

Approaches to Audiological Rehabilitation with Hearing Aids

-studies on pre-fitting strategies and assessment of outcomes



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To Magnus, Linus and Sofia

Why these studies?

My experiences as a clinical audiologist have shown me that, at present, individuals visiting clinics with hearing problems place greater demands on hearing health care than in the past. During my work in the clinic, questions have been raised about how to meet these demands and how to increase the users' hearing aid satisfaction. Between 1999 and 2002, we performed different trials where the users adjusted the amplification of a specific hearing aid by themselves. We noticed that many of the participants appreciated the fact that they were participating more in the rehabilitation process; these observations became the starting point for this thesis.

Abstract

Fourteen percent of the Swedish population report subjective hearing loss. The number of persons suffering from hearing loss is expected to increase in accordance with the increased length of the average life span, causing an associated increase in the demand for hearing health care services as new patient groups who expect a higher quality of life begin to request hearing care. The main goal of this thesis was to develop new approaches in audiological rehabilitation to meet these demands and achieve user satisfaction.

Two randomized controlled trials including 39 and 38 subjects, respectively were performed that evaluated two interventions, user-controlled adjustment and sound awareness training, which were performed prior to a hearing aid fitting. The new approaches focused on increasing user participation and activity. To evaluate the goals of audiological rehabilitation, e.g., reducing auditory impairment, optimizing auditory activities and minimizing participation restrictions, several standardized self-reporting instruments were used to assess activity limitations, participation restriction, satisfaction and psychosocial well-being. Several of the instruments were validated for a Swedish population in a postal survey including 162 subjects. Furthermore, an interview instrument that was appropriate for telephone interviews and a categorization rating scale were developed for assessing the global clinical impression of the audiological rehabilitation.

Few significant differences in outcomes were found between the treatment and control groups in the short term, and the interventions did not achieve additional or more successful hearing aid users in the long term. Thus, it was concluded that the hearing aid rehabilitation was effective in and of itself, as both the treatment and control groups showed significant improvements in psychosocial well-being and reduced activity limitation and participation restriction. The self-report instruments were found to be valid, and a factor analysis indicated that the number of questionnaires could be reduced with a recommendation for further clinical

use. The telephone interviews evaluating the clinical global impression of the audiological rehabilitation were found to be effective and showed success in a vast majority of the users. Advantages such as simpler administration and less time consumption warrant their continued use in additional audiological settings.

The pre-interventions in these studies need to be further investigated before they could be recommended for clinical use also in a Swedish context. The international standardized self reports, however, can already be recommended for clinical use. A first attempt to evaluate global clinical impression by telephone interviews was found to be effective and further validations are suggested.

Original Papers

This thesis is based on four original papers, referred to in the text by their Roman numerals I-IV

- I Öberg M, Lunner T, Andersson G. Psychometric evaluation of hearing specific self-report measures and their associations with psychosocial and demographic variables. *Audiological Medicine* 2007;5:188-199.
- II Öberg M, Andersson G, Wänström G, Lunner, T. The effects of a pre-fitting intervention on hearing aid benefit: a randomized controlled trial. *Submitted*
- III Öberg M, Andersson G, Wänström G, Lunner, T. The effects of a sound awareness pre-fitting intervention: a randomized controlled trial. *Audiological Medicine June* 2008;6:129-140.
- IV Öberg M, Wänström G, Hjertman H, Lunner T, Andersson G. Development and initial validation of the “Clinical Global Impression” to measure outcomes for audiological rehabilitation. *Accepted for publication in Disability and Rehabilitation*

Contents

Abbreviations	10
Introduction	11
Background	13
Counselling and patient education	13
Conventional hearing aid rehabilitation	16
Counselling approaches.....	17
Pre-counselling.....	18
Counselling-during hearing aid fitting	19
Post-counselling-in group	19
Post-counselling-individual.....	20
Overall conclusions about counselling.....	21
Evaluations in audiological rehabilitation.....	22
Evaluations in terms of the ICF.....	23
Self-reports in audiological rehabilitation.....	24
Self-reports in audiological rehabilitation in Sweden	25
Evaluating time period	28
The clinical global impression	29
Rationale for the approaches.....	30
Rationale for the pre-fitting approach.....	30
Rationale for user controlled adjustment	30
Rationale for sound awareness training	30
Rationale for the research design	31
Aims	33
Materials and Methods.....	34
Participants	35
Inclusion and exclusion criteria.....	35
Randomization	36
Questionnaires.....	36
Procedure.....	38
Paper I	38
Paper II.....	38
Paper III.....	41
Paper IV.....	41
Statistical analyses	44
Ethical Consideration.....	45
Results.....	47
Paper I	47
Paper II.....	47
Paper III.....	49
Paper IV.....	49
Functional evaluations of the hearing aid rehabilitation	50
Results of the self-report instruments used in the different studies	51
Discussion	57
Main findings	57
Methodological Considerations.....	67
Suggestions for future research	68
Conclusions	71

Acknowledgements	73
Svensk sammanfattning	75
Appendix	80
References	81

Abbreviations

AR	Audiological Rehabilitation
APHAB	Abbreviated Profile of Hearing Aid Benefit
AR-CGI	Audiological Rehabilitation Clinical Global Impression of Improvement
COSI	Client-Oriented Scale of Improvement
CSS	Communication Strategies Scale
CTRL	Control
ECHO	Expected Consequences of Hearing Aid Ownership
FTU	First-Time hearing aid Users
GP	Gothenburg Profile
HADS	Hospital Anxiety and Depression Scale
HCA	Hearing Coping Assessment
HDHS	Hearing Disabilities and Handicap Scale
HHIE	Hearing Handicap Inventory for the Elderly
HMS	Hearing Measurement Scale
ICF	International Classification of Functioning Disability and Health
IOI-HA	International Outcome Inventory for Hearing Aids
PTA	Pure-Tone Average for hearing threshold at 0.5, 1, 2 and 4 kHz.
RCT	Randomized Controlled Trial
SA	Sound Awareness training
SADL	Satisfaction with Amplifications in Daily Life
SOC	Sense of Coherence Scale
UCA	User-Controlled Adjustment

Introduction

Fourteen percent of the Swedish population from 18-84 years of age report subjective hearing loss (Statistiska Centralbyrån (SCB), 2005). The most common type of hearing disorder in adults is sensorineural hearing loss (Arlinger, 2003). Since this hearing loss is irreversible, the first intervention often consists of providing a hearing aid. The number of persons suffering from hearing loss is expected to increase in accordance with the increased average life span, causing an associated increase in the demand for hearing health care services. New patient groups with greater demands for quality of life are requiring hearing care, and the main goal of this thesis is to develop new approaches in audiological rehabilitation to meet these demands and to achieve user satisfaction.

It has been estimated that only 50% of those Swedes who could benefit from hearing aids actually acquired hearing aids, and approximately half of those reported use of the aids for most part of the day (Rahmqvist, 2002; Statens beredning för medicinsk utvärdering (SBU), 2003). While the technical developments in hearing aids have increased user satisfaction, surveys have shown that approximately 25% of the users in the USA (Kochkin, 2002, 2005) and 11% of the users in Östergötland, Sweden (Rahmqvist, 2002) were still dissatisfied with their hearing aids. An uncorrected hearing loss often results in withdrawal from a variety of social activities, which in turn affects psychosocial well-being and quality of life (Arlinger, 2003). Therefore, it is important to inspire more hearing impaired individuals to seek audiological rehabilitation.

The technical developments in hearing aids have not produced a corresponding improvement in user satisfaction and hearing aid use. One possible reason for this may be that the scientific basis of hearing aid fitting has fallen far behind the technological developments in hearing aids (Cox, 2005). While hearing aids are technically advanced, they can not compensate fully for the hearing loss, and residual rehabilitation needs often persist. Aside

from hearing aids themselves, the learning process and the psychosocial aspects are also important factors for improved outcomes following audiological rehabilitation. In addition, it has often been observed that hearing impaired individuals do not actively seek audiological rehabilitation, do not use their aids frequently and are dissatisfied with their aids. Taken together, these observations indicate a need for new approaches in audiological rehabilitation. These new approaches should focus on increased user participation and activity with the goal of increasing the participants' knowledge, awareness and motivation.

The goals of audiological rehabilitation, consistent with the model of International Classification of Functioning (ICF) (WHO, 2001), are to reduce auditory impairment, optimize individuals' auditory activities and to minimize participation restrictions (Chisolm et al., 2007). Thus, there exist needs for reliable instruments to evaluate these factors, and the National Swedish Health System has an obligation to ensure quality assessments and improvements. In Sweden, however, there are few valid and reliable standardized instruments to evaluate auditory activities, participation and psychosocial well-being (Socialstyrelsen, 1999). Validated instruments and effective means to evaluate the overall impression of the rehabilitation are needed to evaluate to what extent the goals are reached in today's audiological rehabilitation and to evaluate the efficacy of newer, more holistic interventions. The studies cited in this thesis all share the goal of improving scientific knowledge on the effects of different audiological interventions and different evaluation approaches.

The purpose of the present thesis is thus to develop and evaluate new interventions for hearing aid rehabilitation, to validate self-report instruments, and to develop an effective procedure of measuring global clinical improvement following audiological rehabilitation.

Background

Counselling and patient education

Stephens and Héту (1991) described audiological rehabilitation in terms of a problem-solving exercise aimed at reducing disability and avoiding handicap. This description is still accepted but more recently researchers have begun to refer to activity limitation and participation restriction rather than hearing handicap (WHO, 2001). A cornerstone in audiological interventions is the use of amplification through hearing aids, which are aimed at reducing auditory impairment, optimizing the individual's auditory activities and minimizing participation restrictions (Chisolm et al., 2007). Even if the use of amplification is essential, audiological rehabilitation can incorporate a variety of elements such as assistive listening devices, psychosocial counselling and counselling with regard to communication strategies or auditory training presented in either individual or group format (Sweetow and Palmer, 2005).

The main goals of audiological counselling in general involve giving the individuals information about their hearing loss, developing skills needed to operate and care for their new hearing aids and changing patients' belief and behaviour relating to communication (Boothroyd, 2007; Dillon, 2001).

In a review by Webber (1990), it was suggested that patient health care education has been an important area of research for at least thirty years. Webber gave an explanation for the terms health promotion, patient education and health education. Health promotion according to Webber refers to programs aimed at increasing the awareness of the general public, for example programs aimed at weight loss. Patient education refers to the preparation of patients for medical procedures in addition to the provision of existing information. Health education has been suggested to be an umbrella concept that includes both patient education and health promotion (Webber, 1990). Furthermore, patient education is defined by van den Borne (1998) as “ *a systematic learning experience in which a combination of methods is*

generally used, such as the provision of information and advice and behaviour modification techniques, which influence the way the patient experiences his illness and or his knowledge and health behaviour, aimed at improving or maintaining health or learning to cope with a condition, usually a chronic one” (p.90). The author pointed out that patient education is more than simply the provision of information and that it also involves influencing emotions and attitudes aimed at altering behaviour (van den Borne, 1998). Webber (1990) emphasized that health information alone is not designed to change behaviour. The goal with patient education in practical medicine, as described by Hellström (1995), is to contribute to the reduction of symptoms from the patient’s disease and make it easier for the patient to regain health.

Patient education should therefore be seen as an integral part of the four phases of a rehabilitation process that includes assessment (e.g. diagnosis), planning (e.g. goal setting), implementation (e.g. learning activities) and evaluation (Rankin & Stallings, 2001).

There is consensus that patient education has to be interactive and that participation is a key (Rankin & Stallings, 2001; Sweetow & Henderson, 2007; Toman et al., 2001; Webber, 1990). Another important factor to consider when providing patient education related to training is providing interventions that are practical, easily accessible, appropriately demanding and where the patients’ progress can be measurable. To empower the patient, regular feedback from the caregiver is essential (Rankin & Stallings, 2001; Sweetow & Henderson, 2007). Another prerequisite to increase patient participation when providing patient education is the willingness from the clinicians to provide this approach (English, 2005; Hellström, 1995; Webber, 1990).

Boothroyd (2007) described counselling in audiological rehabilitation and suggested that counselling is to be divided into informational counselling and counselling that addresses issues of participation and quality of life. Informational counselling has to be delivered in a

way that most users can easily absorb with an additional recommendation to teach the users in several different ways (e.g. verbal communication, written materials, demonstrations) (Rankin & Stallings, 2001; Toman et al., 2001; Webber, 1990). This informational counselling can be compared to health information and provision of information in patient health care education (Webber, 1990). On the other hand, counselling targeted to quality of life refers to therapeutic counselling by Bally and Bakke (2007). This type of counselling could be said to help the users acknowledge the hearing loss and help them work through negative emotions and overcome feelings that discourage the individual from engaging in the rehabilitation (Boothroyd, 2007; Dillon, 2001). This therapeutic counselling could be compared to the definition of patient education by learning to cope with a condition (Rankin & Stallings, 2001). Providing the appropriate audiological counselling probably increases the likelihood that hearing aids will be used. Dillon (2001) argued that a major part of counselling the new hearing aid user has nothing to do with hearing aids and Danermark (1998) stressed that traditional audiological rehabilitation mainly focused on compensation such as aural perception and speech. Instead, he recommended more focus on acceptance which is related to the emotional side of the counselling. This is consistent with Andersson, (1995) who suggested the management approach (an interdisciplinary approach that emphasizes self-assessed aspects of participation restriction and focuses on the individual) as necessary for successful treatment.

