairment, listening through a CI or HA, requires more top-down cognitive functions for explicit decoding (Moberly et al., 2016; Stenfelt & Rönnberg, 2009). More specifically, the cognitive functions working memory, processing speed, selective attention, and cognitive flexibility and inhibition are considered important to process an incoming auditory signal (Rönnberg et al., 2013). More concretely, to understand a speech signal, the target speech signal must first be extracted from interfering background noises. Selective attention is required for this extraction process (Edwards, 2016). Once attention is focused on the target speech signal, speech information is Rapidly, Automatically, and Multimodally Bound into a PHOnological representation in an episodic buffer, named RAMBPHO, according to the Ease of Language Understanding (ELU) model (Rönnberg et al., 2019; Rönnberg et al., 2013). Then, this sub-lexical information delivered by the RAMPHO is compared to corresponding representations in the semantic long-term memory. If the RAMBPHO information readily matches the corresponding representation in the semantic long-term memory, lexical access will be successful, occur implicitly and the incoming speech signal will be easily understood. During this implicit speech processing, working memory has a predictive role and is involved in priming and pre-tuning RAMBPHO (Rönnberg et al., 2019). In case of attenuated and distorted speech signals, it is possible that the RAMBPHO information fails to match with the representation in the semantic long-term memory (Rönnberg et al., 2019; Rönnberg et al., 2013). Consequently, semantic and contextual cues, as well as more explicit high-level cognitive processes are required to find a match and thus, to understand the speech signal (Moberly et al., 2016). Working memory will explicitly manipulate and combine fragmentary information to reconstruct the speech signal and to access meaning. Moreover, working memory is related to early attention processes in order to selectively focus on the target speech signal (Rönnberg et al., 2013). In addition to working memory, this attentional steering is also mediated by cognitive flexibility and inhibition (Rönnberg et al., 2019). Specifically, the latter plays a general role in distorted signal restoration and ensures that interfering background noise is overcome to maintain focus on the desired speech target (Janse, 2012; Sommers & Danielson, 1999). Lastly, processing speed contributes to the process of speech understanding during retrieval from, and comparison with semantic long-term memory. This comparison must occur rapidly since the rate of conversational speaking often exceeds twelve phonemes per second (Schow & Nerbonne, 2013). Moreover, the slower the processing speed, the greater the chance that previous processing and working memory storage are no longer available when later processing is completed (Rönnberg et al., 2013).

Previous studies showed that, due to the degraded incoming signals and the subsequent need to rely more on cognitive functions, individuals with hearing loss experience more effort to process speech (Perreau et al., 2017; Pichora-Fuller et al., 2016). This so-called listening effort can be defined as the allocation of mental resources to overcome obstacles when carrying out a listening task (Pichora-Fuller et al., 2016). The increased listening effort in individuals with hearing loss can lead to feelings of tiredness and frustrations (Hughes et al., 2018), which negatively affects participation in daily life and consequently quality of life (Pichora-Fuller et al., 2016).

In addition to cognitive functions, the integration of visual information is also important during the process of speech understanding. Speech processing is a multisensory process whereby visual and auditory information is integrated (Pichora-Fuller et al., 2016; Rönnberg et al., 2013; Stevenson et al., 2017). More specially, according to the ELU model, multimodal speech information is bound into the episodic buffer, called RAMPHO (Rönnberg et al., 2013). Visual information from mouth movements (i.e. lip reading), face expressions, and body language is integrated with auditory information in order to increase intelligibility over unisensory speech processing (Massaro & Cohen, 1983; McGurk & MacDonald, 1976). Normal-hearing individuals benefit most from visual speech cues to understand speech in unfavorable listening situations (Sumby & Pollack, 1954). Regarding individuals with hearing loss, the incorporation of visual information is an effective compensatory strategy for the loss of peripheral auditory information (Stevenson et al., 2017).

Because of the multiple factors involved in speech processing (e.g. cognitive functions and integration of visual information), it is important to evaluate the impact of hearing loss and the associated speech understanding difficulties and the impact of hearing rehabilitation on quality of life in a broad perspective. Well-validated measures that assess speech processing in a broad perspective make it possible to adopt a more holistic approach to the evaluation and management of hearing loss, both for clinical and research purposes (Hughes et al., 2019). This information can be obtained through behavioral or objective measures of multiple factors involved in speech processing but given the importance of person-centered care, also information regarding an individual's self-reported experiences in daily life is needed. This information can be obtained, among other things, through subjective measures.

Patient Reported Outcome Measures (PROMs) are tools used to provide immediate or retrospective information from the patient's perspective pertaining to how aspects of the health condition and its treatment impact their quality of life (Meadows, 2011). Although there are some existing questionnaires to obtain this information from individuals with hearing loss, currently there is no consensus regarding the questionnaire to be used, neither for clinical or research purposes. Typically, generic and disease-specific health-related quality of life questionnaires are distinguished. Previous research has shown that generic questionnaires are less suitable to demonstrate improvement in quality of life in individuals with hearing loss as compared to hearing-specific questionnaires (Chisolm et al., 2007; McRackan et al., 2018). Generic questionnaires are mostly not specific enough, i.e. on the one hand they contain items that are not relevant for individuals with hearing loss and on the other hand, other important aspects influencing hearing-related quality of life are not included (e.g. auditory aspects, listening effort etc.). The existing hearing-specific questionnaires mostly focus on auditory functioning and some associated social activities. Moreover, these questionnaires are often insufficient to document the hearing-associated difficulties that impact daily functioning in a broad perspective (e.g. including cognitive factors, listening effort and visual speech processing). In Table 1, the most commonly used existing hearing-specific quality of life questionnaires for adults are presented. This overview was based on the findings of the systematic review regarding outcome measures in audiological research from Granberg et al. (2014), supplemented by some more recent questionnaires.

