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The Design of a Project to Assess Bilateral Versus Unilateral Hearing Aid Fitting

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Binaural hearing provides advantages over monaural in several ways, particularly in difficult listening situations. For a person with bilateral hearing loss, the bilateral fitting of hearing aids thus seems like a natural choice. However, surprisingly few studies have been reported in which the additional benefit of bilateral versus unilateral hearing aid use has been investigated based on real-life experiences. Therefore, a project has been designed to address this issue and to find tools to identify people for

whom the drawbacks would outweigh the advantages of bilateral fitting. A project following this design is likely to provide reliable evidence concerning differences in benefit between unilateral and bilateral fitting of hearing aids by evaluating correlations between entrance data and outcome measures and final preferences.

Keywords: hearing aids; bilateral fitting; randomized cross-over design

Binaural hearing is defined as hearing based on two ears with various complex interactions between the two ears. Bilateral hearing, on the other hand, represents only two auditory channels without assuming any interaction between the channels. The use of bilateral hearing aids by a person with a bilateral hearing loss provides the basis for binaural hearing but does not guarantee it, because the binaural interactions depend on the function of central auditory pathways.

Binaural hearing provides a number of advantages over monaural in terms of spatial hearing, speech

recognition in noise, perception of a dynamic acoustic environment, and so on. Although for a person with bilateral hearing loss, the fitting of hearing aids to both ears seems like an obvious and natural choice, surprisingly few studies have been reported in which the additional benefit of bilateral versus unilateral hearing aid use has been investigated based on real-life experiences. Most reports published so far have been based on laboratory investigations, which in general have shown superior performance for bilateral fittings in identifying the direction to a sound source or in recognizing speech against a background noise presented from a loudspeaker different from the one producing the speech signal (e.g., Köbler & Rosenhall, 2002; Markides, 1977). Gatehouse and Noble (2004) developed the Speech, Spatial and Qualities of Hearing Scale (SSQ) questionnaire to evaluate more complex listening situations in the everyday life of hearing aid users. They found that hearing speech in demanding contexts (divided or rapidly switching attention) showed benefit with one aid and further benefit with two (Noble & Gatehouse, 2006). In the spatial domain, directional hearing showed some benefit with one hearing aid and particular further benefit from fitting with two aids in distance and movement discrimination.

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Among the members of the group, Stuart Gatehouse was in fact the principal mover of this project, and the publication of this research design illustrates in many ways his wide knowledge and experience.

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Clinical experience has shown that in spite of the potential advantages of bilateral hearing aids, some users prefer to use only one aid. Indeed, several investigators (Carter, Noe, & Wilson, 2001; Henkin, Waldman, & Kishon-Rabin, 2007; Walden & Walden, 2005) have shown that some individuals actually perform worse with bilateral fittings, presumably because of deficits in central auditory processing. In addition, because the majority of hearing aid users are older people, there are also problems caused by comorbidity, such as poor vision and/or reduced fine motor control that may make the handling of even one hearing instrument difficult enough. For some people, the programming of the hearing aids may have resulted in a less-than-ideal signal processing, causing drawbacks that outweigh the benefits of wearing two aids. Cosmetic appeal is still an issue for many hearing-impaired people, assuming that one instrument is less visible than two. The occlusion effect can be a further reason for not accepting a second hearing aid, at least for traditional, nonopen fittings. Having one ear open for telephone use is also sometimes an excuse for unilateral fittings. Thus, people with bilateral hearing loss may refuse bilateral hearing aids for a number of possible reasons in spite of the potential benefit for a majority of them, as seen from an audiological perspective. However, we have at present no clinical tools to identify these individuals.

Thus, with this background, a large multicenter, multinational research project was planned with its main aims being to evaluate the benefits of bilateral compared with unilateral hearing aid fittings in real life and to find tools to (a) identify those people for whom the drawbacks of a bilateral fitting would outweigh the advantages and (b) obtain psychophysical and/or performance measures that allow a better quantification of the differences between unilateral and bilateral use of hearing aids. By making the study multicenter and multinational, the results would have greater validity because by a judicious choice of sites, it becomes possible to cover different forms of organization of hearing health care (in terms of national health-based care or that provided by private dispensers with various degrees of financial support from health insurance systems). This report outlines the design of the study in the hope that it may be of use to researchers in studies of this important issue.