In common practice, it is suggested that the users participate more in their own rehabilitation (Clark, 2007; Rankin & Stallings, 2001). Clark (2007) suggested that the audiologist should not act as an authoritative solution provider, but instead as a facilitative coach prepared to engage with the user. The users have to establish their own motivation and make the final decisions. Facilitative coaches who provide a supportive and non-judgmental environment have greater potential to improve the users' receptiveness. Rehabilitation

approaches, which include more of self-activity and participation, have the opportunity to improve the relationship and facilitate an equal dialogue that is beneficial for receptiveness (Boothroyd, 2007; English, 2005; Eriksson-Mangold et al.,1990; Hellström,1995; Rankin & Stallings, 2001). Still, there is a need for more studies in audiological rehabilitation to confirm the effects of users' increased activity and participation.

Conventional hearing aid rehabilitation

The conventional hearing aid rehabilitation can be described as in Figure 1.

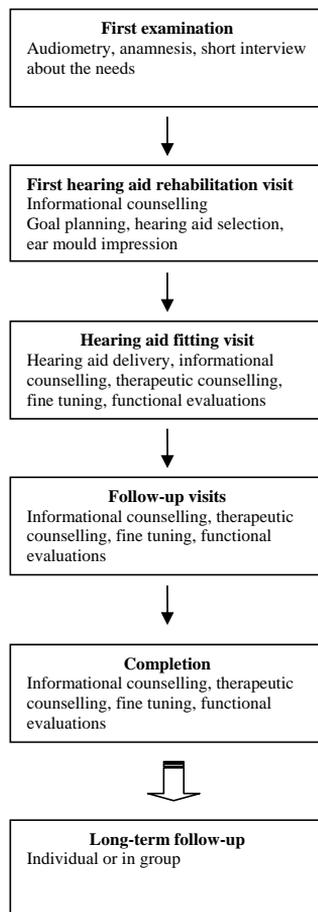


Figure 1. The procedure of a conventional hearing aid rehabilitation described from the hearing clinic in Linköping, Sweden

The first visit to the clinic consists of pure tone audiometry and a medical anamnesis. If required, the individual could be referred to a physician or to other professionals within the hearing health care at any time. Individuals suitable for hearing aid rehabilitation are invited to a first hearing aid rehabilitation visit where the individuals' needs, prerequisites and expectations are discussed. At this first visit the audiologist gives informational counselling about the hearing loss and hearing aids. The audiologist and the individual then formulate goals and plans for the rehabilitation. Based on this discussion, decisions for appropriate hearing aids and earmold impressions (if necessary) are made. The hearing aid fitting visit and the subsequent follow-up visits include informational counselling (e.g. how to operate and adapt to the aids), therapeutic counselling, fine-tuning of amplification, and functional evaluations (e.g. speech in noise and/or real ear insertion gain) where the extent of each element varies with respect to the individual's need. The conventional hearing aid rehabilitation normally includes two to three follow-up visits. At the completion of the hearing aid rehabilitation, functional evaluations and the user's reported benefits from using the aids are evaluated. This subjective evaluation is sometimes complemented by self-report measures (Dillon, 2001; Smeds & Leijon, 2000). Most hearing clinics also offer a long-term follow up subjected to an individual visit or to a group visit.

The conventional hearing aid rehabilitation in Sweden is considered to vary due to regional differences and to individual audiologists. In effect, the number of visits and the time spent in informational and therapeutic counselling may differ from the description and Figure 1 above.

Counselling approaches

There have been many approaches to providing rehabilitation to individuals with hearing impairment in addition to the fitting of hearing aids. For example, counselling can be provided in group or individually. Additional counselling can take place before (pre) or

during the hearing aid rehabilitation or after (post) the hearing aid fitting and each approach may have a different focus. In general, counselling approaches often focus on communication strategies and auditory training (e.g., lip-reading classes).

Pre-counselling

Counselling providing pre-hearing aid rehabilitation is an uncommon counselling approach in research and only three studies have been found that dealt with pre-counselling (Brooks, 1979; Kemker & Holmes, 2004; Norman et al., 1994). The study by Kemker and Holmes (2004) was performed as a group counselling where users were randomized and received two sessions of counselling either pre or pre and post hearing aid fitting. The counselling was a combination of communication skill training and hearing aid orientation. The hearing aid orientation included basic anatomy and physiology and counselling on their specific hearing impairments and needs. The counselling also included a one-on-one session where users received a written packet of materials that went along with the sessions. The other two studies consisted of individual pre-fitting counselling (Brooks, 1979; Norman et al., 1994). The study by Brooks (1979) included not only a pre-fitting home visit but also an extensive follow-up. The pre-visits covered assessment of communication difficulties, modification of attitude and expectations. The purpose with the post-visits was to provide all information and services that could be provided through counsellors. The pre-visit in the study by Norman et al. (1994) was performed at users' homes or at the hospital and included significant others. Hearing related problems were discussed and information about hearing loss and hearing aids were provided.

Kemker and Holmes (2004) showed that those receiving pre-counselling had slightly greater improvements with regard to social listening and indicated that user competency with hearing aids were attained more efficiently. They concluded that pre and pre-post-counselling were more effective and obtained higher satisfaction than the control for those with high initial scores for disability. Brooks (1979) did not show separate analyses for the effectiveness

of pre versus post-fitting but showed that the experimental group used their aids more, perceived less social participation restriction and was assessed to have better competence in manipulating the aids. Brooks and Johnson (1981) indicated the advantages with pre-fitting visits and stressed that this visit established a personal relationship that made the users more relaxed, less anxious and more receptive. By contrast, Norman et al. (1994) failed to show any differences between the treatment and control group with regard to usage, benefit and satisfaction with the aids. The studies above were rather small, had different designs and used different inclusion criteria. Thus, there were certainly conflicting conclusions about the values of pre-counselling.

Counselling-during hearing aid fitting

Another approach aims to extend the counselling during fitting of the hearing aid. Here, like in prior cases, few studies exist. One study where such counselling methodology is well described is a study by Eriksson-Mangold et al. (1990). The purpose of the study was to increase users' own activity by following a task-oriented diary during five visits in the clinic. The users who received this extended counselling showed increased motivation, hearing aid use, and increased awareness of the limitations of hearing aids. Another observation was that users in the treatment group talked more freely with the therapists. The trend of increased hearing aid usage still remained at the 4.5 years follow-up (Eriksson- Mangold, 1991; Eriksson-Mangold et al., 1990). According to these findings the process of an active commitment would thus lead to more positive attitudes to hearing aid use.

Post-counselling-in group

The most common approach of additional counselling is group counselling performed post hearing aid delivery. In a review by Hawkins (2005) investigating the effects of group counselling, all twelve studies identified were conducted post hearing aid fitting. Most of these group courses consisted of four sessions and included information about hearing,

hearing loss and hearing aids and included sessions focusing on communication strategies (Abrams et al.,1992; Andersson et al.,1995c; Beynon et al.,1997; Hallberg & Barrenäs, 1994; Norman et al.,1995), whereas other courses emphasized more on communication strategies such as speech reading training, active listening training, and hearing tactics (Abrams et al., 2002; Chisolm et al., 2004; Hickson et al., 2006, Kramer et al., 2005). Some counselling courses also included the significant other (Hallberg & Barrenäs,1994; Hickson et al., 2006; Preminger, 2003). Individuals who were given post-fitting counselling with information about hearing loss, hearing strategies and communication skills in addition to the hearing aid fitting procedure reported less hearing-related activity limitations and participation restrictions as compared to those who only received hearing aids (Abrams et al., 1992; Andersson et al., 1994; Beynon et al., 1997). Individual or group counselling with a focus on communication strategies and training showed additive effects with regard to improved communication and decreased participation restrictions, but not general improvements in emotional variables (Dillon, 2001; Kramer et al., 2005; Hawkins, 2005; Sweetow & Palmer, 2005). Hawkins (2005) stressed that the assessments from group counselling are often performed within four to eight weeks post-rehabilitation, and that assessment is warranted in the long term. Those studies identified with long term assessment showed no long-term transfer effect (Hawkins, 2005).

Post-counselling-individual

Individual counselling performed post hearing aid rehabilitation focusing on communication strategies was performed in a study by Kramer et al. (2005). Instead of learning communication strategies in groups, the participants received videotapes and an instruction booklet. Improved scores were shown for satisfaction and quality of life for the treatment group. Individual counselling performed post-rehabilitation that was not focused on communication strategies was performed in two studies (Cherry & Rubinstein, 1994;

Primeau, 1997). In a study by Primeau (1997), the counselling consisted of an additional visit regarding hearing aid adjustment, modifications, repairs, remakes and/or counselling in addition to the hearing aid fitting. The authors did not present separate data for those receiving only hearing aid fitting versus those receiving the additional counselling visit, but they did conclude that a majority of the users had reduced feelings of hearing handicap following hearing aid fitting. Cherry and Rubinstein (1994) provided counselling in three telephone interviews where users were asked about problems with the hearing aids and further counselled when needed. This intervention did not result in any additional effects for the treatment group with regard to satisfaction and hearing aid use. However, the number of complaints related to hearing and hearing aids were reduced in the treatment group as compared to that in the control group.

Overall conclusions about counselling

It is obvious that the post-counselling approach is most commonly used in research when providing additional counselling in audiological rehabilitation and that there are indications for its effectiveness. However, it is difficult to draw firm conclusions about the effectiveness of counselling performed before or during the hearing aid rehabilitation due to the limited number of studies. There is no consensus about when the counselling is best provided and Dillon (2001) expressed that most of the counselling could be provided either pre- or post-hearing aid fitting. Issues relating to attitude, motivation and the choice of hearing aid have been stressed to be provided before hearing aid fitting (Dillon, 2001). Thus, successful rehabilitation implicitly presupposes that the hearing impaired person must first acknowledge and accept the hearing loss (Backenroth & Ahlner, 2000; Danermark, 1998).

It should be considered that the approach taken to provide hearing aids differs between countries. In Sweden, the conventional audiological rehabilitation usually includes counselling in the areas described above. Naturally, the amount and content of the counselling

sessions vary, and counselling in communication strategies (i.e., speech reading training and active listening training) is generally not included in Swedish clinics.

Evaluations in audiological rehabilitation

The outcome of hearing aid rehabilitation can be assessed in both subjective and objective ways (Arlinger et al., 1998). Assessments of hearing aid outcomes have gradually changed focus from objective measurements to subjective measurements of activity limitation, participation restriction and general satisfaction. In the past, the audiologists were considered the experts and decided when the hearing aid rehabilitation was complete and how successful it was. The audiologist's decision was essentially based on clinical measurements of auditory functioning that include insertion gain measurements and/or speech recognition tests (Cox, 2003). It was assumed that optimizing auditory functioning with hearing aids would lead to improved activity, participation and quality of life. However, there is no guarantee that these outcomes are automatic or optimal, and objective tests cannot grasp an individual's personal experiences of real-life situations (Boothroyd, 2007; Cox, 2003; Eriksson-Mangold, 1991; Noble, 1998). In fact, a lack of correlation is often seen between clinical measurements of auditory functioning and self-assessed benefit (Boothroyd, 2007). With a changing focus towards a more client-driven rehabilitation process and increasing understanding about the weak relationship between objective tests and user experiences, the amount of interest in evaluating hearing aid rehabilitation with self-reports has increased and their use as valid methods of evaluating rehabilitation has been accepted (Cox, 2003).

In accordance with the ICF, (WHO, 2001) the environmental and the personal factors affecting the outcomes of rehabilitation are increasingly being included in evaluations of rehabilitation schemes.

Evaluations in terms of the ICF

The ICF is a biopsychosocial model of health that describes the consequences of a health condition and the three levels of disablement and functioning: body functions and structures at the organ level, activities at the personal level, and participation at the person-in-society level. These three levels interact with each other and are influenced by personal and environmental factors, which in turn influence a person's health condition (Rimmer, 2006; Saunders et al., 2005).

The ICF framework could be used when assessing the benefits of hearing aid amplification by examining a person's reductions in impairments, activity limitations and participation restrictions (Chisolm et al., 2007). *Impairment* means loss of body functions and structures that result in a significant deviation from or loss of normal function (e.g., hearing loss). *Activities* means what a person can do, and *activity limitation* refers to difficulties an individual may have in executing certain activities in a controlled situation (e.g., inability to understand spoken conversation). *Participation* is involvement in a life situation or *what* a person does, and *participation restrictions* are the effects of problems an individual may experience with involvement in life situations (e.g., withdrawing from social situations) (Chisolm et al., 2007; Rimmer, 2006). The ICF also includes environmental and personal factors, which might have impacts, either negative or positive, on an individual's capacity to execute actions and tasks as well as their health-related state. Environmental factors include the physical, social and attitudinal environments in which a person lives and interacts (e.g., hearing aid wear, support from significant others and attitudes from society). Personal factors are related to gender, age, race, other health conditions, education, lifestyle, interest, coping styles and past and current experiences.

