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Research Note

Adaptation of the Cochlear Implant Quality of Life–35 Profile Into German

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ABSTRACT

Purpose: The adaptation of existing questionnaires is a valuable method to make instruments available in multiple languages. It is necessary to assure the quality of an adaptation by following adaptation guidelines. The Cochlear Implant Quality of Life–35 Profile (CIQOL-35 Profile) was developed and validated to measure the functional abilities in English-speaking adult CI users but is not yet available in German. In this study, we performed a cross-cultural adaptation of this instrument to make it applicable in research and rehabilitation with German-speaking patients.
Method: This study followed established practice guidelines for translating and adapting hearing-related questionnaires. Professional translators and health care professionals with experience with patients with hearing loss translated all items forward and backward multiple times. A committee reviewed the process and decided when a satisfactory consensus was achieved. Next, we examined the intelligibility of the German version using cognitive interviews with 15 adult CI users.
Results: For most items, there was no difficulty with direct translation. In items that turned out to be more difficult to translate, it proved to be very helpful to compare the back translation to the original version, discuss the wording in the committee, and ask the source-language questionnaire developer. During the interviews, issues of comprehension for some phrases were identified. These phrases were changed according to the participant's questions and suggestions.
Conclusions: The CIQOL-35 Profile was successfully adapted into German. The German version of the questionnaire is now available for research and clinical practice. Further validation of the German CIQOL-35 Profile is in progress.
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Patient-reported outcome instruments are important tools to gain insights to the patient's perspective. Constructs such as patient satisfaction or quality of life (QOL) cannot be captured by diagnostic tests. Therefore, instruments are needed in which patients can report their own experience. The development of these patient-reported outcome instruments is very complex, because it has to fulfill certain standards, for example, using item response theory (Mokkink et al., 2010). As the majority of questionnaires are developed in English-speaking countries, researchers and clinicians in countries with other national languages do not directly benefit from these existing instruments. The cross-cultural adaptation of instruments is a solution for this problem. The adaptation of an existing questionnaire has clear advantages over the development of a new questionnaire (Hall et al., 2018). It not only saves time and resources but also ensures that the effort that was put into instrument development is maximized. Moreover, having questionnaires available in multiple languages allows researchers to compare outcomes among different countries.

According to current German guidelines on cochlear implantation, it is essential to assess the QOL of cochlear implant (CI) users for treatment evaluation (Deutsche

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Gesellschaft für Hals-Nasen-Ohren-Heilkunde, Kopf- und Hals-Chirurgie e.V, 2020, 2021). For this purpose, the Cochlear Implant Quality of Life (CIQOL) instruments were developed by a team of researchers at the Medical University of South Carolina (McRackan et al., 2019). There are two versions of the questionnaire: the CIQOL-35 Profile with 35 items that measures functional abilities in six domains (Communication, Emotional, Entertainment, Environment, Listening Effort, and Social) and the CIQOL-10 Global, a short form with 10 items that provides an overall assessment of abilities (McRackan et al., 2019). The completion of the full 35 items version takes no more than 5 min, the short form about 2 min. To facilitate the scoring of the instrument, an automated outcome measure scoring document is available for both versions. It automatically calculates and converts the scores for the different domains and the global score. The converted scores are presented on a scale from 0 to 100, with 0 being the lowest and 100 the highest possible result.

Prior to this study, the instruments were only available in English. Therefore, the aim of this study is to make the CIQOL instruments available for clinicians and researchers who work with German-speaking CI users. For this purpose, we cross-culturally adapted the CIQOL instruments into German language.

The cross-cultural adaptation followed the guidelines for translating and adapting hearing-related questionnaires published by Hall et al. (2018). The aim of the guidelines is to implement good practice in the adaptation process to promote equivalence to the original while accounting for cultural differences. According to this guide, a cross-cultural adaptation should consist of the following steps: (a) preparation, (b) translating the source language into the target language (forward translation), (c) translating the target language back into the source language (back translation), (d) committee review, (e) field testing, and (f) reviewing and finalizing the translation. The adaptation of the CIQOL instruments into German consists of these steps and is reported in this article.