Table 1: overview of some existing hearing-specific quality of life questionnaires

Title	Author(s)	Surveyed domains
Hearing Handicap Inventory for Elderly (HHIE)	Ventry and Weinstein (1982)	Emotional and social/situational consequences hearing loss
The Hearing Aid Performance Inventory (HAPI)	Walden et al. (1984)	Effectiveness of amplification in different listening situations (noisy situations, quiet situations with the speaker in proximity, situations with reduced signal information, and situations with nonspeech stimuli)
Communication Profile for the Hearing Impaired (CPHI)	Demorest and Erdman (1987)	Communication Performance, Communication Environment, Communication Strategies, and Personal Adjustment
Performance Inventory for Profound and Severe Loss (PIPSL)	Owens and Raggio (1988)	Understanding Speech With Visual Cues, Intensity, Response to Auditory Failure, Environmental Sounds, Understanding Speech With No Visual Cues, and Personal
Hearing Handicap Inventory for Adults (HHIA)	Newman et al. (1990)	Emotional and social/situational consequences hearing loss
Hearing Disability and Handicap Scale (HDHS)	Hétu et al. (1994)	Speech and nonverbal sound perception and participation restrictions
Amsterdam Inventory for Auditory Disability and Handicap (AIADH)	Kramer et al. (1995)	Distinction of sounds, intelligibility in noise, auditory localization, intelligibility in quiet and detection of sounds

Abbreviated Profile of Hearing Aid Benefit (APHAB)	Cox and Alexander (1995)	Ease of communication, reverberation, background noise, aversiveness of sounds
Glasgow Benefit Inventory (GBI)	Robinson et al. (1996)	General benefit, Social support and Physical benefit
The Hearing Handicap and Disability Inventory (HHDI)	Van den Brink et al. (1996)	Performance, emotional response, social withdrawal, perceived reaction of others
Communication Scale for Older Adults (CSOA)	Kaplan et al. (1997)	Communication strategies and communication attitudes
Satisfaction with Amplification in Daily Life (SADL-scale)	Cox and Alexander (1999)	Positive effects, service and cost, native features, and personal image
Glasgow Hearing Aid Benefit Profile (GHABP)	Gatehouse (1999)	Preintervention disability, handicap, reported hearing aid use, reported benefit, satisfaction, and residual disability
Nijmegen Cochlear Implant Questionnaire (NCIQ)	Hinderink et al. (2000)	3 main domains with subdomains: 1. physical functioning: basic sound perception, advanced sound perception, and speech production 2. psychological functioning: self-esteem 3. social functioning: activity and social functioning
The International Outcome Inventory for Hearing Aids (IOI-HA)	Cox and Alexander (2002)	Seven items, each one targeting a different domain: daily use, benefit, residual activity limitations, satisfaction, residual participation restrictions, impact on others and quality of life
The Speech, Spatial and Qualities of Hearing Scale (SSQ)	Gatehouse and Noble (2004)	Speech understanding, spatial hearing and other qualities

Effort Assessment Scale (EAS)	Alkhamra (2010)	Cognitive effort
Hearing Implant Sound Quality Index (HISQUI19)	Amann and Anderson (2014)	Sound quality
Cochlear Implant Quality of Life-35 Profile (CIQOL-35 Profile)	McRackan et al. (2019)	Communication, emotional, entertainment, environment, listening effort, and social

To the best of our knowledge, no hearing-specific questionnaires exist whereby the (audio)visual and cognitive factors (including listening effort) involved in speech processing, as well as the hearing-related psychosocial aspects impacting quality of life (e.g. impact on relationships with friends and family) are all included as separate domains, besides the assessment of the auditory factors. Although, for example, the NCIQ has some questions associated with listening effort (e.g. Do you feel it tiring to listen (with or without lip-reading)?) and (audio)visual speech processing (e.g. Can you understand strangers without lip-reading?), no separate scores can be calculated for these factors since they are not included as separate domains.

In conclusion, for research and clinical purposes, there is a need for a validated and standardized self-assessment instrument to assess the effect of HA and/or CI use on different aspects of functioning in daily life for adults. Therefore, the aim of the current study was to develop and evaluate a new holistic PROM to assess a variety of constructs which affect speech processing and therefore hearing-related quality of life, including auditory factors, (audio)visual factors, cognitive factors, listening effort and psychosocial factors.

2. Methods and materials

The different steps pertaining to the development of a conceptual framework, the selection of the test items, and the psychometric evaluation of the new PROM titled the hearing-related quality of life questionnaire for Auditory-VIsual, COgnitive and Psychosocial functioning (hAVICOP) are described below.

This study was approved by the local Ethics Committee and was conducted in accordance with the Helsinki Declaration. All participants provided their written informed consent to participate in this study.

2.1 Conceptual framework and selection of test items

The hAVICOP is intended as a hearing-specific PROM, and therefore, the target population was defined as adults (i.e. ≥ 18 years old) with hearing loss. Specifically, each type and degree of hearing loss can be included. The hearing loss can be unilateral or bilateral, as well as symmetric or asymmetric. Hearing-related quality of life was chosen as the primary outcome of the hAVICOP. The secondary outcome is 'device satisfaction'.

Further, relevant health domains affecting functioning with hearing loss in daily life (i.e. mostly speech processing difficulties) and resulting hearing-related quality of life were determined. These domains were chosen based on findings in literature regarding hearing loss and speech processing, the clinical and scientific experience of the researchers and existing published questionnaires (e.g. NCIQ, SSQ, APHAB, etc.). The multidisciplinary team involved in this process consisted of audiologists and speech and language therapists with clinical as well as research experience in the domain of hearing rehabilitation. In Figure 1, the initial conceptual framework is shown. The conventional approach measuring health-related quality of life was followed in which three general domains are distinguished: physical, psychological, and social functioning (Hinderink et al., 2000). For hearing-related quality of life in specific, the following six main domains are specified in this conceptual framework, each related to one of the three general domains of health-related quality of life: (1) auditory functioning, (2) (audio)-visual functioning and (3) cognitive functioning and (4) listening effort as parts of the general domain physical functioning; (5) social functioning and (6) psychological functioning in the general domains of social and psychological functioning respectively. Two main domains were further divided into subdomains. More specifically, the domain 'auditory functioning' was divided into 'speech understanding in quiet', 'speech understanding in noise', 'localization' and 'music perception' since these aspects are considered as important auditory functions. The domain 'cognitive functioning' was divided into the subdomains 'working memory', 'processing speed', 'selective attention' and 'cognitive flexibility and inhibition' since these are the cognitive functions that are considered to be related to speech processing (Dryden et al., 2017; Pichora-Fuller et al., 2016; Rönnberg et al., 2019; Rönnberg et al., 2013). In this way a broader variety of constructs which affect speech processing and consequently hearing-related quality of life could be evaluated separately per domain and in total.