Self-reports in audiological rehabilitation

There are many existing self-reports used to assess the outcomes of audiological rehabilitation (Bentler & Kramer, 2000; Noble, 1998; SBU, 2003). In audiological rehabilitation, it is common to describe outcomes in terms of *benefit* and *satisfaction*. Benefit, or the degree of change, is measured by the extent of activity limitation and/or participation restriction (Cox, 2003). One of the more frequently used self-reports for evaluating activity limitation is the Abbreviated Profile of Hearing Aid Benefit (APHAB) (Cox, 2003; Cox & Alexander, 1995; SBU, 2003). Self-reports addressing the residual participation restriction are less common (Cox, 2003), but the Hearing Handicap Inventory for the Elderly (HHIE) (Ventry & Weinstein, 1982) is one of the most frequently used to assess this parameter (Chisolm et al., 2007; Hawkins, 2005; SBU 2003; Weinstein, 2000). Satisfaction is a multidimensional construct and is defined by Cox (2003) “as the aggregate of the individually weighted physical, social, psychological and financial changes resulting from acquiring and using hearing aid” (p.92). Satisfaction has been measured with different scales, and in the review of Wong et al. (2003) the most common outcome measure uses a categorical scale. Wong et al. (2003) found only two measures that had been standardized: the Satisfaction with Amplification in Daily Life (SADL) (Cox & Alexander, 1999) and the Marke Trak Satisfaction Survey (Kochkin, 1990). These two self-report measures are frequently used as satisfaction measurement tools.

Saunders et al. (2005) pointed out the difficulties encountered when evaluating hearing aid outcomes, since no single metric is adequate for understanding the full array of possible hearing aid outcomes. Humes et al. (2001) concluded that one specific domain of hearing aid outcome has usually been targeted rather than a wide range of outcome measures, and further suggested that efficacy would be the greatest when assessing seven domains. This is reflected in the International Outcome Inventory for Hearing Aids (IOI-HA) instrument that was developed by a group of researchers (Cox et al., 2000). The IOI-HA includes the seven

domains as: hearing aid use, benefit, residual activity limitation, satisfaction, residual participation restriction, impact on others, and quality of life. This self-report measure has been translated into twenty-three different languages and has been used in several studies (www.ausp.memphis.edu/harl/oiha.html).

Preminger (2007) underscored the importance of multidimensional outcomes and claimed that the measures used to assess psychosocial benefit following additional rehabilitation have not been effective. Preminger claimed that studies have failed to support the use of self-report measures for evaluating the multidimensional psychosocial aspects of hearing loss. The reaction to a hearing loss may be categorized in terms of emotional, cognitive, interpersonal, behavioural and physical effects; therefore, Preminger suggested a combination of outcome measures to encompass all of these areas.

It is reasonable to ask how different aspects of audiological treatment impact quality of life (Chisolm, 2007). The HHIE is effective for measuring emotional and behavioural effects and is the most commonly used outcome for evaluating the psychosocial effects of group rehabilitation (Hawkins, 2005). In a review by Chisolm et al. (2007), the HHIE was found to be the most commonly used disease-specific instrument for measuring health-related quality of life. They also concluded that hearing aid use improved adults' health-related quality of life by reducing the psychological, social and emotional effects of the hearing loss. Saunders et al. (2005) stressed the importance of also including generic outcome measures in audiological rehabilitation, which provides the ability to compare cost-benefit analyses and the impact hearing aids have on quality of life and gives a better understanding of the generic issues underlying rehabilitation.

Self-reports in audiological rehabilitation in Sweden

In the early 1990's, Eriksson-Mangold (1991) noted that hearing clinics in Sweden only sparsely used standardized self-report instruments for measuring perceived activity limitation

and participation restriction. Even today, Swedish research studies related to assessments of participation restriction using standardized self-reports are lacking. Only a few self-report measures have been translated into Swedish or standardized for a Swedish population. Among the standardized self-reports used in Swedish studies are the Hearing Measurement Scale (HMS) (Noble & Atherley, 1970), the Hearing Disabilities and Handicap Scale (HDHS) (Hetu et al., 1994), the Gothenburg Profile (GP) (Ringdahl et al., 1998), the Communication Strategies Scale (CSS) (Demorest & Erdman, 1987), the Hearing Coping Assessment (HCA) (Andersson et al., 1995a), and the Abbreviated Profile of Hearing Aid Benefit (APHAB) (Cox & Alexander, 1995). A short description of the use of the self-report measures follows below.

Some researchers in Gothenburg started to use the HMS (Eriksson-Mangold & Carlsson, 1991; Eriksson-Mangold et al., 1992a; Hallberg et al., 1993; Hallberg & Barrenäs, 1994; Hallberg & Carlsson, 1991;), a rather extensive self-report measure with forty-three items assessing activity limitation and participation restriction. This self-report measure was shortened and renamed the HMS-25 (Eriksson-Mangold et al., 1992b). The original HMS was modified by Hetu et al. (1994) into a 20-item scale, named the HDHS, which was further used in three different Swedish studies (Hallberg, 1998; Hallberg, 1999; Barrenäs & Holgers, 2000).

The GP was a modification of the HMS-25, with the main objective of being routinely used in the clinic not as an evaluation scale but as an assessment of psychosocial needs (Ringdahl et al., 1998). The GP was routinely used in the clinic in Gothenburg and two published studies were found that reported use of the GP (Arlinger et al., 1998; Hörselskadades Riksförbund (HRF), 2004).

The CSS has been translated by Hallberg et al., (1992) and used in at least ten studies (Andersson et al., 1995d; Andersson et al., 1997; Barrenäs & Holgers, 2000; Hallberg 1998;

Hallberg, 1999; Hallberg & Barrenäs, 1994; Hallberg & Carlsson, 1991; Hallberg et al., 1993; Hallberg et al., 2008; Ringdahl et al., 2001)

The HCA was developed by Andersson et al. (1995a) to evaluate the experienced activity limitations and participation restrictions of a treatment. This questionnaire was used by Andersson in seven studies but has not been further reported in Swedish studies (Andersson & Green, 1995; Andersson & Rask-Andersen, 2002; Andersson et al., 1995a; Andersson et al., 1995b; Andersson et al., 1995c; Andersson et al., 1995d; Andersson et al., 1997).

The APHAB primarily evaluates activity limitation and has been used in three Swedish studies (Arlinger et al., 1998; Arlinger et al., 2000, Berninger & Karlsson, 2000).

No Swedish study was found that incorporated the internationally frequently used SADL, HHIE or IOI-HA questionnaires.

Thirteen published Swedish studies were found where multiple standardized outcome measures were used to investigate various aspects of potential benefits of rehabilitation (Andersson et al., 1995d; Andersson et al., 1997; Arlinger et al., 1998; Barrenäs & Holgers, 2000; Eriksson-Mangold & Carlsson, 1991; Hallberg, 1994; Hallberg, 1998; Hallberg, 1999; Hallberg & Barrenäs, 1994; Hallberg et al., 1993; Hallberg et al., 2005; Hallberg et al., 2008; Ringdahl et al., 2001). There might be additional studies reported (and missed here), but the overall picture is that few studies have been reported over a 20-year period of audiological research.

Psychosocial outcomes can be assessed with self-reports such as the HHIE or with the CSS subscale that assesses the maladaptive behaviour in communication situations (e.g., withdrawal). As mentioned by Danermark (1998), hearing impairment also causes emotional consequences related to anxiety, reduced satisfaction and negative self-image. Assessment for the presence or absence of anxiety and depression can be evaluated with the Hospital Anxiety

and Depression Scale (HADS) (Zigmond & Snaith, 1983). Furthermore, the Sense of Coherence questionnaire (SOC) (Antonovsky, 1987) can be useful in audiological rehabilitation. The SOC assesses the subject's intrapersonal sense of experiencing the environment as comprehensible, manageable and meaningful.

To assess whether the audiological rehabilitation has increased satisfaction, the SADL is an appropriate self-report.

Although some studies have used standardized self-reports, there are many aspects of self-report measures that need to be further investigated in Sweden. Thus, there is a need for more reliable self-report instruments for audiological rehabilitation in Sweden that cover different aspects of the rehabilitation.

Evaluating time period

When assessing the effects of rehabilitation, it is important to consider the time period of the evaluation. Often, the most practical time to evaluate is at the final session, when the user has completed the hearing aid fitting. However, there is always a risk that the scores might be exaggerated if the evaluations are performed too soon after the first hearing aid fitting session. Using the HHIE to assess activity limitation and participation restriction, several studies have found better scores three weeks post-fitting as compared to assessments performed 3-6 months later (Hawkins, 2005; Malinoff & Weinstein, 1989; Newman et al., 1993; Taylor, 1993). This has been referred to as the "honeymoon effect" and is described as an initially favourable reaction by the users, who are pleasantly surprised by the benefits of the hearing aids (Malinoff & Weinstein, 1989). To avoid this honeymoon effect, it has been suggested that the assessments should be performed approximately 6-8 weeks after hearing aid fitting, since several studies have shown that the data tend to be stable over this period (Dillon, 2001; McArdle et al., 2005; Mulrow et al., 1992; Wong et al., 2003). It has also been suggested that

rehabilitation should be evaluated over the long term, as this area of study is currently lacking data (Hawkins, 2005; Wong et al., 2003).

The clinical global impression

As mentioned by Saunders et al. (2005), no single outcome measure is adequate to fully understand the overall effect of hearing aid rehabilitation. This means that an evaluation of the treatment outcome often involves several measures that exceed the limits of what could reasonably be administered in typical clinics. In clinical practice, it is important to form an overall clinical impression of the effects of rehabilitation, including the success or failure of a hearing aid fitting. One solution may be to validate and formally evaluate clinical impressions by using a global interview measure, as is done in psychiatric evaluations (Stein et al., 2007). One example of a global interview measure used in psychiatric research is the Clinical Global Impression Improvement scale, which requires the clinician to rate how much the patient's illness has improved or worsened relative to a baseline state. A patient's illness is compared in terms of change over time and rated as very much improved, much improved, minimally improved, no change, minimally worse, much worse, or very much worse (Guy, 1976). In the field of audiological rehabilitation, however, there is no consensus on which parameters should be incorporated into this interview. Consistent with the suggestions by Dillon (2001), the clinician should at least explore whether hearing aid owners use their aids, if they derive any benefit from them, whether they are satisfied, and whether they have any remaining problems with their aids. These and more parameters can be included in a semi-structured interview with the users where they have the opportunity to more freely express their experiences.

Rationale for the approaches

Rationale for the pre-fitting approach

The goal of this thesis was to develop and evaluate new approaches in audiological rehabilitation as related to increased activity and participation. The decision was made to provide increased client activity and participation in pre-fitting interventions. The main justification for the pre-fitting approach was the assumption that a good start to the rehabilitation process might increase the participants' knowledge, awareness and motivation about the hearing impairment and the hearing aids. This might then translate into increased global improvement during rehabilitation. Another reason for choosing the pre-fitting approach is that pre-fitting interventions remain largely unexplored and outcomes from the few pre-fitting studies conducted thus far have been conflicting. In this thesis, the pre-fitting approaches targeted were user-controlled adjustments and sound awareness training.

Rationale for user controlled adjustment

The purpose of user controlled adjustment was to allow the users to try out and explore many possible hearing aid settings, while at the same time reflecting on the consequences of these changed settings. This means that the user is the one who is active in making the decisions, and that the audiologist acts only as a coach (Clark, 2007). These exercises may give users a deeper understanding of the possibilities and limitations of hearing aids. This knowledge might yield more realistic expectations, which could then facilitate the upcoming hearing aid fitting. It has been shown that users with more realistic expectations are more frequent hearing aid users (Brooks & Johnson, 1981; Kricos et al., 1991).

Rationale for sound awareness training

As hearing aid users' most frequent complaint is that the "aids become too loud," (Jenstad et al., 2003), the purpose of our sound awareness intervention was to gradually build up experiences to sounds, in order to reach a level of acceptance. Many first time hearing aid users expected only amplification of speech and were overwhelmed by the many new sounds

amplified through the aids. Thus, it was assumed that if users could be more aware and better experienced to the many new sounds and those sounds that were considered “louder than before,” they might also accept the hearing aids more positively, and increasing their satisfaction. In exercises where users analysed different sounds in their environment, it was hypothesized that the acceptance for sounds would increase; this phenomenon has been previously observed (Eriksson-Mangold et al., 1990). The sound awareness training was also hypothesized to make the users more curious about the sounds coming from their aids, with the additional intention of increasing users’ willingness to start and continue usage of their aids.