Method and Results

The adaptation followed the good practice guide for translating and adapting hearing-related questionnaires for different languages and cultures by Hall et al. (2018), as discussed below. The completed checklist of the preferred reporting items and a translation certificate are available in Supplemental Materials S1 and S2, respectively. There were numerous people involved in the adaptation process, including professional translators, health care professionals, researchers, and CI patients. During the entire adaptation, the first author acted as translation lead and coordinated and documented all necessary steps. The translation lead and another team member are researchers in the field of education and aural rehabilitation of people who are deaf or hard of hearing and both have professional experience as speech and language therapists for patients with CIs. Both are native German speakers and are fluent in English as well. The source-language questionnaire developer was involved in the adaptation as an expert for the original questionnaire. Additionally, a bilingual linguist was included in the process. She has lived in German- as well as in English-speaking countries and is an expert in sign language and Deaf studies. Some translations were conducted by professional translators and CI users were included in the adaptation through interviews.

Step 1: Preparation

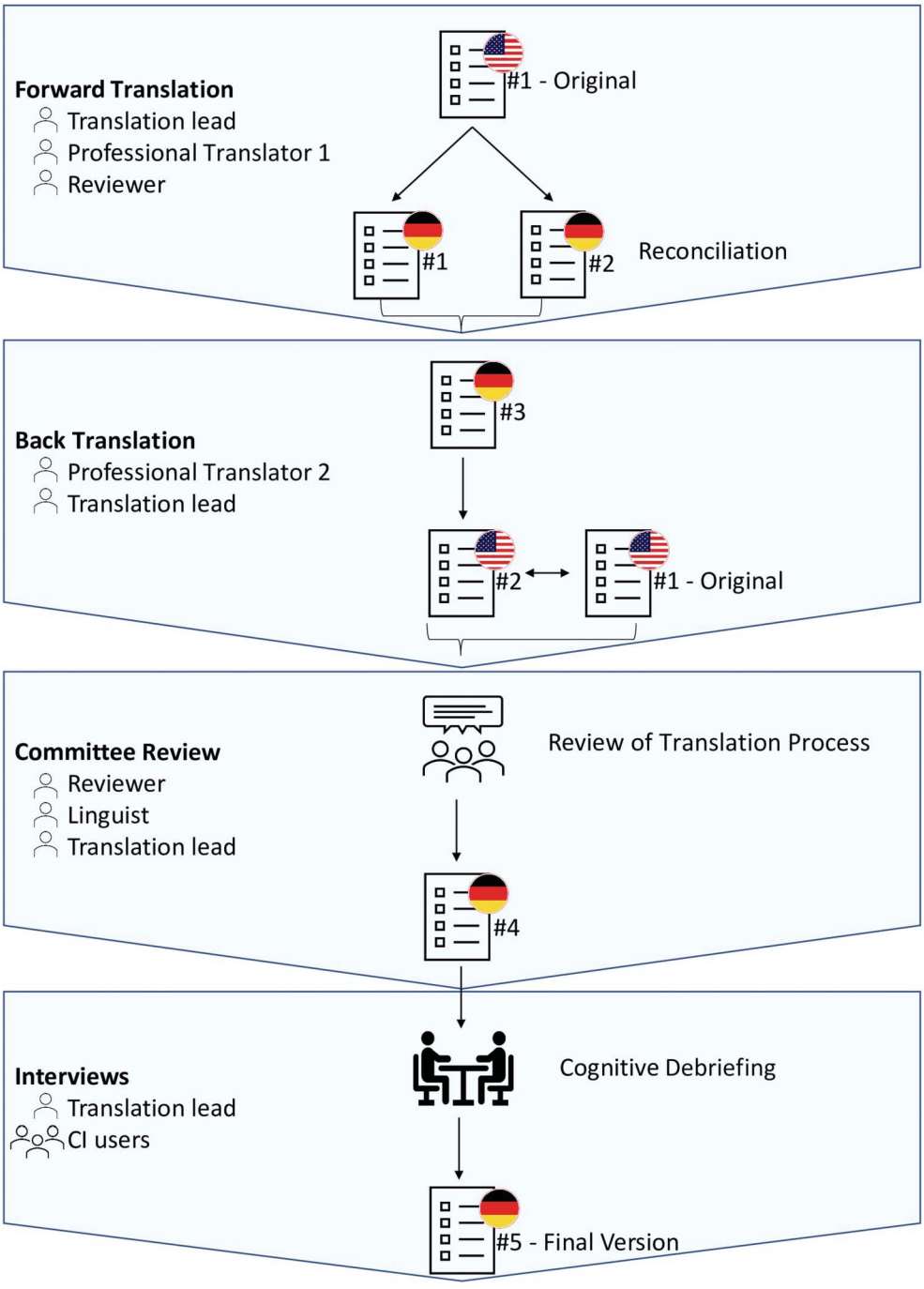
For adequate preparation of the process, the translation lead contacted the corresponding author of the CIQOL development and publication. No documented German language version of the CIQOL existed or was in progress prior to this study. Therefore, the adaptation of the CIQOL instruments was reasonable and the source-language questionnaire developer granted written permission. He was contacted during the process whenever questions about the methods or the original questionnaire emerged. He provided a list of concept definitions for each subscale. These were available for translators and committee members during translation and review. To record the translation and adaptation process, we modified and used the template given by Hall et al. (2018).