Participant Entrance Criteria

Participants should be first-time users of hearing aids because experienced users are likely to have bias

related to their previous experience. Also, those with mild to moderate hearing loss can be regarded as prime candidates for bilateral fitting because they usually have no problems when it is quiet but need help in noisy environments. These arguments are considered more important than the fact that experienced users would be likely to have greater hearing loss and, therefore, more potential benefit from bilateral fitting. The age range would be from 18 years on. The local language should preferably be the participants' native language. If not, successful self-completion of the Glasgow Hearing Aid Benefit Profile (Gatehouse, 1999) could be used as a screening test with regard to literacy and language competence. The hearing loss should be relatively symmetrical because asymmetrical losses invariably would offer greater problems in providing sufficiently good balance between left and right instruments. A significant asymmetry is likely to represent not only the quantitative differences illustrated by the hearing thresholds but also qualitative differences, for example, different loudness functions, diplacusis, and other psychoacoustic relationships. The difference between sides of average air and bone conduction hearing threshold levels (0.5–1–2–4 kHz) should not exceed 20 dB. No specific requirement on air–bone gap is included. The hearing loss should be presumed to remain stable for the project duration, as judged by the diagnostic evaluation and medical history. Obviously, no otological contraindication against hearing aids or ear-molds should be present. An informal assessment of a candidate's potential to complete the project is a natural part as well as the candidate's informed consent and a formal approval of the study by an ethics committee.

Entrance Data

A series of different tests is suggested to provide a description of those patient characteristics that are presumed to be of importance for the acceptance and potential benefit of bilateral hearing aids. Pure tone audiometry by both air and bone conduction provides a basic description of the type and degree of hearing loss. Tympanometry and the recording of middle-ear reflexes will add information regarding the middle ear function.

Binaural auditory function is likely to play a role in the benefit of bilateral hearing aids. However, standard tests like the binaural masking level difference do not seem to provide reliable guidance in this respect (Gatehouse & Akeroyd, 2006). Gatehouse

and Akeroyd (2006) designed a more complex, dynamic test of binaural function that seems to be better related to real-world benefit of binaural hearing, therefore, this test is suggested to be part of the test battery. The target signal is a 500 Hz tone burst of 30 ms duration, presented in the middle of a 500 ms broadband noise masker. Its threshold is measured in two binaural conditions: (a) diotic signal in diotic masker and (b) dichotic (out-of-phase) signal in dichotic masker noise but whose interaural correlation is varied sinusoidally from -1 to $+1$ and back to -1 at 2 Hz (Grantham & Wightman, 1979). In condition b, the signal is presented only at the moment when the masker correlation is 1.0. The dynamic measure is the difference in thresholds between the two conditions. Gatehouse and Akeroyd (2006) showed that its size was correlated significantly with the subscales of Speech-in-Noise, Speech-in-Speech, Multispeaker Processing, and Speaker Identification in the SSQ questionnaire.

Several recent studies have shown cognition in general and working memory in particular to be significantly correlated to the ability to recognize speech in complex acoustic environments (Gatehouse, Naylor, & Elberling, 2006; Lunner, 2003; Lunner & Sundewall-Thorén, 2007). Furthermore, Hällgren, Larsby, Lyxell, and Arlinger (2001) found significant correlations between cognitive performance and dichotic speech recognition, which indicates a possible relation between cognition and binaural functions. A simple test of working memory capacity, the Visual Monitoring Test (Knutson et al., 1991) is, therefore, proposed to be included. This test is based on digits shown one by one on a screen. The target combination is odd–even–odd. When such a sequence has occurred, the participant is to press a button. An alternative is the reading span test (Lunner, 2003), in which short simple sentences are shown on a screen. The participant is to determine whether the sentence makes sense or not. After a certain number of sentences, he or she is asked to repeat the first or the last words in the sentences presented. Thus, the test requires both processing and storing information.

Dexterity is another potential factor that may affect the acceptance of two hearing aids. To quantify this factor, the Purdue pegboard test is proposed to be used (Desrosiers, Hebert, Bravo, & Dutil, 1995). This test involves sequential insertion of pegs and assembly of pegs, collars, and washers. In addition to the dexterity aspect, this test also includes a significant visual component, also important for the handling of modern hearing aids.

Social and psychological aspects are to be included by using the Auditory Lifestyle and Demand (ALD) questionnaire (Gatehouse, Elberling, & Naylor, 1999) with some modifications—for example, to include also the individual family situation. By using the Expected Consequences of Hearing aid Ownership (ECHO) questionnaire (Cox & Alexander, 2000), the hearing-impaired person's expectations of the hearing aids are assessed and included.