During the exercises in the pre-fitting interventions, the users were automatically subjected to the terminology used in audiological rehabilitation. This was intended to increase the users’ knowledge and provide a better opportunity to interact with the audiologist in the upcoming rehabilitation (Boothroyd, 2007; English, 2005; Eriksson-Mangold et al., 1990; Hellström, 1995; Rankin & Stallings, 2001).

Rationale for the research design

It has been concluded that there is a lack of well-designed experiments (e.g., randomized controlled trials; RCTs) from which to draw firm conclusions on the effects of different interventions (Chisolm et al., 2007; Hawkins, 2005). Besides the lack of RCTs, there is an absence of studies that clarify the long-term effects of interventions on a general population of persons with hearing impairment. It will also be desirable in future studies to include multiple outcome measures that tap into various aspects of potential benefits, such as reduction in perceived activity limitation and participation restriction, personal adjustment, anxiety and depression, use of communication strategies, hearing aid benefit and satisfaction, and quality of life (Hawkins, 2005). In light of these considerations, the intervention studies in this thesis were designed as RCTs with a one-year follow-up. Participants were recruited consecutively

from a regular clinical waiting list. Various outcomes were evaluated, including hearing aid benefit, hearing aid satisfaction, activity limitation, participation restriction and psychosocial well-being.

Aims

The general aim of this thesis was to develop and evaluate new interventions and to develop new evaluation approaches in audiological rehabilitation.

Specific aims:

Paper I:

Collect descriptive data on a range of translated hearing specific self-report questionnaires and a number of psychosocial self-reports in order to investigate their psychometric properties and investigate the interrelationships.

Paper II:

Develop and evaluate the effects, in both the short and long term, of a user-controlled pre-fitting adjustment intervention as compared to those of a control group.

Paper III:

Develop and evaluate the effects, in both the short and long term, of a sound awareness pre-fitting training intervention as compared to those of a control group.

Paper IV:

Develop and investigate the validity of a new telephone administered interview instrument evaluating the clinical global impression of audiological rehabilitation (AR-CGI) in the long term.

Materials and Methods

Table 1 shows the aims, participants, designs and the outcomes used in the studies. A subset of one to eight questionnaires has been used in the different papers. The different questionnaires were numbered and were as follows: 1. SOC, 2. HHIE, 3. ECHO, 4. SADL, 5. CSS, 6. HADS, 7. IOI-HA, 8. COSI (for a further description see below questionnaires). All users were first time users (FTU), meaning that they received their first hearing aids (HA). Papers II and III reported the results of RCTs, and in these studies the questionnaires were filled out four times. In study IV, the aim was to evaluate an audiological rehabilitation clinical global impression (AR-CGI) measure.

Table 1. Outline of papers in the thesis

Paper	Aim	Participants	Design	Outcomes and time for evaluations
I	Evaluations of data and psychometric properties of self-reports	162 FTU	Survey Descriptive	One year follow-up 1,2,4,5,6,7
II	Evaluate the effects of a user-controlled adjustment pre-fitting intervention	19 FTU (treat) 20 FTU (ctrl)	RCT	Baseline 1,2,3,5,6 Pre HA 2,3,5,6 Post HA 2,4,5,6,7 Post one year, 2,4,5,6,7,8
III	Evaluate the effects of a sound awareness training pre-fitting intervention	19 FTU (treat) 19 FTU (ctrl)	RCT	Baseline 1,2,3,5,6 Pre HA 2,3,5,6 Post HA 2,4,5,6,7 Post one year, 2,4,5,6,7,8
IV	Development and validation of a clinical global impression instrument	69 FTU (from RCT sample) 21 FTU (clinic)	Telephone-interview	One year follow-up Categorization 7

Participants

Information about the participants regarding age, gender and mean pure tone average (PTA) is presented in Table 2.

Table 2. Age, gender and PTA for included participants

Paper	Mean Age (years)	SD	Gender men/women	Mean PTA (dB HL) better ear	SD (dB)
I	66.6	9.5	96/66	37.0	9.5
II Treatment	68.6	7.7	10/9	37.8	6.3
II Ctrl	69.8	7.5	12/8	35.7	6.7
III Treatment	67.1	7.9	12/7	35.6	7.1
III Ctrl	65.5	6.9	13/6	35.6	7.9
IV RCT-sample	68.1	7.1	41/28	36.2	7.0
IV Clinic sample	65.4	5.3	13/8	32.3	11.1

Inclusion and exclusion criteria

The criteria to be included in studies I, II, and III were as follows: symmetric sensorineural mild (PTA 26-40 dB HL) to moderate (PTA 41-60dB HL) hearing loss (WHO, 2001), and first-time-users aged 20-80 years, in good general health and fluent in the Swedish language.

Participants included in study I were recruited from a follow-up list in the county of Östergötland. In studies II and III, the hearing impaired individuals were recruited consecutively from the regular clinic waiting list at the University Hospital in Linköping, Sweden. The sample in study IV consisted of participants from studies II and III and a clinical sample recruited from a follow-up list at the same clinic. The criteria for the clinical sample in study IV included first-time-users aged 20-80 years, fitted with monoaural or binaural digital hearing aids at least six months prior. The exclusion criterion in study II and III was evidence

of cognitive deficits during the interview or on a test of verbal fluency (the Controlled Oral Word Association Test, Lezak, 1995).

Randomization

The randomization procedure was performed by an independent researcher (papers II and III). The researcher allocated the participants according to a computer-generated randomization list, and the audiologists who saw the participants in the clinic were blind to this list.

Questionnaires

Eight standardized questionnaires were used in the studies to evaluate hearing aid outcomes as well as psychosocial well-being (Table 1). The instruments chosen were considered to be short, easy to fill out and appropriate for clinical use. Four of the questionnaires, the Expected Consequences of Hearing aid Ownership (ECHO) (Cox & Alexander, 1999, 2000), the Satisfaction with Amplification in Daily Life (SADL) (Cox & Alexander, 1999), the Hearing Handicap Inventory for the Elderly (HHIE) (Ventry & Weinstein, 1982) and the International Outcome Inventory for Hearing Aids (IOI-HA) (Cox et al., 2000), were independently translated into Swedish by three researchers. The translations were compared, and when minor discrepancies were found, these were discussed and corrected before the questionnaires were translated back into English by a native English-speaking person. The two resulting English versions were then compared, and any discrepancies were subsequently resolved. The characteristics of the questionnaires are described below.

The ECHO (Cox & Alexander, 1999, 2000) was used to identify clients' expectations *before* hearing aid rehabilitation. It was a 15-item questionnaire divided into four subscales measuring personal image (PI), positive effect (PE), negative feature (NF) and service and cost (SC). The users rated their expectations on a seven-point scale and the items were presented as statements assessing different degrees of agreement or disagreement. Higher scores indicated higher expectations.

The SADL (Cox & Alexander, 1999) included the same items as the ECHO questionnaire but assessed the level of satisfaction *with* the hearing aid. Comparing the scores between ECHO and SADL may reveal whether expectations have been reached.

The HHIE (Ventry & Weinstein, 1982) was designed to assess the effects of hearing impairment in elderly people. It consisted of 25 items divided into two subscales. Thirteen items explored the emotional consequences of hearing impairment (HHIE E), and 12 items explored the social and situational effects (HHIE S). There were three response options for each item: yes (score=4), sometimes (2), or no (0). Higher scores represented greater perceived activity limitation and participation restriction.

The Communication Strategies Scale (CSS) was a part of an extensive questionnaire, namely the Communication Profile for the Hearing Impaired (Demorest & Erdman, 1987). The CSS consisted of 25 items divided into three subscales: maladaptive (M), verbal (V) and nonverbal scales (NV). Thus, the CSS assessed both adaptive and maladaptive communication strategies. Responses were rated on a five-point scale from almost never (1) to almost always (5). Higher scores for CSS M indicated less maladaptive behaviour and higher scores for CSS V and CSS NV indicated greater use of verbal and nonverbal strategies.

The IOI-HA (Cox et al., 2000) was a seven-item questionnaire designed to evaluate the effectiveness of the hearing aid treatment. Each item represented a different outcome domain and had five possible responses, ranging from the worst (1) to the best (5) outcome. Higher scores indicated a better outcome. The represented outcome domains were: daily use, benefit, residual activity limitation, satisfaction, residual participation restriction, impact on others, and quality of life.

The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) was useful for assessing presence or absence of symptoms of anxiety and depression in medical outpatients. The HADS consisted of 14 items, each of which has four response choices (0-3),

with subscales for anxiety (HADS A) and depression (HADS D) consisting of seven items each. Higher scores indicated more symptoms of anxiety or depression.

The short form of the Sense Of Coherence scale (SOC) (Antonovsky, 1987) consisted of 13 items scored on a seven-point scale (1-7) where the response was a choice between different degrees of agreement or disagreement. The items were related to the participants' feelings and experiences, and were expressed as: "Do you have the feeling that you are treated unfairly?" or "How often do you have feelings that you are not sure you can keep under control?" Participants with higher scores were expected to cope more successfully with stressful situations.

The Client Oriented Scale of Improvement (COSI) (Dillon et al., 1997) was used to evaluate the benefit of the conventional hearing aid fitting (II, III). In COSI, the user identified and ranked one to five listening situations in which hearing aids were expected to help. In this study, the COSI questionnaire was completed for both the unaided (before hearing aid fitting) and the aided (after hearing aid fitting) conditions.

Procedure

Paper I

One year after hearing aid fitting, six questionnaires (see Table1) were sent out to a consecutive sample of 203 first-time-users in the province of Östergötland, Sweden. The questionnaires were administered from October 2004 to February 2005 and were completed by 162 users with a response rate of approximately 80 percent.

Paper II

This study was conducted in the autumn of 2004 and participants were randomly assigned to a pre-fitting intervention, including user-controlled adjustments (UCA) of the amplification, or to a control group (the design is shown in Figures 2 and 3). The pre-fitting intervention consisted of three visits to the clinic, one visit per week. At the first visit, the participants

were fitted with a specific user-controlled adjustment experimental aid (Elberling & Vejby Hansen, 1999) programmed at an initial setting. At the following two visits, the users adjusted the experimental hearing aid themselves to their preferred settings in various dialogue situations with natural background sounds. The users wore the hearing aids at home between visits. This exercise focused on the user's own activities and interactions, and was thought to explore the possibilities and limitations of the amplified sound.

Following the first pre-fitting phase, both groups received an identical hearing aid fitting procedure (see Figure 2). Assessments of the effects were performed with self-reports at four different times: baseline, before (pre) HA, after (post) HA and after (post) one year (see Figure 2 and Table 1).

The audiological rehabilitation also included a one year follow-up consisting of a visit to the clinic, administration of questionnaires (see Table 1) and a telephone interview assessing the AR-CGI. This follow-up process was identical for both the treatment and control groups (see paper IV).

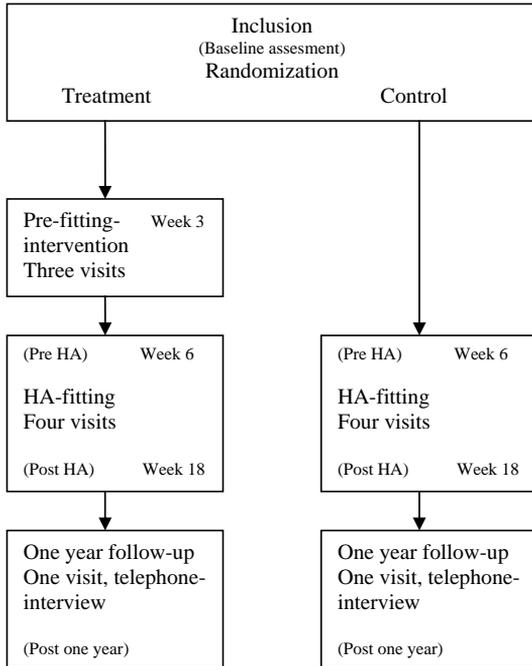


Figure 2. Design of studies II and III

Hearing aid fitting procedure

The hearing aid fitting consisted of 3-4 visits. Each visit lasted about one hour (with extra time for outcome measures). At the first appointment, the participants' individual goals for hearing rehabilitation were assessed through the COSI questionnaires (Dillon et al., 1997).

All participants were fitted with digital binaural hearing aids, Oticon Atlas Plus with the NAL-NL1 prescription (Byrne et al., 2001), and the users were allowed to select in-the-ear (ITE) or behind-the-ear (BTE) types. The prescription was modified by fine-tuning at the follow-up visits according to the participants' subjective feedback. All follow-up visits included counselling, assessment of goal achievement and fine-tuning. Functional evaluations were performed by speech recognition tests involving phonetically balanced monosyllabic words presented in quiet and noisy environments (Magnusson, 1995), and sentences in noise test (Hagerman & Kinnefors, 1995). Subjective assessments through self-reports were performed before and after the rehabilitation (Figure 2 and Table 1).