Possible differences between the English-speaking and German-speaking target population were discussed between two of the authors. We did not detect any relevant differences between the population of the original questionnaire and the German-speaking target group regarding literacy, population characteristics or administration of the questionnaire. This rendered any modifications regarding language complexity or format of administration unnecessary.

Step 2: Forward Translation

In the second step, the questionnaire was translated forward from the source language into German (see Figure 1). First, items were translated from the original English version into German language by the translation lead and a professional from a translation agency. The professional translator was informed about the purpose and target group of the questionnaire. It was also disclosed that the translation was part of a multistep adaptation. As the translation lead was involved in the process,

Figure 1. Adaptation process. CI = cochlear implant.



she was aware of the health concepts and the requirements of the translation. The two forward translations were completed independently. There are some dialects in German-speaking countries; however, standard German is used in written language and in education. Therefore, it was not necessary to translate the questionnaire into different dialects.

The two forward translations were compared for discrepancies. A third independent team member reviewed the two forward translations. The reviewer commented on the translations with reasons for or against using the different translation options and thus reconciled any discrepancies. Through this process of reconciliation, a preliminary German version of the CIQOL-35 Profile was developed.

The two independent forward translation manuscripts were an exact match in the rating scale and in two items of the questionnaire. The reviewer of the forward translations reconciled 29 of 35 items by selecting one of the suggested translations. For example, "I am able to have a conversation with a group of three or more people" was translated as "*Ich kann mich mit einer Gruppe von drei oder mehr Personen unterhalten*" and "*Ich kann ein Gespräch mit einer Gruppe von drei oder mehreren Personen führen*." The reviewer argued that "*Gespräch mit einer Gruppe*" ("conversation in a group") is closer to the English original than "*Unterhaltung*" ("talking to each other") and, therefore, suggested to use the second version. She proposed alternative translations for four items and the introduction of the questionnaire. The translations of two items were detected as difficult during the forward translation. They were resolved by using a definition that the source-language questionnaire developer gave upon request.