Hearing Aids

Each person should be fitted with the type of hearing aid that they would wear if the project did not exist for the project to be representative for the hearing center. Therefore, all hearing aid types that are available in each national system should be available to the participants, but behind-the-ear types should be the default choice to minimize occlusion by using as open fittings as possible. All functionality of a particular hearing aid type may be used. Proportions of different styles in the samples (behind the ear, completely in the canal, etc.) should reflect the proportions typical of the local clinical practice. In each center, hearing aids are offered to the participants following the same financial conditions according to local rules as though the project had not existed.

General Design

The general design of the project is a crossover study with randomized selection of which arm (unilateral or bilateral fitting first) a given person would enter. The crossover design will allow each participant to experience and evaluate unilateral as well as bilateral fitting. The randomization is important to avoid any bias as to who will start with unilateral or bilateral fitting first. Each arm consists of two strands, each having a duration of approximately 10 weeks of hearing aid use. The programming of the hearing aids at the beginning of the first strand should start by using the manufacturer's suggested fitting rules as well as fine-tuning scheme for each ear. A gradual increase in gain over time may be used if this is normally done in local clinical practice. The fine-tuning should be performed after 1 to 2 weeks of real-life experience with the instruments. When programming for the second strand, experience from the first strand is an obvious base, with adjustment of hearing aid overall gain a likely complement. Measurement of real-ear gain was considered optional but should be used if this is

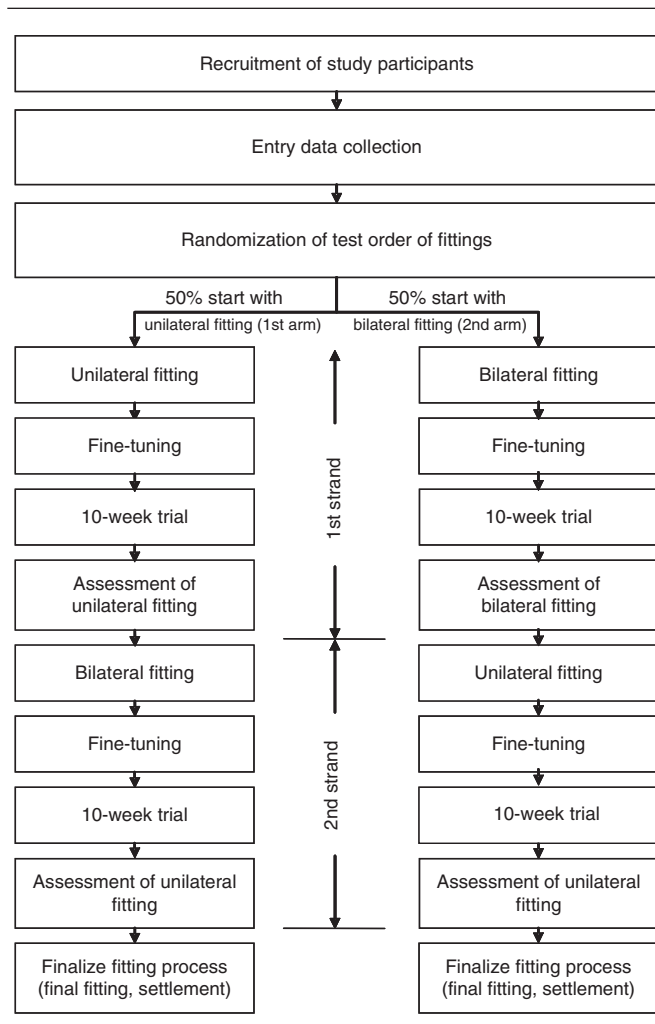


Figure 1. Flow chart for the study.

common practice in the center. The normal procedure with cross-over studies of hearing aids does not include any washout period between the two strands. A washout period would add to the total duration of the study, which is lengthy as it is. Furthermore, it is likely that some participants would object to not having access to hearing aids after having started adjusting to life with hearing aids. Figure 1 illustrates the overall structure.