Paper III

This study was conducted in the autumn of 2005 and the design for study III (Figures 2 and 3) was the same as that of study II. In this study, however, the pre-fitting intervention was performed as sound awareness training (SA). The intervention consisted of three weekly visits (Figure 2). Each visit in the clinic consisted of different listening exercises. The participants were fitted with an experimental aid (the same as in study II). Participants were advised to listen both with and without amplification when evaluating different sounds in their daily environment. Furthermore, their experiences with the different sounds were written down in a specific diary. The first week with amplification included analyses of simple sounds such as those coming from one speaker. The following two weeks included listening tasks involving more complex sounds. The participants were equipped with a mini-disc (to record different sounds) and a Sound Activity Meter (SAM). The SAM was a tie-tack sized device that logged both quantity (in loudness and percentage of time) and quality of the sounds (with respect to quiet, noise, speech and speech in noise) (Flynn, 2005). The sounds gathered by the SAM were downloaded to a computer and presented to each user. The presented sounds could then be compared with the users' descriptions and the recorded environments.

Following the first pre-fitting phase, both groups received an identical hearing aid fitting procedure. The hearing aid fitting and the one year follow-up activities were identical to those of study II.

Paper IV

In this study, telephone interviews were administered to investigate the long term (one year post hearing rehabilitation) treatment vs. control group differences in numbers of successful and non-successful users. A semi-structured interview guide was developed as a clinical interview instrument for assessing the impression of global improvement following hearing aid fitting, here named Audiological Rehabilitation Clinical Global Impression of Improvement (AR-CGI). This guide was used during the telephone interview. The dimensions

in the interview guide mainly focused on real world experiences with amplification. A rating scale was developed, where responses to the questions were categorized into different levels of success. From the user responses and impressions gained from the interview, the interviewer then categorized the user into one of three categories: (1) successful, (2) successful with some limitations, or (3) unsuccessful.

The participants were recruited from two different samples and the procedure differed somewhat between the samples. For the RCT sample, the one year follow-up assessment included two parts: a follow-up visit at the clinic (see papers II and III) followed by the telephone interview and questionnaires (including the IOI-HA; see Table 1 and Figures 2 and 3). All telephone interviews were performed by an independent audiologist. In addition, the audiologist who saw the user at the follow-up visit and the audiologist who performed the telephone interview both assessed the overall impression (AR-CGI) of the effects, and these assessments were further compared.

To further validate the interview guide, the telephone interview approach was also repeated for a clinical sample. The follow-up activities for the clinical sample were subjected to the telephone interview and administration of one questionnaire (the IOI-HA). The individuals who declined participation in the interview were anyhow asked to fill out the IOI-HA (Figure 4). In this sample, only the telephone interviewer had the opportunity to assess the users' AR-CGI.

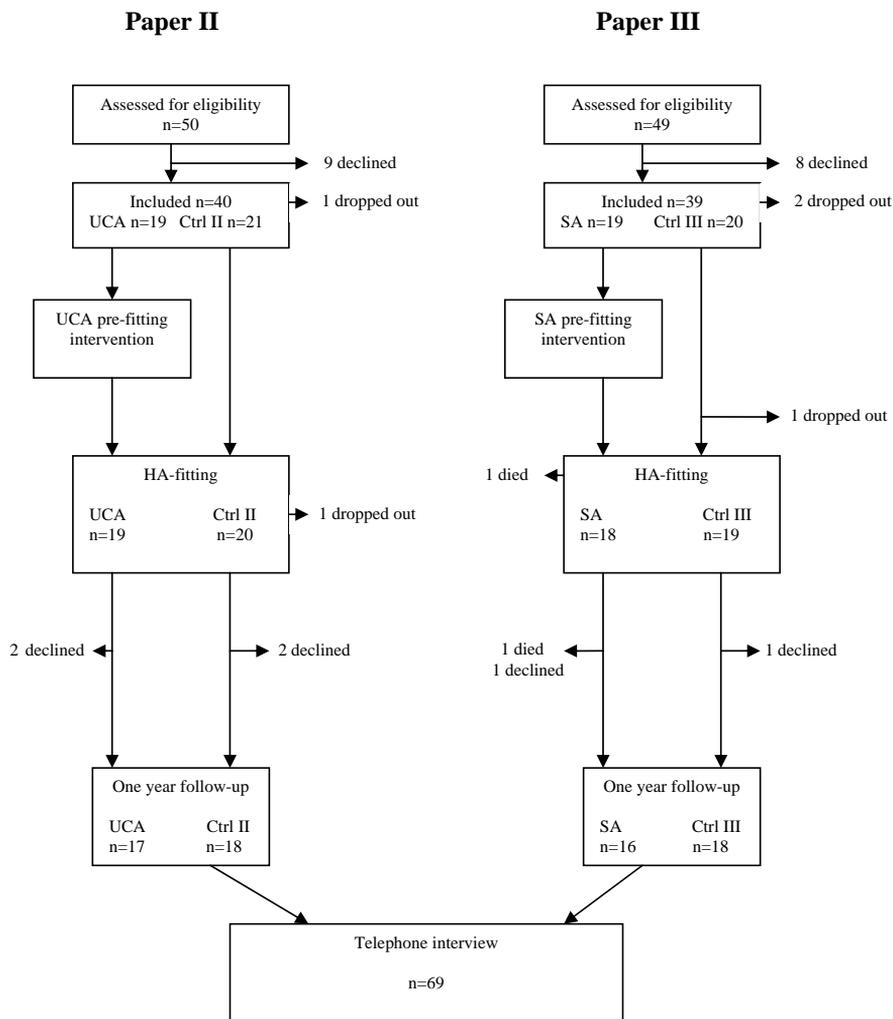


Figure 3. Flowchart for papers II, III and IV

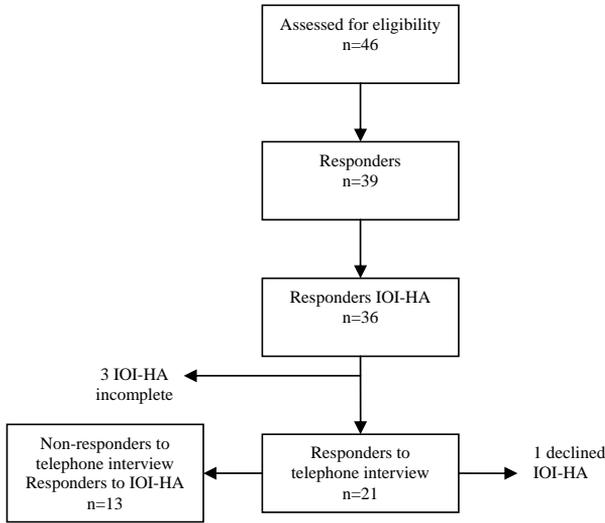


Figure 4. Flowchart for clinical sample, paper IV

Statistical analyses

A variety of statistical tests, including parametric and non-parametric statistics, were used to analyse the data.

In study I, Spearman rank order correlation and Pearson’s product moment correlation were used to investigate the association between different questionnaires. A principal components factor analysis was used to explore the interrater relationship between different questionnaires.

In studies II and III, the data were analysed with repeated measures analyses of variance (ANOVA) implemented as a general linear model to investigate between-group, within-group and interaction effects. Significant effects were examined with Bonferroni corrected post-hoc t-tests.

In study IV, the between group differences for the subscales were analyzed with the non-parametric Mann-Whitney U test due to scales that were not normally distributed or due to too few responders. Interrater reliability between the audiologists was analyzed with Cohen's kappa, which considers the amount of agreement that could be expected by chance (Clark-Carter, 2004)

All data were analyzed with the software package STATISTICA (Statsoft, 2004, version 7) and results with a $p < 0.05$ were considered significant. Results described as significant in these studies mean *statistical* significant.

Ethical Consideration

The studies were approved by the Medical Research Ethics Committee of Linköping University, Sweden (registration no. 23-04).

Results

Paper I

Mean scores for the different questionnaires were in line with the international reference data.

The internal consistency Chronbach's alpha exceeded 0.75 for all questionnaires except SADL where the test-retest reliability varied between 0.49-0.83 for the different subscales in the questionnaire.

Significant correlations were frequently observed between the different self-reports whereas few significant correlations were found between demographic variables and the self-report outcomes. Higher age was found to be related to lower satisfaction. The psychosocial variables were more associated with participation restriction (i.e., between HADS D and HHIE) and satisfaction (i.e., between HADS D and SADL PI) than with the demographic variables. The strongest correlation was seen between two questionnaires assessing satisfaction (IOI-HA F1 and SADL PE) and between two psychosocial instruments (SOC and the HADS A, and SOC and HADS D).

The varimax rotation factor analysis accounted for 67% of the total variance and extracted four factors interpreted as "psychosocial well-being", "hearing aid satisfaction", "adaptive communication strategies" and "residual participation restriction". The factor for "psychosocial well-being" explained most of the variance (22.4%) and had high factor loadings for the HADS scales, the HHIE scales, the SOC and maladaptive communication strategies (CSS M).

Paper II

Significant immediate (i.e., Baseline to Pre-HA) interaction effects and between group effects were found where the post-hoc analysis showed improvements for the treatment group with regard to activity limitation/ participation restriction (HHIE tot, HHIE E and HHIE S) and expectations (ECHO tot; ECHO PI showed only between group effects) after the pre-fitting

intervention. The detailed results of HHIE and ECHO are found in figures 6 and 8 in the below section “Results of the self-report instrument used in the different studies”. No interaction (between group and time) or between group effects were found when analysing between Baseline and Post HA and between Post HA and one year follow-up. This indicated no transfer effect of the pre-fitting intervention over either the short or long term. Significant within group effects were found for almost all subscales in the analyses from Baseline to Pre HA and from Baseline to Post HA. This meant improvements both immediately and when the conventional hearing aids were fitted. Significant within group effects were found when measuring the long term effects (between Post-HA and Post one year) for several subscales, indicating deteriorations over time. The numbers of successful users assessed in the telephone interview performed at the one year follow up was the same for both groups (Figure 5).

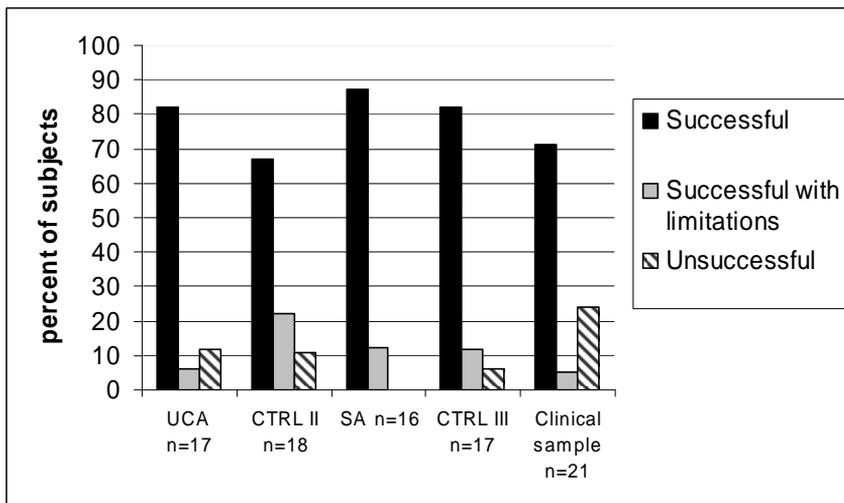


Figure 5. Distribution of the audiological rehabilitation categories, successful, successful with limitations and unsuccessful, for treatment and control groups (II, III) and the clinical sample (IV).

Paper III

One immediate interaction effect between group and time was found (Baseline to Pre HA) for ECHO negative feature (NF), where the sound awareness group became more positive on the scale assessing the negative features of hearing aids (see Figure 7). No interaction effects between group and time were found from Baseline to Post-HA. This study also showed significant within group improvements for most subscales (Figures 6 and 8). The assessment performed after one year revealed no differences between groups in regard to the questionnaires or the numbers of successful users as assessed in the telephone interview (Figure 5). Within group effects showed significant deterioration over the long term (Post-HA to Post one year) for most items/subscales.

Paper IV

The semi-structured interview guide was found to be valid due to a straightforward categorization as well as a good interrater reliability. The interrater reliability for the RCT sample had a kappa of 0.68. The majority of the users were categorized as successful, and a description of the numbers of successful and less successful users in the separate groups is seen in Figure 5.

Significant differences were found between those categorized as successful and unsuccessful users in relation to the self-reported measures (e.g., IOI-HA). The self-reported IOI-HA data correlated with the audiologists' impressions and ratings, where those categorized as successful also had higher scores for the items in IOI-HA.

In the RCT sample differences were found between successful and unsuccessful users in terms of hearing aid use, symptoms of depression, residual activity limitation and participation restriction, satisfaction and quality of life (all items in the IOI-HA). In all cases the successful users scored significantly better. Furthermore, a relationship was found between high age and less successful users.

In the clinical sample, significant differences were found between successful and unsuccessful users. It was found that successful users scored higher for hearing aid use, residual activity limitation, satisfaction and quality of life (items 1, 3, 4 and 7 in the IOI-HA). Neither PTA on the better ear nor gender differed between successful and unsuccessful users in either sample.

The analysis between non-responders (i.e., those who declined the interview and only responded the IOI-HA see Figure 4) and responders showed one significant difference: the non-responders reported less use of hearing aids.