Step 3: Back Translation

This preliminary German version was translated back into English by an additional professional translator from a different translation agency (see Figure 1). The aim of a back translation is to ensure that the translation uses equivalent language as the original questionnaire. If items that are back translated differ from the original items, they should be reconciled. The translation lead reviewed the back translation against the original version of the questionnaire. All items were scanned for discrepancies, such as different wording or sentence structure. Each section of the back translation that differed from the source was highlighted. All items were rated on a scale from A to D for their equivalence with the original as suggested by Hall et al. (2018). Items classified as A have perfect semantic equivalence between the back translation and the source version. Items classified as B show satisfactory semantic equivalence but use one or two different words. Items classified as C preserve the meaning of the original but do not have satisfactory semantic equivalence. Items classified as D have no agreement. The translation lead made alternative suggestions for items that were classified as C or D and discussed the equivalence of items classified as B. All members of the committee review received the discrepancies, the reasons for the ratings and alternative suggestions before the discussion in the committee review.

The comparison between the back translation and the original English version resulted in further modifications in some items. The translation of the rating scale and of 24 items was classified as A for their perfect equivalence with the original version. The translation of the title and of nine items was classified as B for satisfactory equivalence. The translation of the introduction of the questionnaire and of two items was classified as C because they preserved the meaning of the original, but the semantic equivalence was not satisfactory. None of the items had to be classified as D for missing agreement.

Step 4: Committee Review

In this step, a committee is tasked to compare the forward and back translations against the source-language questionnaire and to resolve any discrepancies that occurred. To review the translation process, the committee used the translation report where all steps in the translation process and any item changes or discrepancies were documented. The translation lead, the reviewer from Step 2, and a linguist formed the committee (see Figure 1). All committee members had local language expertise and knowledge of the field. The source-language questionnaire developer was not proficient in German and could not participate in the committee. However, he was available for any questions that occurred in the discussion.

The linguist commented on the discrepancies and the suggestions by the translation lead. Those comments formed the base for the discussion of the translation process. Conceptually problematic items and solutions for translation were discussed. Whenever items were problematic, the translation lead contacted the source-language questionnaire developer to ask for advice. Any items that were changed during the committee review were back translated once more and rated and discussed with the committee. When the committee members unanimously approved a translation for each item, the consensus was reached and adaption of the first final version of the German CIQOL instruments was completed.

The committee review led to changes in instructions and 13 items in the questionnaire. One sentence in the instruction was changed because its meaning in the German version was not clear even though it matched the English sentence very well. One item was changed because the German version had the word "*häufig*" ("frequently") in it, which might have been difficult to answer on a frequency scale. One original item used a term that could have been interpreted in different ways ("clear"). The German translation "*klar*" ("clear") might mean "distinct," "crisp," or "comprehensible." Therefore, it was hard to find an adequate German translation. We found a solution after reconciliation with the source-language questionnaire developer who let us know the meaning of this item was "easy to perceive and identify." Two more items were changed because a more common wording was found that seemed to be more culturally adequate in German: "*mühelos*" as translation for "easily" and "*Es frustriert mich*" for "I get frustrated."

Two items were formally changed to match the original version (e.g., putting brackets at the end of the sentence). We harmonized the wording of a few items that used the same term (e.g., "due to my hearing loss" as "*aufgrund meines Hörverlustes*"; "asking someone" as "*jemanden zu bitten*"). The committee discussed the use of gender-sensitive language and decided to use gender-neutral terms whenever possible (e.g., "*mein Gegenüber*" ["the person facing me"] instead of "*Gesprächspartner:in*" ["conversational partner"]; "*die sprechende Person*" ["speaking person"] instead of "*Sprecher:in*" ["speaker"]). In two items, we used the generic masculine of the plural ending to avoid a confusing notation or a rather long term naming both genders ("*Freunde*" for "friends"; "*Nachbarn*" for "neighbors").

All changes underwent another back translation and comparison with the source-language questionnaire. In one item, we found a discrepancy with the original after the second back translation. Therefore, it was changed and then translated back once more. The final version was used for the field testing. Through the rigorous implementation of the guideline with multiple forward and back translations with the participation of multiple experts, the comparability of the German adaptation with its English original was obtained.