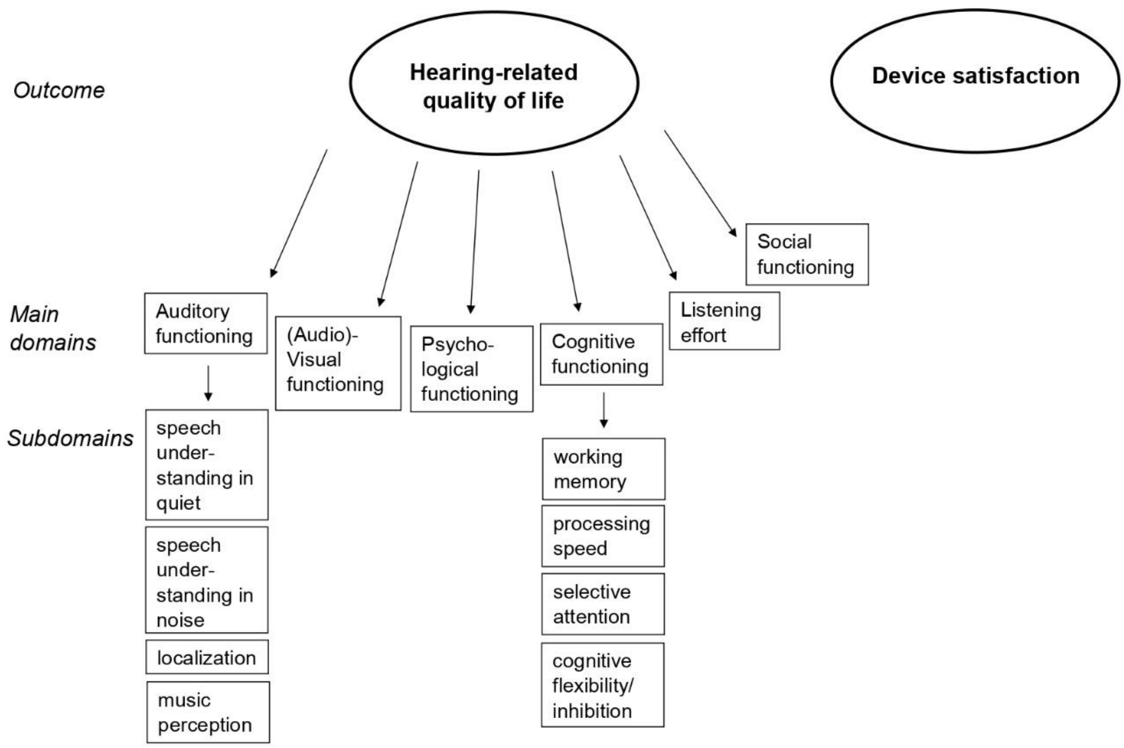

Figure 1: Conceptual framework

First, to select and construct the specific test items for each separate (sub)domain, a large pool existing of 68 possible test items was selected. Numerous items were adapted from several published questionnaires for CI users (e.g. NCIQ, HISQUI19, EAS) and HA users (e.g. APHAB, SSQ). Several other items were formulated based on non-standardized interviews that were used over the years to monitor the rehabilitation of HA users and CI users within our team. Also cognitive questionnaires, like the Cognitive Impairment Questionnaire (CIMP-QUEST) (Åstrand et al., 2010) and the Dysexecutive Questionnaire (DEX) (Shaw et al., 2015) for self-assessment, were analyzed for setting up the test items in the domain 'cognitive functioning'. Secondly, the most relevant test items were selected from this pool, similar test items were deleted and the test items were grouped per (sub)domain of the initial conceptual framework. The following criteria were used for the final formulation of the test items: (1) all items are phrased in a similar way, (2) all items are suitable for constructing a Visual Analogue Scale (VAS), as it has a greater sensitivity for change in comparison with, for example, a Likert scale (Pfennings et al., 1995), and (3) all items should be suitable for self-assessment by the individual with hearing loss. Each test item was formulated as a statement whereby the subject has to indicate on a VAS ranging from 0-100 how often this statement is applicable. More specifically, a score of 0 accords to rarely or never applicable and a score of 100 accords to (almost) always applicable. A pilot version of the hAVICOP consisting of 50 test items, 42 test items regarding the primary outcome 'hearing-related quality of life' and eight test items regarding the secondary outcome 'device satisfaction', was developed based on all previous steps.

2.2 Psychometric evaluation

Preliminary testing was completed to identify and rectify problems with items and response scales prior to undertaking further psychometric evaluation. Specifically, preliminary testing involved a semi-structured interview-based assessment in three groups: (1) ten individuals with hearing loss including five adult HA users and five adult CI users, (2) a multidisciplinary independent expert panel consisting of six experts in the domain of hearing loss and hearing rehabilitation, i.e. two audiologists working in a CI team, an audiologist working in a hearing center with HA users, a psychologist, a speech and language therapist and an Ear, Nose & Throat specialist specialized in the domain of hearing loss and cochlear implantation, and (3) 32 normal-hearing adults. Based on a qualitative analysis of their feedback on the comprehensibility and relevance of the test items, some minor adjustments were made (Ceuleers et al., 2019).