Functional evaluations of the hearing aid rehabilitation

All groups showed significant improvements in the speech recognition test results (II, III).

The improvement of scores for phonetically balanced monosyllabic words in quiet or noise (Magnusson, 1995) as well as the speech-to-noise ratio (S/N) for sentences in the noise test (50% correct) (Hagerman & Kinnerfors, 1995) are shown in Table 3. No significant differences in scores of improvement were found between groups.

Table 3. Results of speech recognition tests. Improvement scores and standard deviations (SD) for monosyllabic words in quiet and in noise, and speech-to-noise ratio (S/N) for sentences in the noise test (50% correct)

	UCA n=19		Ctrl (II) n=20		SA n=18		Ctrl (III) n=19	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Monosyllabic words in quiet (%)	18	13 ***	16	13 ***	16	13 ***	24	19 ***
Monosyllabic words in noise (%)	23	11 ***	24	11 ***	22	8 ***	19	9 ***
Sentences in noise ^a (dB)	2.9	2.7 ***	2.4	2.7 ***	2.2	2.6 **	2.8	2.6 ***

^a Assessed at the one year follow up. UCA n=17 Ctrl (II) n=18. SA n=16, Ctrl (III) n=18.

Results of the self-report instruments used in the different studies

The HHIE, the HADS and the CSS were used in studies I-III and in studies II and III, assessments were performed four times. The ECHO was assessed two times before hearing aid fitting, and both the SADL and IOI-HA were assessed two times after the hearing aid fitting procedure (II-III). The SOC was assessed before the interventions started (II-III). In study I, the HHIE, HADS, CSS, SADL, SOC and IOI-HA were assessed one year after hearing aid fitting.

The mean HHIE scores for users in UCA, SA and the two control groups (II, III) are shown in Figure 6.

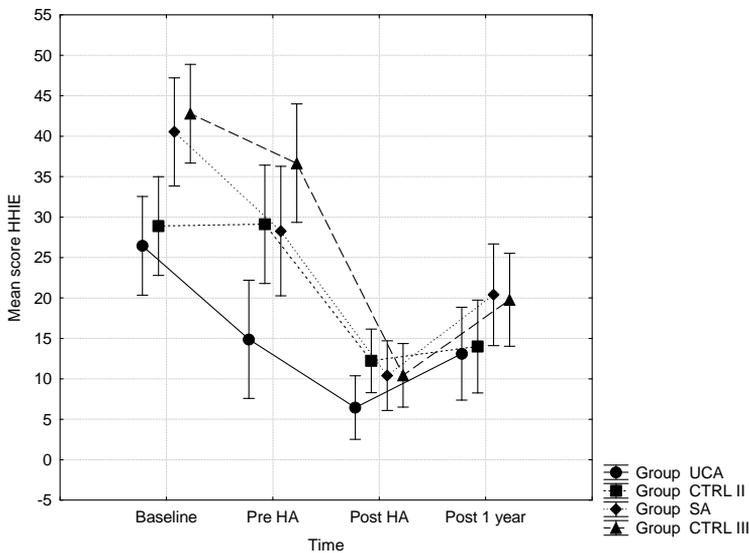


Figure 6. Mean scores and confidence intervals for HHIE measurements at Baseline, Pre-HA, Post-HA and Post one year for the different groups (II, III).

As shown in Figure 6, the pattern was the same in the two intervention studies, where significant improvements were seen once hearing aids were fitted and deterioration occurred over one year. It was concluded that activity and participation improved (from Baseline to

Post-HA) by 76% for UCA, SA and CTRL III, and 57% for CTRL II. The mean score and standard deviation (SD) for the HHIE of the sample in study I was 24.2 (17.4).

No differences between treatment and control groups were found for psychosocial well-being (HADS) in either study II or III. Significant improvement in psychosocial well-being was found for all groups between Baseline and Post-HA (Figure 7). All groups (except UCA) had mean scores of approximately 9 at Baseline, a score typical for a general Swedish population (Lisspers et al., 1997). The treatment groups SA and UCA improved their scores after audiological rehabilitation (Baseline to Post-HA) for psychosocial well-being by 54 and 44%, respectively, and the control groups II and III improved by 36 and 42%, respectively. No significant deterioration was seen over one year for either group. The mean score and SD for the HADS of the sample in study I was 6.7 (5.2).

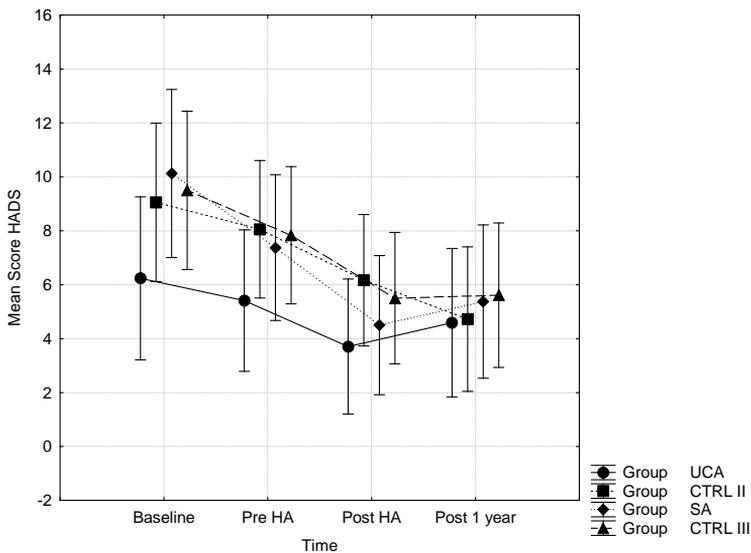


Figure 7. Means and confidence intervals for HADS measurements at Baseline, Pre-HA, Post-HA and Post one year for the different groups (II, III).

At Baseline and Pre-HA, the ECHO questionnaires were used to assess the users' expectations. At Post-HA and Post one year, the SADL was used to assess the actual perceived satisfaction. As seen in Figure 8, the expectations for treatment groups started to increase between Baseline and Pre-HA (although they were only significant increased for UCA) whereas the controls were unchanged. The pattern was the same for studies II and III in the assessments with the SADL at Post-HA, where all groups showed significantly higher scores as compared to Baseline. This indicated that users were more satisfied than they expected to be at Baseline. The satisfaction rates decreased over the long term for all groups (Post-HA to Post one year), but the deterioration was only significant for the two treatment groups.

The mean and SD of 5.2 (0.7) for the sample in study I was comparable to the scores assessed at Baseline for the intervention sample, and it could not be concluded whether the sample in study I scored lower in general or whether it was due to a larger deterioration over time.

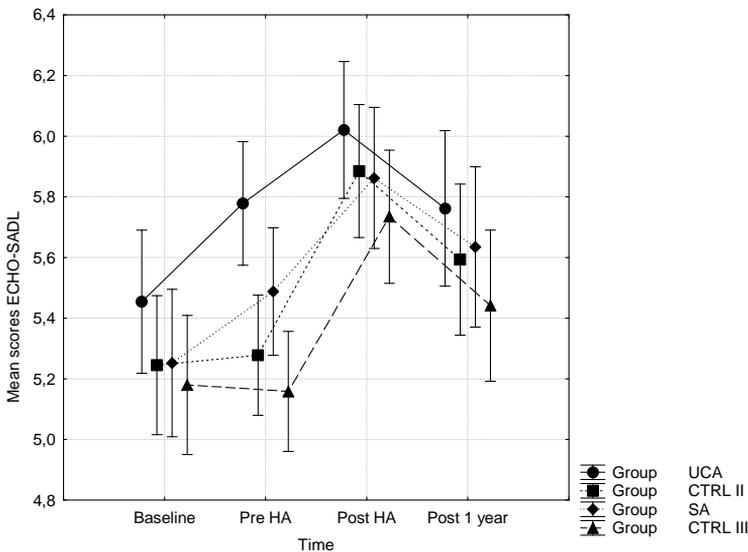


Figure 8. Means and confidence intervals for ECHO-SADL measurements at Baseline, Pre-HA, Post-HA and Post one year for the different groups (II, III).

The CSS self-report was divided into the three subscales: maladaptive behaviours (M), verbal strategies (V) and non-verbal strategies (NV). It was shown that all groups (treatments and controls) significantly improved their scores for maladaptive behaviour over time (Baseline to Post-HA). All groups reduced their scores for NV and V strategies once hearing aids were fitted (NV and V scales in the UCA group and NV scale in the SA group were not significantly reduced, see paper II and III). Lower NV and V scores meant that the participants less frequently asked for repetition or that they sought less places where the opportunity to hear was better in order to facilitate communication. A moderate to large correlation was found between maladaptive communication strategies (CSS M) and psychosocial factors (e.g., HADS/ HHIE) in which those avoiding maladaptive strategies also had higher psychosocial well-being (I).

Mean scores for the SOC were quite similar for the participants in intervention and control groups and those in the survey. Subjects with higher scores were expected to cope more successfully with stressful situations and might be more successful in their rehabilitation (Antonovsky, 1987). To investigate whether there were any relationships between coping ability, such as measured benefit, (e.g., differences between Baseline and Post one year) and SOC scores, the benefit for the different questionnaires and the subscales, for participants in the intervention studies were correlated to SOC. No significant correlation was found between SOC and self reported benefits.

As previously mentioned a high correlation was found between SOC and HADS, indicating that individuals with lower scores for SOC also seemed to be more anxious and depressed (I). Significant correlations were also found between SOC and several subscales; for example, the HHIE E, CSS M, IOI- HA F2 (the factor related to participation restriction) and hearing aid use (I). This meant that high scores for SOC were related to less participation

restriction, less use of maladaptive communication strategies and more frequent use of hearing aids.

When comparing users' scores for the IOI-HA questionnaire Post-HA with those Post one year, it was found that all items deteriorated over time in study III, whereas deterioration occurred only for the items for hearing aid use and activity limitation in study II.

Mean scores assessed Post one year for the intervention groups and the survey group were quite similar. The total scores ranged from 27.9 to 31 when comparing the intervention, control and survey groups. In all, it was concluded that approximately 40% of the users used their hearing aids more than eight hours a day. Five percent of the participants in the survey and none of the participants in the intervention studies stated that they had never worn their aids (item 1). The fourth item in the IOI-HA assessed satisfaction, and the users judged to what extent the hearing aids were "worth the trouble". It was shown that 92% in the intervention studies and 87% in the survey group rated the hearing aids as "quite a lot worth" or "very much worth" the trouble. Four percent of the users in the survey and none in the intervention studies rated the aids as "not at all worth" the trouble. It was also concluded that 75% of users in the interventions and 62% of users in the survey group stated that their quality of life (item 7) had changed to "quite a lot better" or very much better" one year after hearing aid fitting.

Discussion

The aim of this thesis was to develop new approaches for audiological rehabilitation (papers II and III). To have an opportunity to evaluate the effects of the interventions in accordance with ICF (e.g., auditory activity and participation), international self-reports had to be translated and validated (paper I). In the search for effective and concise evaluation approaches regarding the long term effects of rehabilitation, the AR-CGI (the telephone interview guide) was developed and investigated (paper IV).

Main findings

The general effects of audiological rehabilitation

As the goals of audiological rehabilitation are to reduce auditory impairment, optimize the individual's auditory activities and minimize participation restrictions, it is clear that these factors also have to be evaluated. As suggested by Saunders et al. (2005), this can not be accurately evaluated using only one simple questionnaire. Therefore several new (for a Swedish population) self-reports were included in these studies. Also as a new approach, the AR-CGI was developed and tested to take these factors into consideration when evaluating the effects of audiological rehabilitation.

The implementation of the translated standardized self-report measures was found to be successful. Internal consistencies and test-retest correlations were acceptable even if somewhat higher correlation coefficients had been desirable for some of the SADL subscales (Clark-Carter, 2004). The data were compared to previous international studies that were quite similar in demographic data to the sample and the time of measurement, and seemed to be in accordance with, or sometimes somewhat better than, the references (I). Generally, we found the outcomes of audiological rehabilitation one year after the completion of hearing aid fitting to be high, and overall the users seemed satisfied (I-IV).

Effects of pre-fitting interventions

The essential goal of a hearing aid fitting is to increase auditory function. Increased audibility cannot occur if the hearing-impaired individual does not use the provided aids. Therefore, our first aim in the rehabilitation process is to give the individuals a good start by making them receptive to hearing aid use. The pre-fitting counselling in this thesis, where the users participated in the rehabilitation more actively, was thought to create an environment supportive for changing the individual's attitudes (Eriksson-Mangold et al., 1990). The tasks and exercises in the pre-interventions were aimed at improving the overall rehabilitation, and were intended to facilitate learning and increase awareness and motivation, with a transferred effect to the following hearing aid fitting. The results, however, showed only a few short term effects and no long term effects were found. This suggested only small additional effects for the pre-interventions implemented in this thesis.