Step 5: Field Testing

We used cognitive interviews for the field testing to examine feasibility and intelligibility of the questionnaire. Cognitive interviews are a qualitative method for testing a translated instrument in the target language (Hall et al., 2018). This allows the population of interest to review each item and confirm that each has the intended meaning. The guideline proposes a sample size between eight and 20 for this evaluation (Hall et al., 2018). For this study, a midsize sample was chosen to balance advantages for the validity and reliability with ecological and ethical aspects. A sample of 15 adult CI users was recruited via the Cochlear Implant Center of the University Hospital of Cologne. Approval from the institutional review board of the Faculty of Human Sciences of the University of Cologne was received before contacting eligible patients (EPHF0128). Written informed consent was obtained from participants prior to the interviews.

Inclusion criteria were selected according to the criteria in the validation study of the source-language questionnaire (McRackan et al., 2021). Participants were required to be at least 18 years of age, have bilateral hearing loss, and have at least 1 year of experience with their CI. Furthermore, sufficient knowledge of spoken and written German was necessary to ensure the feasibility of the interview. For recruitment convenience sampling was used. Potential participants were contacted if they had an upcoming appointment to minimize the effort for the participants.

The intelligibility of the questionnaire was tested in face-to-face semistructured interviews. The aim was to find out how the participants understand the instruction and items of the questionnaire. The interviewer asked the participants to think aloud while they filled out the questionnaire. They were asked to paraphrase items in their own words. The interviewer motivated them to comment if they perceive anything remarkable and to mention anything that might be misinterpreted or difficult to understand.

Participants

A total of 15 CI users participated in the study (see Table 1). Our goal was to conduct a sample that comprises CI users with various ages, educational and socioeconomic backgrounds, as well as various hearing loss and CI characteristics. They were aged from 24 to 79 (M = 52.2, SD = 18.7) years. Overall, more women participated than men (five male, 10 female). About half the sample lived in a domestic partnership. About half the sample was employed and the other half retired. The majority of the sample rated their subjective social status in the medium range of the MacArthur Scale (Adler et al., 2000). All participants were able to read and speak German fluently. Due to the recruitment in a University Hospital in North Rhine-Westphalia, most participants lived in the same state, with only one exception. Five participants reported that they have medical conditions in addition to their hearing loss, for example diabetes or arthritis. Although these conditions might affect the general QOL, we do not expect them to affect the hearing-related QOL.

Per inclusion criteria, all participants used at least one CI for at least 1 year (see Table 2). The duration of the use of the (first) CI was between 1 and 24 years (M = 9.21, SD = 7.65). The participants stated that they had their hearing loss for at least 1 year, some of them had a hearing loss for over 30 years or since birth. Seven participants were bilateral CI users, six participants used a CI and a hearing aid (bimodal), and two participants had one CI with no contralateral hearing aid. Three participants had a congenital hearing loss and therefore were prelingually deaf. Two participants had had a reimplantation and nobody stated that they used hybrid CI.

Interviews

The interviewer used field notes to record the answers and reactions of the interviewees. The field notes were transcribed into a general chart for analysis. Comments that indicated that the participant had difficulties

Table 1. Demographic characteristics of the study sample.

Variable	*n* (%)
Sex	
Female	10 (67)
Male	5 (33)
Age	
20–39 years	4 (27)
40–59 years	5 (33)
60–79 years	6 (40)
Language	
German	13 (87)
Bilingual–German	2 (13)
Marital status	
Married/domestic partnership	8 (53)
Not married/no domestic partnership (including widowed/separated)	7 (47)
School education	
Main school (9–10 years)	10 (67)
Secondary school (12–13 years)	4 (27)
Other	1 (7)
Highest level of education	
Completed vocational training	10 (67)
State-certified technician	2 (13)
University degree	2 (13)
Other	1 (7)
Employment	
Employed	7 (47)
Retired	7 (47)
Other	1 (7)
Size of household	
Live by themselves	2 (13)
With 1 person	5 (33)
With 2 people	6 (40)
With more than 2 people	2 (13)
Residential setting	
Urban	4 (27)
Suburban	3 (20)
Rural	7 (47)
Other	1 (7)
Country, state	
Germany, North Rhine-Westphalia	14 (93)
Germany, other state	1 (7)
Subjective Social Status (MacArthur Scale)	
High (7–10)	3 (20)
Medium (4–6)	11 (73)
Low (1–3)	0
Missing data	1 (7)
Additional medical conditions	
Yes	5 (33)
No	9 (60)
Missing data	1 (7)

Table 2. Hearing loss and cochlear implant characteristics of the study sample.