For the psychometric evaluation of the refined version of the PROM after the semi-structured interview-based assessment, a new sample of 15 adult HA users, 20 adult CI users, and 20 normal-hearing adults, not included in preliminary testing was included. An equal distribution of gender, age and education level in the different groups was foreseen (Table 2). In the group of HA users, 13 participants (86.7 %) had bilateral hearing aids and two participants had a unilateral hearing aid. They were all experienced HA users, using a HA for more than two years. Different grades and types of hearing loss were included. In the group of CI users, all participants had a post-lingually acquired bilateral severe to profound hearing loss, meeting the Belgian criteria for CI (*Ministrieel Besluit* 2019). They all had a unilateral CI and were experienced users (i.e. they had all been using their implant for more than two years). Thirteen of them (65.0 %) wore a hearing aid in the contralateral ear. Specific information regarding the degree of hearing loss of both the groups of HA and CI users was obtained retrospectively based on information in the patient record. For the normal-hearing participants, the hearing status was subjectively questioned, whereby all of them considered themselves as being normal-hearing individuals and none reported hearing-related complaints or had ear surgery in the past two years. Furthermore, the normal-hearing participants administered the online version of the Digit Triplet Test to ensure normal hearing (Jansen et al., 2013; Smits et al., 2006). This online screening test could be administered from home, so no physical appointment was necessary to participate in this study which allowed data collection during the lockdown due to the COVID-19 pandemic. Seventeen of the normal-hearing participants (85%) had bilateral good results on the online Digit Triplet Test, which corresponds with a Pure Tone Average (PTA) better than 23 dB HL on the frequencies 0.5, 1, 2 and 4 kHz ($PTA_{0.5,1,2,4}$). The three remaining subjects had a moderate score on the online Digit Triplet Test, which corresponds with a $PTA_{0.5,1,2,4}$ between or equal to 23 and 46 dB HL (Smits et al., 2006). In Table 2 the main characteristics of the participants are presented.

Table 2: demographic characteristics of the participants per group (n = 55).

Characteristics	**HA users (n = 15)**	**CI users (n = 20)**	**Normal-hearing participants (n = 20)**
Gender			
Male	46.7%	45.0%	45.0%
Female	53.3%	55.0%	55.0%
Age (mean (yrs), SD, and range)	57.25 (SD 16.07, range: 29.67-75.85)	53.35 (SD 17.32, range: 26.25-78.02)	53.93 (SD 17.38, range: 27.00-78.48)
Working situation			
Student	6.7%	0.0%	0.0%
Working	40.0%	65.0%	50.0%
Retired	46.7%	35.0%	50.0%
Unemployed	6.7%	0.0%	0.0%
Age at onset of hearing loss (mean (yrs), SD, and range)	28.80 (SD 18.84, range 0.00-55.00)	22.73 (SD 20.37, range 0.00-66.00)	N/A
Cause of hearing loss			N/A
Otosclerosis	13.3%	15.0%	
Hereditary	33.3%	25.0%	
Age related hearing loss	0.0%	20.0%	
Unknown	20.0%	30.0%	
Others	33.3%	10.0%	

Years of device (HA or CI) experience (mean (yrs), SD, and range)	11.07 (SD 8.95, range 2.00-36.00)	3.4 (SD 1.84, range 2.00-8.00)	N/A
HA/CI use per day			N/A
0-4 hr	13.3%	0.0%	
5-9 hr	13.3%	0.0%	
10-12 hr	6.7%	25.0%	
13-16 hr	53.3%	60.0%	
> 16 hr	6.7%	15.0%	
Unknown	6.7%	0%	
Grade of hearing loss			N/A
Mild (21-35 dB HL)	20.0%	0.0%	
Moderate (36-50 dB HL)	20.0%	0.0%	
Moderate to severe (51-65 dB HL)	33.3%	5.0%	
	20.0%	20.0%	
Severe (66-80 dB HL)	0.0%	50.0%	
Profound (81-95 dB HL)	0.0%	25.0%	
Total hearing loss (> 95 dB HL)	6.7%	0.0%	
Unilateral (≤ 20.0 dB HL in the better ear, > 35.0 dB in the worse ear)			

Note: yrs = years, SD = standard deviation, N/A = not applicable; grade of hearing loss is based on the average hearing threshold on the frequencies 500, 1000, 2000 and 4000 Hz in the better ear (Stevens et al., 2013).

All participants filled in a digital version of the refined version of the hAVICOP. Furthermore, the CI users also filled in the NCIQ, a hearing-specific quality of life questionnaire specifically developed for CI users(Hinderink et al., 2000). The HA users also filled in the SSQ, a hearing-specific questionnaire designed to measure a range of hearing disabilities across several domains (Gatehouse & Noble, 2004). At last, both CI users and HA users filled in a generic health-related quality of life questionnaire, the TNO-AZL Questionnaire for Adult's Health-Related Quality of Life (TAAQOL) (Bruil et al., 2001).

2.3 Statistical analysis

Statistical analysis was performed using the statistical program SPPS version 26 (Statistical Package for the Social Sciences). First, the scores for 25 test items of the hAVICOP that were phrased in the opposite form were recoded (i.e. 100 – score). Subsequently, a factor analysis was conducted, internal consistency was assessed, scores per domain were computed, and discriminant validity and concurrent construct validity were evaluated. For all statistical analyses, a significance level of $p < 0.05$ was used.

First, a factor analysis was conducted to assess the underlying structure of the test items of the primary outcome of the hAVICOP (i.e. hearing-related quality of life) and to establish the unidimensionality of its domains. Initially, to determine whether factor analysis was adequate for the data, the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was computed. The KMO determines the proportion of variance among variables that might be common variance. Factor analysis is deemed appropriate when the KMO ratio among the observed variables is close to 1.0. To further evaluate the structure of the questionnaire, the first factor analysis based on six factors (based on the six proposed domains of the initial conceptual framework) was conducted using oblimix rotation, assuming correlated factors (e.g. it is assumed that the domains 'cognitive functioning' and 'listening effort' can be correlated). This first factor analysis revealed six factors with eigenvalues greater than one. To determine the shared features among the items, the proportion of variance in each item (or communality values) was examined. Values greater than 0.50 indicate high correlations between the items and the factors. Based on the results of the first factor analysis, the six initial domains were reduced to three domains: (1) auditory-visual functioning, (2) cognitive functioning, and (3) psychosocial functioning. Afterwards, a second factor analysis was conducted based on these three factors using varimax rotation, assuming no correlated factors. This second factor analysis revealed three factors with eigenvalues greater than one and which explained 53.7%, 10.2%

and 8.0% of the total variance, respectively. Further statistical analysis was based on these three factors.