The number of participants needed to provide the project with acceptable statistical power has been estimated to be approximately 50 completing each arm. Assuming certain dropout percentages at the various stages from recruiting to completing, it was estimated that a total of approximately 300 people passing the entrance criteria are needed. Of these, we estimate that 70% will accept the randomization, leaving us with 210 participants. Furthermore, it is assumed that 90% will accept to start with unilateral

fitting, and 80% will accept to start with bilateral fitting. This will result in 95 and 84 people entering, respectively. Assuming a dropout rate of 10% during the first strand, 85 and 75 patients, respectively, will be available for assessment after the first strand. We then assume that 90% of those who started with unilateral fitting will accept to continue into the second strand with bilateral fitting, whereas we estimate that only 75% will agree to leave the bilateral fitting and go into the unilateral second strand. Thus, 76 participants will go into the second strand bilaterally fitted, and 56 will enter the unilaterally fitted second strand. Again, we calculate with a 10% dropout rate during the 10 weeks, leaving us with 68 participants to assess after being fitted bilaterally in the second strand and 50 after being unilaterally fitted in the second strand. The estimated dropout rates are likely to vary somewhat between test sites and are based on experiences from previous studies.

Assessment

The focus of the assessment to take place at the end of each strand is one benefit as the participants' perceived experience of the hearing aids during each strand. The SSQ questionnaire has an obvious role here. In addition to the original 53 questions, another 7 are included to assess problems with loud sounds and the perception of the user's own voice (see Table 1).

A detailed questionnaire regarding use time should also be part of the assessment because it is reasonable to assume that increased benefit leads to increased use. The questionnaire specifies 15 different situations or environments (see Table 2). For each of these, the participant is asked to state whether it is relevant or not in his or her normal life and, if so, if hearing aids are used, on which ear(s) and average daily use time. If the instruments are not used, the reason for this is requested.

A measurement of the health-related quality of life is an essential factor in assessing health care interventions. Most generic instruments for measuring it are relatively insensitive to sensory function: For instance, few of the dimensions in the popular "EQ5D" (Brooks, 1996)—target mobility, self-care, usual activities, pain and discomfort, and anxiety and depression—if any, would be strongly affected by a hearing impairment. Gatehouse and colleagues (see Murray, Gatehouse, & Summerfield, 2005) developed five additional dimensions reflecting the

Table 1. Extra Questions Regarding Aversiveness of Sounds and Own Voice Effects, Added to the SSQ

| | | Without HA | With HA |
|---|---|---|---|
| 1 | Sounds in the kitchen, e.g., from china, glasses, silverware dropped on the sink, are unpleasant. | Visual Analog Scale 0 (<i>not at all</i>) to 10 (<i>extremely much</i>) | Visual Analog Scale 0 (<i>not at all</i>) to 10 (<i>extremely much</i>) |
| 2 | Household noise from the kitchen fan, vacuum cleaner, toilet flushing are too loud | | |
| 3 | When I am with many people in a large group their speech becomes uncomfortably loud | | |
| 4 | Noise from the wind when I am outdoors annoys me | | |
| 5 | My own voice sounds hollow and strange | | |
| 6 | Traffic noise from buses, trucks, and snow-tires on the road surface is annoying | | |
| 7 | Acoustic feedback causes me problems, e.g., the hearing aid starts whistling when I keep a telephone to the ear | | |

NOTES: For each item, the participant is asked to state whether right, left, or both ears are aided and the average hours per day he or she is using the instruments when applicable. HA = hearing aid.

Table 2. Questionnaire Regarding Use Time

| | Relevance | Use of HA | If Not, Why Not? |
|---------------------------|-----------|-----------|------------------|
| Conversations at home | Y/N | Y/N | |
| During meals | Y/N | Y/N | |
| Watching TV | Y/N | Y/N | |
| Reading | Y/N | Y/N | |
| Doing household work | Y/N | Y/N | |
| Using telephone | Y/N | Y/N | |
| At work | Y/N | Y/N | |
| At school | Y/N | Y/N | |
| At meetings | Y/N | Y/N | |
| At sports facilities | Y/N | Y/N | |
| At clubs/restaurants | Y/N | Y/N | |
| At meetings | Y/N | Y/N | |
| In church/theater | Y/N | Y/N | |
| In the car | Y/N | Y/N | |
| At other leisure activity | Y/N | Y/N | |

NOTES: For each item the participant is asked to state whether right, left, or both ears are aided and the average hours per day he or she is using the instruments when applicable. HA = hearing aid.