It has been shown that first time hearing aid users often have too high expectations (Cox & Alexander, 2000; Kricos et al., 1991) and that this may be an important reason for their infrequent use of the aids (SBU, 2003). The purpose in study II was to adjust the users' expectations to realistic levels by allowing user controlled adjustments, which were thought to give the users a deeper understanding of the possibilities with and limitations of hearing aids. However, it was found that the users in these studies might already had realistic expectations, as the majority showed greater scores for satisfaction (in the SADL) after rehabilitation than they did at Baseline (in the ECHO) (see Figure 8). It is possible that the questionnaires used in the intervention studies were not sensitive enough or that the assessed domains were not the most appropriate to evaluate the effects of the interventions. The users in treatment group (II) were considered to be more talkative and more engaged in the fine-tuning session in the ensuing hearing aid fitting, but these aspects were not subjected to structured evaluation. It is

possible that these exercises may have been more useful for individuals with more negative attitudes towards hearing aids (II).

In the SA intervention study (III), the purpose was to gradually build up experiences to sounds and reach acceptance for new sounds, as the users' most frequent complaints of hearing aids often involved the "aids being too loud" (Jenstad et al., 2003). It was assumed that if users could better accept the "louder-than-before sound," they might also be more receptive towards the hearing aids.

Only few short term effects and no long term effects were found, indicating only small additional effects for the pre-interventions (II, III). It is difficult to draw firm conclusions about the effects of pre-fitting interventions over the long term, since only the study by Brooks (1979), conducted nearly 30 years ago, has taken this factor into consideration. There are several possible reasons for the absence of additional effects in the treatment groups. It is possible that the participants in the studies did not experience sufficient overall problems in the area that was the subject of these interventions. The participants' initial scores on measures of activity limitation, participation restriction and psychosocial well-being were assessed and can be characterized as indicating only moderate distress. It has previously been concluded that those with greater initial scores for activity limitation received the most benefit from hearing aid rehabilitation (Borg & Bergkvist, 2007). Kemker and Holmes (2004) concluded that pre-fitting interventions were the most beneficial for users with greater initial scores for activity limitations. As mentioned by Dillon (2001), the issues relating to attitude and motivation were most likely to respond to pre-counselling, and no special attention was paid to these areas in the recruitment or evaluation process. Both the sound awareness training and the user controlled adjustment worked out well in practical terms, and the participants reported no problems in performing the exercises. One suggestion could be to somehow implement the exercises within the conventional hearing aid rehabilitation when it was

indicated that the user needed additional counselling. For example, users who returned several times to the clinic to get the hearing aids fine-tuned might be regarded as having too high of expectations or having low confidence in the audiologist doing the fine-tuning.

Considerations like this could be reasons for offering user controlled adjustment (on the assumption that this approach is available for the specific hearing aid). When a user in the clinic has great difficulties in getting used to amplified sound and/or has considerable complaints about all “new sounds” supplied by amplification, additional exercises like those included in the sound awareness intervention could be appropriate and beneficial for the user.

Few between-group differences were found between Baseline and Pre-HA; instead, it was observed that outcomes were significantly improved for all groups, treatment or control, after audiological rehabilitation. These improvements indicated that the hearing aid fitting procedure was successful. It might be speculated either that the pre-fitting interventions were not effective enough or that the hearing aid fittings were adequate, therefore masking possible group differences. However, it is possible that both the sound awareness training and the user-controlled adjustment might be ineffective over the long term regardless of inclusion criteria, time for the intervention or a more comprehensive pre-intervention.

Experiences with the self-reports

Irrespective of the groups, it was found that the psychosocial variables were significantly improved (HHIE, HADS) after hearing aid fitting (studies II and III). The fact that audiological rehabilitation influenced psychosocial well-being has been shown in other studies (Abrams et al., 2002; Bridges & Bentler, 1998; Gatehouse, 1994; Mulrow et al., 1992). Moreover, the approximately 50% improvement in the HADS score (Baseline to Post HA) in the present intervention studies is comparable to the effects of cognitive behavioural therapy (CBT) for elderly people with tinnitus (Andersson et al., 2005). It is also important to

note that the improvement was stable, since no significant deterioration was found for psychosocial well-being over the long term.

In study I, it was found that the psychosocial well-being (HADS) was associated with participation restriction and satisfaction. This association has also been reported in other studies (Bridges & Bentler 1998; Eriksson-Mangold 1991; Gatehouse, 1994). This result confirmed the importance of the psychosocial variables and suggested that it may be useful to implement a psychosocial variable when planning the individualized audiological rehabilitation. The HADS questionnaire is a generic outcome measure that performs well for primary care patients and a general population (Bjelland et al., 2002). Saunders et al. (2005) stressed the importance of also including generic outcome measures in audiological rehabilitation. The advantages of including generic self-reports in audiological rehabilitation are the ability to compare cost-benefit analyses, the improved understanding of the generic issues underlying rehabilitation and the ability to perform a direct comparison of the impact hearing aids have on quality of life in relation to other health areas. The importance of psychosocial well-being is well known in health care (Fitzgerald, 2000), and if audiological rehabilitation could increase users' psychosocial well-being, then this should be interpreted as a valuable advantage for the users as well as for the society as a whole.

The significant improvements in activity limitation and participation restriction measured with the HHIE (II, III) were consistent with other studies using this self-report measure (Abrams, 1992; Mc Ardle et al., 2005; Mulrow et al., 1992; Newman et al., 1993; Newman & Weinstein, 1988; Stark & Hickson, 2004; Taylor, 1993).

It was found that expectations increased during the pre-interventions, which indicated that the intervention gave the users positive knowledge about hearing aids (II, III). The scores for SADL indicated that the users were more satisfied than they had expected to be. This could be interpreted as participants having too low of expectations when responding to ECHO

at Baseline. In these studies, however, the participants had ECHO scores comparable to the study by Cox and Alexander (2000) in which the authors interpreted expectations scores at this level as being too high. With regard to the increased scores evaluated by SADL, this could instead be interpreted as realistic expectations at Baseline and that the users were further positively affected by the effects of the hearing aids and the rehabilitation process.

All groups reduced their scores for nonverbal and verbal strategies once hearing aids were fitted (II, III). The result showed that participants less frequently asked for repetition or sought out places where the opportunity to hear was better. This could be due to that the users' considering these strategies as unnecessary as they do well in communication situations with the use of hearing aids. The improved scores for maladaptive behaviour might be related to improved speech recognition, which may have encouraged the users to be more involved in social activities. This could also be related to the rather high association between less use of maladaptive strategies and high psychosocial well-being. Associations between more frequent use of maladaptive strategies and higher scores for participation restrictions have been reported in several Swedish studies (Barrenäs & Holgers, 2000; Hallberg, 1998; Hallberg & Carlsson 1991; Hallberg et al., 1993). These results suggested that it is important to be observant of users' communication strategies following hearing aid rehabilitation and to complement these strategies with additional communication programs when necessary, since this may well increase participation and quality of life (Abrams et al., 1992; Andersson et al., 1994; Beynon et al., 1997; Hallberg et al., 2008).

The hypothesis that could be deducted from Antonovsky's theory (1987), that individuals with a higher sense of coherence cope more successfully in rehabilitation was not fully confirmed in these studies (II, III). Nonetheless, relations between high SOC scores and high scores for other outcomes evaluating the rehabilitation (e.g., HHIE E, CCS M, IOI-HA F2 and hearing aid use) were found in study I. However, no relations were found between

degrees of benefit and the initial SOC scores for the users in the intervention studies. More investigations are needed before the SOC can be recommended as a reliable predictor of outcome in hearing aid rehabilitation.

The IOI-HA questionnaire was found to be useful. The results of the factor analysis and the correlations indicated that the questionnaire can accurately evaluate activity limitation and participation restriction as well as satisfaction (I). The findings in study IV showed a correlation between this self-report measure and the audiologists' rating of the users as being either successful or less successful, and further confirmed the usefulness of the questionnaires in clinical evaluations. Another advantage of the IOI-HA questionnaire is that it included an item measuring the quality of life. The results showed that approximately three-quarters of the users rated enjoyment of life as "very much" or "quite a lot better" after hearing aid fitting, thus confirming the importance of audiological rehabilitation for these individuals. It was also very encouraging to be able to show that the hearing aids were used frequently and not stored away. It was concluded that the number of dissatisfied users was low (I-IV), especially when compared to the studies by Kochkin (2005) and Rahmkvist (2002).

The factor analyses suggested that the use of two short self-reports (HADS, IOI-HA) was sufficient to assess satisfaction, residual activity limitation and participation restriction, and psychosocial well-being (I). These two self-reports may be sufficient to cover most aspects of audiological rehabilitation in clinical settings. Evaluation procedures that required less time and effort have the best chance of becoming routine in the clinic. Clinically implementing self-reports could affect several positive outcomes of rehabilitation. Self-reports might not only be helpful in the evaluation of the rehabilitation, but they could also be therapeutic by themselves (English, 2005; Eriksson-Mangold, 1991; Rankin & Stallings, 2001; HRF, 2004). Simply answering the questionnaires may help individuals to be more aware of problems, as well as reflect on how much their hearing loss is impacting their lives,

thereby helping them to problem solve on their own (Dillon, 2001; Eriksson- Mangold, 1991; Preminger, 2007). Since genuine clinical dialogue is the basis for developing a relationship with the user, the questionnaires might facilitate initiation of a dialogue between the audiologist and the user, giving the audiologist a better opportunity to be aware of the problems specific for an individual (English, 2005; Hellström, 1995; HRF, 2004). This may partly explain the good results for the control groups in papers II and III.

Long term effects

Data from participants in all studies in this thesis were compared with those from international studies that have assessed outcomes for at least six months after hearing aid fitting. The mean scores for participants in our studies were somewhat higher overall for satisfaction (SADL) (Cienkowski et al., 2006; Cox & Alexander, 2001; Hosford-Dunn & Halpern, 2001; Souza et al., 2000) and for the items in the IOI-HA (Cook & Hawkins, 2007; Cox et al., 2003; Kramer et al., 2002). It was difficult to identify a main reason for the somewhat better scores for satisfaction in this Swedish population. It is not impossible that cultural differences alone might explain this difference. Another possible factor might be that the repeated visits during the hearing aid fitting positively affecting the users. Contrary to the few studies evaluating SADL and IOI-HA over the long term, several studies were found where assessments were performed over the long term using the HHIE questionnaire, showing that mean scores ranged between 11-56. Some studies showed similar or better scores than the studies in this thesis (McArdle et al., 2005; Newman et al., 1993; Taylor, 1993; Tesch-Romer, 1997), whereas some showed worse scores (Kricos & Holmes, 1996; Mulrow et al., 1992; Newman & Weinstein, 1988; Preminger, 2003).

A small but significant deterioration was found over the long term (Post-HA to Post one year) for activity limitation and participation restriction (HHIE), satisfaction (SADL) and hearing aid use (II, III). This may be due to increased social activities after rehabilitation and,

possibly, to poorer experiences with the hearing aids than were expected in some contexts (Taylor, 1993). Another possibility may be that the scores assessed at Post-HA (two-three months after the first fitting) were somewhat exaggerated due to a delayed honeymoon effect. The users visited the clinic continuously during the rehabilitation process, and this continued counselling might have been beneficial (Newman et al., 1993). It can be speculated that audiological rehabilitation without this continuous counselling would have yielded Post-HA outcome scores equal to those assessed after one year. As mentioned earlier, it is interesting to note that no significant deterioration was found for psychosocial well-being over the long term. Even if users experienced increased activity limitation and participation restriction and were less satisfied with their aids one year after the hearing aid fitting, these factors did not affect their psychosocial well-being (II, III).

The telephone interviews were developed with the purpose of providing a clinical global impression of the audiological rehabilitation (AR-CGI) one year after the rehabilitation. The use of the AR-CGI was found to provide a clinically meaningful summary of the individual's functioning. The pattern was the same for the users' participating in the intervention studies as that for the clinical sample. The majority of the users in both samples seemed to be successful. The rated success (from the audiologist's point of view) was related to the self reported outcomes for the items in IOI-HA and was not related to demographic data such as PTA or gender. These vague associations for the demographic variables when evaluating hearing-specific and psychosocial outcomes were also confirmed in the correlation analyses in study I. However, a relationship was seen between increased age and less successful users when evaluating AR-CGI, and this relationship was also confirmed in paper I, where age was the strongest demographic variable related to hearing-specific and psychosocial outcomes. Specifically, higher age was related to lower satisfaction and more

maladaptive behaviour. The interview worked well and was effective in terms of being less time consuming than a visit to the clinic, confirming that it was appropriate for clinical use.

The results of the studies described in this thesis confirm the importance of self-reported assessments, support the increased use of these assessments, and emphasize the importance of further investigations into appropriate self-assessment approaches in audiological rehabilitation.

Differences between conventional hearing aid rehabilitation in research and in the clinic.