Second, internal consistency was assessed in the three definite domains of the primary outcome (i.e. hearing-related quality of life) of the hAVICOP and for the domain ‘device satisfaction’ (i.e. the secondary outcome) by calculating inter-item and item-total correlations and Cronbach’s alpha (Cronbach, 1951). A Cronbach’s α coefficient of 0.70 or higher is considered sufficient (Kline, 2000). The inter-item and item-total correlations were calculated for every domain. Calculating inter-item correlations provides an indication whether an item is part of a (sub)scale.

Third, scores were computed for every domain by calculating the mean score of the test items included in this domain. Also, a general total mean score was calculated, i.e. the mean score of all test items of the hAVICOP related to hearing-related quality of life (i.e. the primary outcome).

Fourth, discriminant validity was assessed, based on the final version after factor analysis, to evaluate if the hAVICOP could discriminate between normal-hearing individuals and individuals with hearing loss (i.e. HA users and CI users). One-way Analysis Of Variance (ANOVA) was used with hearing status (i.e. normal-hearing, HA user, or CI user) as independent variable and the total score and the scores on the proposed domains as dependent variables. Homogeneity of variances was violated for all domains and for the total score, as assessed by Levene's Test of Homogeneity of Variance ($p < 0.05$). Consequently, one-way Welch’s ANOVA and Games-Howell post hoc tests were conducted for further analysis. The secondary outcome, ‘device satisfaction’ was not included in this analysis, because the normal hearing participants did not fill in the test items of the secondary outcome ‘device satisfaction’.

Finally, scores for the hAVICOP were related to the answers on the two other hearing-related questionnaires (i.e. NCIQ and SSQ) and the generic health-related quality of life questionnaire (i.e. TAAQOL) to evaluate concurrent construct validity. The correlation between the scores on the different domains of the hAVICOP and relevant domains of the other existing questionnaires was investigated using the bivariate Pearson Correlation. A correlation of more than or equal to 0.50 between a new PROM and existing instruments measuring similar constructs indicates a good concurrent construct validity (Mokkink et al., 2016). In general, correlation coefficient values less than 0.3 were considered poor, correlation coefficients from 0.3 to 0.5, from 0.6 to 0.8 or 0.8 and higher were considered fair, moderately strong and very strong, respectively (Chan, 2003). The test items related to the secondary outcome, 'device satisfaction' were not included in this analysis, because the other existing questionnaires (i.e. NCIQ, SSQ and TAAQOL) do not include questions related to this domain.

3. Results

3.1 Factor analysis

A first factor analysis was based on the six proposed domains for the primary outcome 'hearing-related quality of life' in the conceptual framework: (1) auditory functioning, (2) (audio-)visual functioning, (3) cognitive functioning, (4) social functioning, (5) psychological functioning and (6) listening effort (Figure 1). The secondary outcome, 'device satisfaction' was not included in this analysis, because the test items of this secondary outcome were not divided into different domains. Consequently, the initial factor analysis was based on 42 test items. An overall KMO ratio of 0.82 was found for the set of 42 items, which can be classified as meritorious (Kaiser, 1974). The communality values of all test items were greater than 0.50, except for one test item. This test item was excluded from the further analysis. Further analyses, is thus based on 41 test items. Analyzing the six separate factors, it was seen that 15 of the 42 items loaded on more than one factor. Considering the other items (i.e. items that loaded clearly on one factor), zero items loaded on the first factor, six items on the second factor, ten items on the third factor, one item on the fourth factor, three items on the fifth factor and six factors on the sixth factor respectively. After examining the test items loading on more than one factor, the six domains were reduced to three domains: (1) auditory-visual functioning, (2) cognitive functioning, and (3) psychosocial functioning. This was based on visual inspection of the scree plot (Cattell, 1966) and detailed inspection of the content of the items that loaded on more than one factor. Afterwards, a second factor analysis was conducted based on these three factors. The proportion of variance of all items was greater than 0.50. Analyzing the three separate factors, it was seen that 11 of the 41 items loaded on more than one factor. Three other items loaded on an unexpected factor. These 14 items (i.e. 11 items that loaded on more than one factor and three items that loaded on an unintended factor) were excluded from further analysis. All other items (i.e. 27 items) grouped under the expected factors. A last factor analysis was conducted, using varimax rotation, with these 27 items. Results are presented in Table 3. All items loaded on the expected factor: 12 items on the first factor, labeled as 'auditory-visual functioning'; nine items on the second factor, labeled as 'psychosocial functioning' and six items on the third factor, labeled as 'cognitive functioning'. These three main domains could be divided into subdomains based on the content of the test items. The domain 'auditory-visual functioning' is divided into five subdomains: (1) speech understanding in quiet, (2) speech understanding in noise, (3) music perception, (4) localization and (5) audio-visual speech perception. The domain, 'psychosocial functioning', is divided into two subdomains: (1) psychological functioning and (2) social functioning. The third domain 'cognitive functioning' is divided into four subdomains: (1) working memory, (2) processing speed, (3) selective attention and cognitive flexibility and inhibition and (4) listening effort.

Table 3: Factor structure matrix.