expected effects on health of sensory-based disabilities—though avoiding any direct reference to hearing loss—which were presented in the same format as the original dimensions (see Table 3). Therefore, the option suggested for the project was to use this extended version of the EQ5D. Each participant would have completed it by choosing whichever of the three options (*no*, *moderate*, or *great problems*)

Table 3. The Items in the Extended Quality-of-Life Questionnaire

| | |
|----|--|
| 1 | I have no problems in walking about I have some problems in walking about I am confined to bed |
| 2 | I have no problems with self-care I have some problems washing or dressing myself I am unable to wash or dress myself |
| 3 | I have no problems with performing my usual activities I have some problems with performing my usual activities I am unable to perform my usual activities |
| 4 | I have no pain or discomfort I have moderate pain or discomfort I have extreme pain or discomfort |
| 5 | I am not anxious or depressed I am moderately anxious or depressed I am extremely anxious or depressed |
| 6 | I have no problems in communicating with other people I have some problems in communicating with other people I have great difficulty in communicating with other people |
| 7 | I have no problems with confidence and embarrassment I have some problems with confidence and embarrassment I have great difficulty with confidence and embarrassment |
| 8 | I have no problems taking part in family activities I have some problems taking part in family activities I have great difficulty taking part in family activities |
| 9 | I have no problems taking part in social activities or work I have some problems taking part in social activities or work I have great difficulty taking part in social activities or work |
| 10 | I do not get mentally or physically tired during the day I get moderately mentally or physically tired during the day I get extremely mentally or physically tired during the day |

NOTES: Items 1 to 5 are from the original questionnaire; Items 6 to 10 are the additions.

Table 4. International Outcomes Inventory for Hearing Aids—Significant Other (IOI-HA-SO)

The following questions are designed to be answered by the partner (husband, wife, or similar close companion) of someone with a hearing impairment who has acquired a hearing aid. Note that the first three questions ask for your assessment of the use and benefit of the aid for your partner whose hearing is impaired. The remaining questions ask about the value and effect of the hearing aid(s) for *you*.

| | | | | |
|--|---|--------------------------|---|--|
| 1. Think about how much your partner used their hearing aid(s) both when they had a single hearing aid and when they had two hearing aids. On average, how did their use compare between when they had one and when they had two hearing aids? | | | | |
| Two used much more than one | Two used a little more than one | No difference | One used a little more than two | One used much more than two |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Think about the situation where you most wanted your partner to hear better, before getting hearing aids. How much has having two hearing aids helped compared with having one? | | | | |
| Two helped much more than one | Two helped a little more than one | No difference | One helped a little more than two | One helped a lot more than two |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Think again about the situation where you and your partner wanted to hear better. When your partner used one or two hearing aid(s), how much difficulty did they <i>still</i> have in that situation? | | | | |
| Two had much less difficulty than one | Two had a little less difficulty than one | No difference | One had a little less difficulty than two | One had a lot less difficulty than two |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Considering everything, how do you think your partner's having two hearing aids compared with having one hearing aid? | | | | |
| Two much more worth it than one | Two a little more worth it than one | No difference | One a little more worth it than two | One a lot more worth it than two |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. How much did your partner having two as opposed to one hearing aid affect the things that <i>you</i> can do? | | | | |
| Two affected me much more than one | Two affected me a little more than one | No difference | One affected me a little more than two | One affected me a lot more than two |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. When your partner had two hearing aids as opposed to one hearing aid, how much more or less bothered were <i>you</i> by your partner's hearing difficulties? | | | | |
| Bothered much more when they had two | Bothered a little more when they had two | No difference | Bothered a little more when they had one | Bothered a lot more when they had one |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Considering everything, how much do you think having two hearing aids compared with having one hearing aid has affected <i>your</i> enjoyment of life? | | | | |
| Two affected me much more | Two affected me a little more | No difference | One affected me a little more | One affected me a lot more |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

for each dimension that best described their state of health on the day of testing.

A rating of listening effort should be included. This is based on the assumption that increased auditory input requires less listening effort. Among potential tests of listening effort, methods using simple rating on a Visual Analog Scale have shown some promise (e.g., Behrens & Sundewall, 2005; Dreschler, van Esch, & Sol, 2007). Sentences (Hagerman, 1982; Wagener, Josvassen, & Ardenkjaer, 2003) are presented to the participant in background noise with noise level reduced by 3 dB below that corresponding to 50% correct in a speech recognition test. Five sentences are produced for the rating, and each sentence is to be repeated by the participant.