Variable	*n* (%)
Listening modality	
Bilateral CI	7 (47)
Bimodal CI with contralateral hearing aid	6 (40)
Unilateral CI with no contralateral hearing aid	2 (13)
CI side (both ears are listed for bilateral CI)	
Right	8 (53)
Left	14 (93)
CI company	
Advanced Bionics	2 (13)
Cochlear	8 (53)
MED-EL	5 (33)
Reimplantation	
No	13 (87)
Yes	2 (13)
Hybrid CI/EAS	
Yes	0
No	9 (60)
I do not know	6 (40)
Duration of hearing loss	
1–5 years	3 (20)
5–10 years	2 (13)
10–20 years	3 (20)
20–30 years	2 (13)
More than 30 years	2 (13)
Congenital	3 (20)
Duration of (first) CI	
1–5 years	5 (33)
5–10 years	6 (40)
10–20 years	1 (7)
More than 20 years	3 (20)

Note. CI = cochlear implant; EAS = Electric Acoustic Stimulation.

in understanding or misinterpreted an item were highlighted. For each item, we analyzed the frequency and the nature of the problems that occurred in the interviews. Based on these results, the committee discussed any phrases in which at least one difficulty occurred. If the committee decided that the phrase had to be changed, it developed alternative translations. Any changes underwent back translation and were reviewed once more until a satisfying consensus was found and the final instrument was approved.

After 10 interviews, we found that more than half of the participants had difficulties understanding two items and one sentence of the instruction. It became clear that these sentences needed to be changed. The phrases were changed after reconciliation with the source-language questionnaire developer. We decided to test a new version of these sentences in the remaining five interviews. For

example, in one item, the meaning of the word "*unzulänglich*" ("inadequate") was unclear to many interviewees. The source-language questionnaire developer explained that "inadequate" in this context means "not good enough or deficient." Therefore, we decided to use the translation "*nicht gut genug*" ("not good enough").

When all interviews were finished, the committee decided to change phrases in four more items and one sentence of the instruction according to the participants' suggestions and misunderstandings. These changes underwent another back translation and review from the committee.

Step 6: Finalization

All steps in the adaptation process were documented in the modified template included in the guideline by Hall et al. (2018). Any item versions and discussions were reported and archived therein. The final version of the questionnaire was proofread and formatted similarly to the source-language questionnaire. As the short version consists of 10 of the CIQOL-35 Profile items, we were able to assemble the CIQOL-10 Global as well. Finally, the German instruments were published on the CIQOL research website (https://education.musc.edu/CIQOL). There, access to the instruments is granted for use in research and clinical practice upon request at no cost. The German version of the CIQOL instrument will be validated in a following study.

Discussion

For a cross-cultural adaptation of a questionnaire, it is important to translate the language while keeping cultural differences in mind, such as common phrases and living situations of the population. The translation process aims to find phrases that fit the original version best to construct a comparable questionnaire. At the same time, the translation must be comprehensible for native speakers of the target language and be adequate for the cultural region. To assure that this is considered in the translation process, native German speakers living in Germany performed the translations into the target language. During the adaptation process, we did not encounter any items which would be problematic to understand if people speak a dialect or live in another German-speaking country. Thus, every German speaking person should be able to understand the produced German version.

The comparison of back translation and source language questionnaire was necessary to identify discrepancies between the translation and the original questionnaire. When it was difficult to find a fitting German translation, it was very helpful to ask the source-language questionnaire developer for alternative terms or examples. The exchange with the source-language questionnaire developer and the discussions in the committee were very valuable to find a solution for the discrepancies.