Test item content		Intended domain	1	2	3
			AV	Psysoc	Cogn
1.	Speech understanding in silence: conversation with one person.	AV	0,669	-0,167	0,286
2.	Speech understanding in silence: conversation with more than two persons.	AV	0,797	0,040	0,176
3.	Speech understanding in silence: telephone conversation.	AV	0,736	0,222	0,131
4.	Speech understanding in noise: conversation with one person.	AV	0,733	0,191	0,414
5.	Speech understanding in noise: conversation with more than two persons.	AV	0,816	0,307	0,315
6.	Speech understanding in noise: telephone conversation.	AV	0,686	0,405	0,210
7.	Enjoying listening to music.	AV	0,633	0,303	0,100
8.	Understanding lyrics of a song in your own language.	AV	0,648	0,391	0,238
9.	Recognizing the melody of familiar songs.	AV	0,695	0,329	0,077
10.	Localization of car noise in a quiet environment.	AV	0,782	0,432	-0,026
11.	Localization of everyday noises in the house (e.g. Slamming door).	AV	0,788	0,458	0,003
12.	Speech understanding without visual information of the mouth movements and face expressions.	AV	0,594	0,371	0,386
13.	Following a long story/conversation.	Cogn	0,317	0,354	0,710
14.	Forgetting what someone said before answering.	Cogn	-0,011	0,056	0,828
15.	Needing time to process what is said before answering.	Cogn	0,277	0,376	0,770
16.	Thinking longer than other people to answer a question.	Cogn	0,300	0,275	0,741
17.	Attention and distraction during a conversation.	Cogn	0,086	0,161	0,808
18.	Giving up following a conversation because it takes too much effort.	Cogn	0,399	0,303	0,737
19.	Having a problem with having hearing loss.	Psysoc	0,334	0,824	0,303
20.	Self-esteem.	Psysoc	0,242	0,771	0,475
21.	Worries regarding hearing abilities.	Psysoc	0,390	0,673	0,190
22.	Feelings of loneliness due to hearing loss.	Psysoc	0,178	0,715	0,490
23.	Hiding hearing difficulties for others.	Psysoc	0,045	0,804	-0,022
24.	Experiencing hearing difficulties as an obstacle for leisure activities and / or hobbies.	Psysoc	0,320	0,712	0,270

25.	Feelings of dependence due to hearing difficulties.	Psysoc	0,267	0,814	0,255
26.	Experience hearing difficulties as an obstacle when dealing with formal matters.	Psysoc	0,409	0,711	0,316
27.	Feeling hindered by hearing loss for social activities and personal life.	Psysoc	0,426	0,692	0,351

Note: Factor analysis (varimax rotation): 1, 2, 3 = the three identified factors in the final version of the hAVICOP; AV = auditory-visual functioning, Cogn = cognitive functioning, PsySoc = psychosocial functioning

3.2 Internal consistency

Internal consistency was assessed in the three definite domains (i.e. 'auditory-visual functioning', 'cognitive functioning' and 'psychosocial functioning') of the primary outcome (i.e. hearing-related quality of life) of the hAVICOP and for the domain 'device satisfaction' (i.e. the secondary outcome). No test items were deleted based on the calculated inter-item and item-total correlations. For 'auditory-visual functioning', 'cognitive functioning', and 'psychosocial functioning', an α coefficient of 0.94, 0.92 and 0.94 was found, respectively. For 'device satisfaction' an α coefficient of 0.90 was found. For each factor, deleting one of the items did not increase its α coefficient.

3.3 Scores per domain

Mean scores per domain and a general total mean score were calculated per group. These scores can range between 0 and 100, since the VAS ranges from 0 to 100. A higher score means a lower impact of the hearing loss on functioning in daily life and subsequently on the hearing-related quality of life. The mean scores per domain and the mean total score are presented per group in Table 4.

Table 4: mean scores with standard deviations (SD) and range; and results of the one-way Welch's ANOVA.

	HA users	CI users	Normal-hearing individuals	Results one-way Welch's ANOVA	
				Test Statistic	p
Primary outcome: hearing-related quality of life					
Auditory-visual functioning	56.27 (SD 17.98, range 9.58-80.83)	54.05 (SD 17.61, range 23.50-80.00)	94.55 (SD 4.81, range 78.25-99.42)	F(2, 23.94) = 74.95,	< 0.001
Cognitive functioning	56.51 (SD 27.59, range 17.33-95.83)	63.53 (SD 25.39, range 15.67-99.00)	90.86 (SD 14.00, range 39.33-99.67)	F(2, 28.55) = 15.24,	< 0.001
Psychosocial functioning	45.44 (SD 23.63, range 5.22-88.56)	61.78 (SD 23.73, range 10.67-98.89)	97.67 (SD 3.18, range 87.89-100.00)	F(2, 22.14) = 56.06,	< 0.001
Total score	56.02 (SD 15.78, range 33.51-81.29)	63.97 (SD 14.55, range 31.69-84.54)	94.77 (SD 5.51, range 79.96-99.37)	F(2, 25.58) = 71.27,	< 0.001
Secondary outcome: Device satisfaction	67.21 (SD 19.77, range 37.38-99.50)	81.65 (SD 14.32, range 53.38-99.38)	N/A	N/A	

3.4 Discriminant validity

The discriminant validity was assessed using one-way ANOVAs for the three final domains of the primary outcome 'hearing-related quality of life' (i.e. 'auditory-visual functioning', 'cognitive functioning' and 'psychosocial functioning') separately and for the total mean score. The assumption of homogeneity of variances was violated, as assessed by Levene's test for equality of variances for the domains 'auditory-visual functioning' ($p < 0.001$), 'cognitive functioning' ($p = 0.002$) and 'psychosocial functioning' ($p < 0.001$) and for the total mean score ($p < 0.001$). Consequently, one-way Welch's ANOVA and Games-Howell post hoc tests were conducted for further analysis. Statistical significant different mean scores were found between the three groups of participants for all domains and for the total score (Table 4). More specifically, Games-Howell post hoc analysis revealed a significant difference in the mean score between the normal-hearing individuals and the HA users for the domains ‘auditory-visual functioning’ ($p < 0.001$), ‘cognitive functioning’ ($p = 0.001$) and ‘psychosocial functioning’ ($p < 0.001$) and for the total score ($p < 0.001$) on the one hand; and between the normal-hearing individuals and the CI users for the domains ‘auditory-visual functioning’ ($p < 0.001$), ‘cognitive functioning’ ($p = 0.001$) and ‘psychosocial functioning’ ($p < 0.001$) and for the total score ($p < 0.001$) on the other hand. For none of the three domains as well as for the total score a statistical difference was found between the mean score from the HA users and CI users ($p > 0.05$).

3.5 Concurrent construct validity

The correlation between the three domains of the primary outcome (i.e. hearing-related quality of life) of the hAVICOP and specific relevant domains from the SSQ for the HA users, the NCIQ for the CI users and the TAAQOL for both HA users and CI users was assessed to evaluate concurrent construct validity. In Table 5, an overview is presented of the Pearson correlation coefficients per domain.