The listening effort is to be rated afterward on a Visual Analog Scale (e.g., the scale ranging from *no effort* to *largest possible effort*).

Each participant's satisfaction with instruments and fitting should be assessed. We suggest the use of the Satisfaction with Amplification in Daily Life (SADL) questionnaire (Cox & Alexander, 1999). This questionnaire returns to the same issues as were raised in the questionnaire on expectations, ECHO, and a comparison between ECHO and SADL, for an individual will thus illustrate to what extent his or her expectations have been fulfilled.

The International Outcome Inventory for Hearing Aids (IOI-HA; Cox & Alexander, 2002), is a rather simple 7-item questionnaire assessing use, benefit,

Table 5. Questionnaire on Preference for Bilateral or Unilateral

Questions 1-13 to be answered by one of five alternatives, comparing bilateral with unilateral advantage. In addition, the importance of each issue is to be stated as *not at all*, *a little*, or *very important*

Questions 14-21 are statements for which the participant is to answer to what extent this aspect played a role in the decision.

1. Environmental sounds can be very loud. The loudness may differ whether you wear one or two hearing aids. How did you experience the loudness of normal sounds?
2. Hearing aids can give you the feeling that sounds are locked in your head instead of coming from the outside. To what extent was this the case?
3. When you compare the loudness wearing one or two hearing aids, how did you experience the loudness of your own voice?
4. When you hear a sound, can you immediately tell from which direction the sound is coming?
5. How well could you talk with one person in a quiet room?
6. How well could you talk with someone when you are driving a car?
7. How well could you talk with a number of people in a quiet room?
8. How well could you talk with people in a noisy place?
9. How well could you understand a conversation on the television?
10. How well could you understand a person talking to an audience without using the T setting of the hearing aid?
11. Ear molds can cause some discomfort or even pain. Please indicate degree of problem.
12. Whistling of the hearing aid (or feedback) is an annoying sound. Please indicate degree of problem.
13. a. Do you use the telephone?
b. When you use the telephone, do you use a hearing aid in that ear?
c. When you don't use a hearing aid in that ear, what is the reason for that?
14. Ears will get lazy from the use of hearing aids and I want to diminish this by using one hearing aid.
15. Someone advised me to use one or two hearing aid(s) and I followed this advice.
16. I feel ashamed to wear two hearing aids.
17. I look stupid when I wear two hearing aids.
18. If I take two hearing aids, I always have a spare unit to fall back on for one ear.
19. The hearing in my better ear is still too good. I don't need a hearing aid at that side.
20. I use the phone often and it is uncomfortable to do it with the hearing aid, so I take only one.
21. Was there any other reason for your decision?

residual disability, participation, and quality of life, intended as a complement to other instruments and based on questions that are independent of specific cultural or environmental conditions. Because hearing loss affects not only the person with the impairment but also his or her family, friends, colleagues, and so on, it is suggested to include also the modified version for significant others, IOI-HA-SO (Noble, 2002). The latter is modified so as to focus on differences between the partner using one versus two hearing aids (see Table 4).

A final questionnaire after finishing the second strand concerns each participant's preference for one or two hearing aids. This will present 21 questions or statements concerning the importance of different factors for the individual preference. Table 5 illustrates the design of this questionnaire.

As an additional outcome measure, it is suggested to administer a speech recognition test. This test is based on the presentation of everyday sentences from a varying direction, using a spatial arrangement of sources at 0°, +45°, and -45°. Uncorrelated background noise (ICRA noise simulating one interfering speaker with pause durations limited to 250 ms;

Wagener, Brand, & Kollmeier, 2006) is presented from all three loudspeakers with a sound level of 60 dB SPL (sound pressure level) each—that is, 65 dB SPL together. The speech signal is presented from one of the three loudspeakers, selected randomly for each sentence. This more complex real-life-simulating listening scenario may discriminate better than standard speech recognition tests between unilateral and bilateral hearing aid use.

Conclusion

A project following the design presented here is likely to provide reliable scientific evidence concerning differences in benefit between unilateral and bilateral fitting of hearing aids for first-time users with bilateral symmetric hearing losses. It will also provide knowledge that is likely to help in predicting with reasonable reliability who will and who will not benefit from bilateral fitting compared with unilateral. It is the hope of the group behind this proposal that the design will be used, in total or in parts, with the purpose of improving audiological services to hearing-impaired persons, which would be entirely in the spirit of our late colleague Stuart Gatehouse.

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