The field testing was very helpful to discover phrases that were confusing or unclear for people filling out the questionnaire. Although the translation strictly followed the best practice guide and the committee consisted of experts in rehabilitation of people who are deaf or hard of hearing, the interviews still discovered difficult phrases. The results of our interviews show that the field testing of an adapted questionnaire is very important to assure that it is comprehensible in the target language and for the target group. Including people of the target population in the process appears to be a useful method to assure that the instrument will be accepted upon implementation.

The field testing was conducted with a sample of people living mostly in the same state as the CI center. To assure the feasibility in other German-speaking regions, a more diverse sample would have been preferred; however, due to resources and recruiting methods, we only conducted interviews in this area. As stated before, standard German is used for example in schools and literature anywhere in Germany. We did not find any terms in the questionnaire that are known to be used differently in specific German regions (e.g., there are different words for "bread rolls" in Germany). However, the following validation study should include a regionally more diverse sample, to make sure the questionnaire can be implemented in any German-speaking regions.

To the best of our abilities, we generated a sample that was diverse regarding personal characteristics such as age, gender, education, and living situation. A sample of only 15 CI users cannot be representative, but that is not necessary for a qualitative pretest. We tried to reach participants with various characteristics regarding hearing loss and their CI—as far as possible within the inclusion criteria. This study only included participants that already had a CI for at least 1 year to make sure it can be used in the full range of outcomes in CI users. However, the questionnaire can be used in clinical settings before and after CI to evaluate the effects that CI has on the hearing-related QOL of patients. Thus, it should be considered to test the questionnaire with people who have not yet a CI or who have had their CI for less than 1 year in the validation study.

Some participants made comments that went beyond the capabilities of this study. Suggestions for the question order or changes of the rating scale could not be considered in the adaptation. This would have interfered with the conformity to the original questionnaire. However, the participants expressed interest and many ideas in our study, for example for rephrasing some items. This suggests that

participatory research is well received in the population of adults with CI and may give valuable insights for future research projects.

We noticed that one prelingually deafened person in our sample had difficulties with many items that we did not observe with the other participants. This might be explained by a suspected reduced vocabulary due to the prelingual deafness (Jallu et al., 2019). Even though most adults with CI have acquired hearing loss, there are some cases where adults with congenital deafness or hearing loss receive a CI. For this population, it is also important that QOL is measured in addition to audiometric outcomes (Straatman et al., 2014). In general, it is possible to use the CIQOL instruments with prelingually deafened adults. However, it is a written questionnaire that contains questions about the hearing-related QOL with CI, including questions about communication in spoken language. Therefore, the questionnaire might not be applicable for people who do not communicate in spoken language. A plain language version of the questionnaire might broaden the area of application to people with special needs regarding written language. To survey the QOL of Deaf people using sign language, a different instrument is needed. The validation of the adapted German version of the CIQOL instrument will follow to determine its reliability and validity.

Conclusions

A culturally adapted German version of the CIQOL instruments was developed and published for use in CI rehabilitation and research. Clinicians and researchers working with German-speaking adults with CI can use these instruments to meet the recent requirements to evaluate the QOL before and after cochlear implantation. The study indicates that field testing with participants of the target group is crucial to assure the intelligibility and acceptance of the adapted version for the target population. The validation of the questionnaire is in progress.

Author Contributions

Elena Pützer: Conceptualization (Equal), Formal analysis (Lead), Investigation (Lead), Methodology (Lead), Project administration (Lead), Visualization (Lead), Writing – original draft (Lead). **Theodore R. McRackan:** Conceptualization (Supporting), Methodology (Supporting), Writing – review & editing (Equal). **Ruth Lang-Roth:** Resources (Supporting), Writing – review & editing (Equal). **Karolin Schäfer:** Conceptualization (Equal), Methodology (Supporting), Investigation (Supporting), Supervision (Lead), Writing – review & editing (Equal).

Data Availability Statement

The data sets generated and analyzed during the current study are available from the corresponding author on reasonable request.

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