Table 5: Pearson correlations between the domains of the hAVICOP with relevant domains of the SSQ, NCIQ and TAAQOL for HA users and CI users.

	HA users	**CI users**
	hAVICOP: auditory-visual functioning	
NCIQ: basic sound perception	N/A	0.64*
NCIQ: advanced sound perception	N/A	0.91*
SSQ: speech	0.62*	N/A
SSQ: space	0.70*	N/A
SSQ: sound qualities	0.69*	N/A

	hAVICOP: cognitive functioning	
TAAQOL: cognitive functioning	0.71*	0.63*
	hAVICOP: psychosocial functioning	
TAAQOL: social contacts	-0.20	-0.31
TAAQOL: daily activities	0.45	0.11
NCIQ: self esteem	N/A	0.82*
NCIQ: social interactions	N/A	0.44
NCIQ: activity limitations	N/A	0.72*
	hAVICOP: total score	
TAAQOL: total score	0.44	0.07
NCIQ: total score	N/A	0.87*
SSQ: total score	0.73*	N/A

Note. N/A = not applicable, * = correlation is statistically significant at $p < 0.05$ level.

4. Discussion

According to the ICF, the presence of hearing loss can lead to speech understanding difficulties which can have a negative impact on daily activities and participation, and consequently quality of life (World Health Organization, 2018). This study developed a new holistic PROM to assess a variety of constructs that affect speech understanding and consequently functioning (with hearing loss) in daily life and resulting hearing-related quality of life. Furthermore, a psychometric evaluation of this PROM, titled the hAVICOP, was conducted.

The results of a factor analysis revealed that the test items of the primary outcome ‘hearing-related quality of life’ grouped into three domains, named as ‘auditory-visual functioning’, ‘cognitive functioning’, and ‘psychosocial functioning’. Besides, the total amount of test items in these domains was reduced from 42 to 27 items. High levels of internal consistency were found for the three final domains of the primary outcome (i.e. hearing-related quality of life) and for the secondary outcome ‘device satisfaction’.

Discriminant validity of the new PROM showed significant differences between normal-hearing individuals and HA users on the one hand and between normal-hearing individuals and CI users on the other hand. Significant higher scores were found for normal-hearing individuals for all three main domains as well as for the total score of the primary outcome (i.e. hearing-related quality of life) of the hAVICOP, reflecting a better hearing-related quality of life. This result was expected since the hAVICOP aimed to be a hearing-specific quality of life questionnaire. The test items in the questionnaire were specifically developed to reflect hearing-related problems in daily life.

More specifically, the largest mean difference between normal-hearing individuals and HA users was found in the domain ‘psychosocial functioning’. This result confirms the important impact of hearing loss on participation and psychosocial functioning in daily life and is consistent with results from for example Chisolm et al. (2007), showing that social isolation, loss of independency and feelings of loneliness and fear are some of the subsequent effects of hearing loss. The lowest mean difference was found between normal-hearing individuals and CI users for the domain ‘cognitive functioning’. A possible explanation for this finding might be the fact that the cognitive functions involved in speech processing (i.e. working memory, processing speed, selective attention, and cognitive flexibility and inhibition as well as listening effort), are also affected by other factors than hearing status. For example, independent of hearing sensitivity, increasing age can negatively affect listening effort (Degeest et al., 2015; Desjardins & Doherty, 2013). Subsequently, also normal-hearing individuals can experience a negative impact of difficulties with cognitive functions on their functioning in daily life, although this is significantly lower than for individuals with hearing loss.

It should be noted that for the scores on the three domains and for the total score no significant difference was found between HA users and CI users. Despite the CI users having a more severe hearing loss than the HA users, they experienced a similar impact of their hearing loss on their quality of life. A possible explanation is that all CI users and HA users were experienced users. Consequently, they may be supposed to be completely familiarized with their devices and its sound which could possibly lead to a similar impact of the hearing loss in daily life. However, no information regarding the auditory performances with their CI or HA is available. Nevertheless, it can be important to be able to measure change in hearing-related quality of life when a HA user with a severe to profound hearing loss is implanted with a CI. Further research in a larger sample is necessary to investigate whether this trend persists as well as to assess the sensitivity for change in hearing-related quality of life and satisfaction.

Furthermore, the concurrent construct validity of the new PROM was assessed. A very strong significant positive correlation was found between the domain ‘auditory-visual functioning’ of the hAVICOP and the domain ‘advanced speech perception’ from the NCIQ for the CI users. This high association was expected since the NCIQ is also a hearing-specific questionnaire, and developed for CI users in particular (Hinderink et al., 2000). Furthermore, when analyzing the items in the domain ‘advanced sound perception’ of the NCIQ, it was seen that these items are related to speech understanding in different circumstances, which is also assessed in the domain ‘auditory-visual functioning’ of the hAVICOP. Besides, significant moderate strong positive correlations were found between the domain ‘auditory-visual functioning’ of the hAVICOP and the domain ‘basic sound perception’ from the NCIQ for the CI users and the domains ‘speech’, ‘space’ and ‘sound qualities’ from the SSQ for the HA users. In all of these domains, similar constructs are assessed, i.e. the auditory perception. Since all these correlations are greater than 0.50, concurrent construct validity for the domain ‘auditory-visual functioning’ is considered good.

For the domain 'cognitive functioning', a moderate strong significant positive correlation was found for both the HA users and the CI users between the domain 'cognitive functioning' of the hAVICOP and the domain 'cognitive functioning' of the TAAQOL. The domain 'cognitive functioning' of the TAAQOL was selected to assess construct validity because no other validated hearing-related questionnaire including a separate domain regarding cognitive functions has been identified for a suitable comparison. When analyzing the test items of the domain 'cognitive functioning' of the TAAQOL, it is seen that some of the cognitive functions specifically involved in speech processing are questioned. More specifically, questions regarding working memory and selective attention and cognitive flexibility and inhibition are included (e.g. Did it happen in the last month that you had difficulty concentrating on what others said?; Did it happen in the last month that you had difficulty remembering things?). Therefore, the domain 'cognitive functioning' of the TAAQOL is considered measuring a similar construct as in the domain 'cognitive functioning' of the hAVICOP, although the TAAQOL is not a hearing-specific questionnaire. Consequently, based on their moderate strong positive correlation, concurrent construct validity for the domain 'cognitive functioning' is considered good.

Regarding the domain 'psychosocial functioning', a fair non-significant positive correlation was found for the domain 'social interactions' from the NCIQ for the CI users. Analyzing the items in these domains, it was observed that the items in the domain 'social interactions' of the NCIQ assess social interactions in different social situations (e.g. communication with friends and family, communication with deaf people etc.), while in the domain 'psychosocial functioning' of the hAVICOP the social interactions are assessed more general and the majority of the test items focuses more on activity limitations and self-esteem. Furthermore, a poor correlation was found with the domains 'social contacts' and 'daily activities' of the TAAQOL for the HA users and CI users. The TAAQOL is a generic health-related questionnaire, while the hAVICOP is specifically set up to measure the impact of hearing loss on the psychosocial functioning. Consequently, this result highlights the importance of the use of a hearing-specific PROM to question psychosocial functioning in individuals with hearing loss. Finally, a moderate to strong significant positive correlation was found with the domains 'self-esteem' and 'activity limitations' of the NCIQ for the CI users. These domains are considered as similar constructs within the domain psychosocial functioning of the hAVICOP, so concurrent construct validity for the domain 'psychosocial functioning' is also considered good.

Finally, a fair to poor non-significant correlation was found for the total score of the hAVICOP and the total score of the TAAQOL, for the HA users and for the CI users respectively. The TAAQOL is a generic quality of life questionnaire based on a multidimensional construct of health-related quality of life. The TAAQOL consists of 12 scales: (1) gross motor functioning, (2) fine motor functioning, (3) cognition, (4) sleep, (5) pain, (6) social contacts, (7) daily activities, (8) sex, (9) vitality, (10) happiness, (11) depressive mood and (12) anger. Most of the constructs measured in these domains are not included in the framework of the hAVICOP (i.e. gross motor functioning, fine motor functioning, sleep, pain, sex, vitality, happiness, depressive mood and anger) since they are not considered to impact the specific hearing-related quality of life. This result confirms the findings from previous research where it has been shown that generic questionnaires are less suitable to measure quality of life in individuals with hearing loss, compared to hearing-specific questionnaires (Chisolm et al., 2007; McRackan et al., 2018). Accordingly, a moderate and very strong positive correlation was found for the total scores of the hearing-specific quality of life questionnaires, namely the SSQ (for the HA users) and the NCIQ (for the CI users) respectively and the total score of the hAVICOP. The NCIQ and SSQ are measuring a similar construct as the hAVICOP, namely the hearing-related quality of life, so concurrent construct validity of the total hAVICOP is considered good. However, the SSQ and NCIQ focus mostly on auditory functioning and some associated social activities and psychosocial wellbeing. Items regarding cognitive functioning or auditory-visual functioning (including visual speech perception) are not included as a separate domain. Therefore, it is suggested that the hAVICOP has considerable potential for a broader evaluation of the hearing-specific quality of life.

However, some study limitations and suggestions for further research should be considered. First, the secondary outcome ‘device satisfaction’ was only assessed to a limited extent in this study. In future research and for clinical purposes, it is suggested to analyze the answers of this test items qualitatively. Discussing the answers of these test items with individuals with hearing loss during hearing rehabilitation could lead to better fitting of the HA or CI and subsequently to better satisfaction. Second, the evaluation of the hearing status of the group of normal-hearing participants was only based on self-report and results of the Digit Triplet Test, which might be less robust compared to standard audiometric testing through pure-tone audiometry. Likewise, in the current study, vision was not evaluated. Since there is a focus on visual speech in the questionnaire, in future research with the hAVICOP, normal vision could be evaluated using a short screening test (e.g. Snellen Eye Test (Snellen, 1873)). Third, more research with a larger sample size is required to further examine the validity and reliability of the hAVICOP. It is recommended to include both individuals with hearing loss with and without a hearing device (HA or CI) in this sample, since the hAVICOP is developed to be suitable for all adults with hearing loss. Short- and long-term test-retest reliability should be investigated in a group of normal-hearing individuals and individuals with hearing loss, with and without HA and/or CI. Furthermore, criterion validity could be further determined by comparing results of the hAVICOP with scores on audiometric test results (e.g. pure-tone audiometry and speech perception tests in quiet and in noise (i.e. speech audiometry in quiet and in noise)), and cognitive tests assessing the cognitive functions involved in speech processing, as well as a dual-task paradigm for assessing listening effort (Degeest et al., 2015).

In conclusion, in this study, a new PROM to assess hearing-related quality of life was developed, named the hAVICOP (hearing-related Quality of life questionnaire for Auditory-VIsual, COgnitive and Psychosocial factors). Moreover, a psychometric evaluation of this PROM was conducted. The final version of the hAVICOP consists of three domains for the main outcome (i.e. hearing-related quality of life): (1) auditory-visual functioning, (2) cognitive functioning and (3) psychosocial functioning. Besides, device satisfaction can be assessed (i.e. secondary outcome). Scores can be calculated for every domain separately and also a total score can be calculated. A lower score reflects a higher impact of the hearing loss on the health-related quality of life. The hAVICOP has good internal consistency, discriminant validity, and concurrent construct validity. In the future, including the hAVICOP as an evaluation of the subjective impact of hearing loss in a broad perspective can lead to more person-centered rehabilitation based on the individual needs and abilities of the individuals with hearing loss. This can give a holistic overview of the impact of hearing loss on individual functioning in daily life. Moreover, the hAVCIOP can provide a starting point to set individualized rehabilitation goals and to evaluate the progress throughout the rehabilitation process from the persons perspective, highlighting its clinical added value.

Statement of Ethics

All of the study subjects gave written informed consent. This study was approved by the Ethics Committee of the Ghent University Hospital (study approval reference No. B6702020000795).

Conflict of Interest Statement

The authors have no conflict of interests to declare.

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Data Availability Statement

Research data are not publicly available due to privacy restrictions. Participants in this study did not give permission for sharing of these data. Further enquiries can be directed to the corresponding author.

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