The intention was to perform a “conventional” hearing aid fitting equal to the rehabilitation performed in clinical practice. A comparison of mean scores for the different self-report measures between the control groups and the survey sample showed them to be rather similar. However, there was a tendency of the control groups to have better scores for most outcomes (although often this difference was not significant) (I-III). The data from the interview also indicated a higher percentage of successful users in the control groups as compared to clinical users (Figure 5). It was anticipated that the hearing aid rehabilitation included four systematically introduced phases, assessment, planning, implementation, and evaluation (e.g., diagnosis, goal planning and learning activities) (Rankin & Stallings, 2001). This systematic may explain the satisfactory result. However, it is clear that some parts of the rehabilitation were different between the intervention studies and the survey. For example, all participants in the intervention studies filled out several self-report measures that were not routine in the regular clinical rehabilitation. Another differing aspect is the use of the COSI questionnaire (II, III), which is only sparsely used in the clinic. The COSI was used to document the users’ goals and needs and to measure the improvements in perceived hearing. This procedure promoted a greater focus on the individual user’s needs, clarified these needs, and required acknowledgement of the hearing problems, all of which might have effects on both the hearing-specific and psychosocial outcomes. It is also important to view the somewhat

different distribution of time spent on informational and therapeutic counselling. The hearing aid fitting in these studies might have included less informal counselling with regard to predetermined hearing aids. The participants were well informed that they could not change hearing aids during the rehabilitation; therefore, no time was spent on information and instructions about new devices. The aspects explained above mean more time and more focus on the user and on therapeutic counselling. Therapeutic counselling, including emotional processing, might have increased psychosocial aspects such as awareness, acceptance and acknowledgement of the hearing loss and willingness to be a hearing aid wearer (Backenroth & Ahlner, 2000; Boothroyd, 2007; Danermark, 1998; Dillon, 2001; English, 2005).

Audiological rehabilitation should thus first provide basic information about the hearing loss, the rehabilitation process and instructions about how to handle the device. One point to consider is that this informational counselling has to be more in focus in the clinic, and that this approach, which leans on informational counselling in a way similar to other approaches leaning too heavily on technology, is not always sufficient to enhance the user's emotional aspects (Backenroth & Ahlner, 2000; Boothroyd, 2007; Danermark, 1998; Dillon, 2001; Eriksson-Mangold et al., 1990; English, 2005; McLeod & McPehrson, 2007).

Methodological Considerations

In general, these four studies were considered to have been conducted successfully. We found high response rates and few drop outs. We also found that the users' willingness to participate and perform the different tasks was generally high.

The decision to perform the intervention on an ordinary clinical sample was based on our wish to investigate the clinical relevance of the new approaches. It was found that the participants initially had realistic expectations and low to moderate initial scores for activity limitation and participation restriction (II, III). Other inclusion criteria, such as greater scores

for disability and participation restriction, might have revealed larger differences between the intervention and control group.

Studies II and III were underpowered with respect to the number of participants. The differences in mean scores between the groups did not produce statistically significant differences. This might have been seen with larger samples. Since several of the questionnaires were never previously used in Sweden, it was difficult to estimate prior to the trials the power and the number of users needed.

In study IV, the response rate for the clinical sample was only 46%. Thus, it is difficult to draw a firm conclusion about the occurrence of successful users in clinic.

Suggestions for future research

The findings in study I showed the importance of psychosocial variables in audiological rehabilitation and encouraged us to improve understanding of the impact of psychosocial factors in hearing aid rehabilitation. The HADS questionnaire was effective in these studies and its effectiveness in hearing aid rehabilitation should be further explored in future trials.

Few short term effects indicated no long term transfer effects of the pre-fitting interventions. This suggested that more investigations are needed before these approaches can be recommended for general clinical use (II, III). Altered versions of the approaches could be developed and investigated, such as implementing the sound awareness training or the user controlled adjustment within the “conventional” rehabilitation. Above all, there exists a great demand to investigate the needs for these approaches as well as for a pre-counselling approach. There is a lack of evidence for the effectiveness of pre-counselling due to fewer studies analyzing this approach. More investigations on predictive factors should be able to identify population samples that are most in need of additional counselling. These samples could then be subjected to different pre-counselling approaches.

Study IV was a first attempt to investigate the effects and the suitability of a clinical global impression scale for audiological rehabilitation (AR-CGI). Due to increasing demands for brief, validated outcome instruments in evidence-based medicine, this is an evaluation approach that can be further explored. The interview guide and the rating system worked well in these studies, and this approach in evaluating audiological rehabilitation may be clinically useful. Before AR-CGI is implemented on a daily basis in the clinic, the interview guide and the rating systems have to be further validated.

Conclusions

The conclusions from this thesis can be summarized as follows:

- *Pre-fitting interventions did not yield additional or more successful hearing aid users in the long term as compared to the control group, only receiving hearing aid rehabilitation.* The pre-fitting intervention had a positive effect over the short term on activity limitations and participation restrictions, but was not powerful enough to have lasting effects past the hearing aid fitting or over a year. It was concluded that this hearing aid fitting procedure within itself was effective, as both groups showed significant improvements with regard to psychosocial well-being and reduced participation restriction, confirming the importance of audiological rehabilitation.
- *The translated self-reports were both valid and useful, and should be recommended for further clinical use.* The mean scores for this Swedish population were in agreement with those of international studies. The psychosocial variables were associated with hearing-specific outcomes. This confirmed the importance of subjective self-report measures and suggested that psychosocial self-reports such as HADS should be implemented in audiological rehabilitation.
- *The telephone interview evaluating Audiological Rehabilitation Clinical Global Impression (AR-CGI) was an effective method to evaluate audiological rehabilitation.* The interview was found to be valid due to its relationship to the self-reported data and good interrater reliability. Advantages such as simpler administration and shorter completion time allowed us to consider the approach appropriate for clinical use. Telephone interviews can be an important tool in the regular quality assessment of the hearing health care centre.

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Svensk sammanfattning

Metoder i Audiologisk rehabilitering – interventioner före hörapparat-anpassning samt utveckling och bedömning av utvärderingsinstrument
Fjorton procent av den svenska befolkningen anger subjektiv hörselnedsättning. Antalet

personer med hörselnedsättning förväntas öka på grund av den ökande medellivslängden. De nya generationer med nedsatt hörsel som söker hörselrehabilitering förväntas ha större krav på rehabiliteringen. Den tekniska utvecklingen inom hörselvården har de senaste decennierna varit mycket omfattande. Trots denna tekniska utveckling finns det fortfarande många personer med hörselnedsättning som inte bryr sig om att söka till hörselvården, är missnöjda med sin rehabilitering eller inte använder sina hörapparater. För att möta nya generationers krav på hörselrehabilitering och för att få flera personer att söka hörselvård behöver nya rehabiliteringsmetoder utvecklas.

Målet med en hörselrehabilitering är, förutom att få personen att höra bättre, även att förbättra individens möjligheter till delaktighet såväl i närmiljön som i samhället i övrigt. En ökad delaktighet förväntas förbättra det psykosociala välbefinnandet och livskvaliteten.

För att kunna utvärdera de olika effekterna av en hörselrehabilitering krävs bra utvärderingsmetoder. I Sverige saknas studier som använt standardiserade frågeformulär för att utvärdera delaktighet, psykosocialt välbefinnande och livskvalitet.

Syftet med den här avhandlingen är att utveckla och utvärdera nya behandlingsmetoder för hörselrehabilitering, utvärdera olika frågeformulär samt att utveckla effektiva metoder för att värdera hörselrehabiliteringens helhetseffekter.

Syftet med *studie I* var att utvärdera giltigheten och att samla in svenska referensdata för flera översatta internationella standardiserade frågeformulär, samt att undersöka sambanden mellan psykosociala, hörselspecifika och demografiska data.

Etthundrasextiotvå personer i Östergötland besvarade sex olika frågeformulär ett år efter att de erhållit sina första hörapparater. Frågeformulären hade som syfte att utvärdera psykosocialt välbefinnande, hörapparatnytta, nöjdhet med hörapparaterna, aktivitets- och delaktighetsbegränsning samt kommunikationsstrategier.

Frågeformulären ansågs som giltiga och medelvärdena för frågeformulären för de svenska brukarna överensstämde med internationella studiers värden. De hörselspecifika faktorerna visade större samband med psykosociala faktorer än med demografiska faktorer, såsom utbildningsår och kön. Höga samband mellan flera av frågeformulären tyder på att antalet frågeformulär skulle kunna reduceras, vilket är en fördel vid klinisk användning.

Syftet med *studie II* var att undersöka om en förutbildning (en utbildning som sker före hörapparat Anpassningen) skulle ge förbättrade effekter på kort och lång sikt för hörapparatnytta, nöjdhet med hörapparaterna, psykosocialt välbefinnande och aktivitets- och delaktighetsbegränsning, jämfört med en kontrollgrupp som bara fick en hörapparat Anpassning. Trettionio personer fördelades slumpvis och 19 och 20 personer deltog i behandling respektive kontrollgrupp. Syftet med förutbildningen var att öka deltagarnas egen aktivitet och delaktighet i behandlingen. Förutbildningen bestod av tre besök där brukarna själva fick ställa in förstärkningen i en speciell experiment-hörapparat som användes under tre veckor. Dessa övningar syftade till att öka brukarnas förståelse för hörapparatens möjligheter och begränsningar. Effekterna utvärderades med samma frågeformulär som använts i studie I och deltagarna besvarade dessa vid fyra tillfällen; före fördelningen till behandling eller kontrollgrupp, före hörapparat Anpassningens start, efter Anpassningens avslut och ett år efter hörapparat Anpassningens avslut.

Signifikanta skillnader konstaterades mellan behandling och kontrollgrupp vid utvärderingen som gjordes före hörapparat Anpassning för förväntningar på hörapparaterna och för aktivitets- och delaktighetsbegränsning. Behandlingsgruppens förväntningar ökade

och aktivitets- och delaktighetsbegränsningen förbättrades efter förutbildningen jämfört med kontrollgruppen. Det fanns inga skillnader i effekter mellan grupperna vid utvärderingarna som gjordes efter hörapparatanpassningens avslut eller efter ett år. Det visade sig att båda grupperna signifikant förbättrade sina värden för samtliga frågeformulär så snart de avslutat hörapparatanpassningen. Det kunde även konstateras att de flesta mätvärden förändrades vid utvärderingen som gjordes efter ett år, och visade en viss reducering av de förbättrade värdena uppmätta vid hörapparatanpassningens avslut. Någon förändring över tid fanns dock inte för värden som gällde det psykosociala välbefinnandet.

Studie III hade samma upplägg som studie II. Denna förutbildning syftade till att göra brukarna mera medvetna om alla vardagliga ljud. Trettioåtta personer fördelades slumpvis där 19 personer deltog i behandling och 19 i kontrollgrupp. Brukarna utvärderade olika ljud och ljudmiljöer vid tre kliniska besök samt under tre veckor i hemmiljön. Dessa övningar förväntades underlätta hörapparatanpassningen.

Inga signifikanta skillnader konstaterades mellan behandling och kontrollgrupp, varken på kort eller på lång sikt. Även i denna studie visade båda grupperna stora förbättringar efter hörapparatanpassningen men även en viss reducering av de uppmätta värdena vid utvärderingen efter ett år.

Syftet med *studie IV* var att utveckla och undersöka pålitligheten och giltigheten för en intervjuguide och en kategoriseringsskala, som värderade hörselrehabiliteringens helhetseffekt. Frågeguiden och kategoriseringsskalan var utvecklade för att användas i en telefonintervju.

Intervjuguiden bestod av 16 frågor som berörde effekterna av hörselrehabiliteringen. Kategoriseringsskalan bestod av de tre kategorierna lyckad rehabilitering, lyckad rehabilitering med vissa begränsningar och mindre lyckad rehabilitering. Brukare från behandlingsstudierna II och III telefonintervjuades, av en för dem okänd audionom, ett år

efter hörapparatpassningens avslut. Brukarna fick även per post besvara flera frågeformulär. Deltagarna hade besökt kliniken för en ettårsuppföljning. Audionomen som träffade brukaren vid besöket gjorde en kategorisering av brukarens rehabilitering och intervjuaren kategoriserade brukaren efter telefonintervjun. Kategoriseringarna mellan behandlaren och intervjuaren jämfördes sedan.

För att ytterligare säkerställa giltigheten utfördes 21 kompletterande telefonintervjuer med brukare från kliniken (personer som inte ingått i någon forskningsstudie). Dessa personer besvarade endast ett frågeformulär per post.

Det visade sig att 70-80 procent av rehabiliteringarna i de olika grupperna bedömdes som lyckade. Intervjuguiden och kategoriseringsskalan bedömdes som pålitliga och giltiga. Det fanns en god överstämmelse för kategoriseringarna av brukarnas rehabilitering mellan behandlande audionom och telefonintervjuare. Jämförelsen mellan brukarnas självskattade värden i frågeformuläret och intervjuares kategoriseringar visade också på samstämmighet. De brukare vars rehabilitering kategoriserats som lyckad visade sig ha signifikant bättre värden för frågorna i frågeformuläret jämfört med dem som bedömts som mindre lyckade.

Att låta personer som ska anpassa sina första hörapparater först genomgå en så kallad förutbildning visade sig inte ge några ytterligare förbättrade effekter för rehabiliteringen. Den efterföljande hörapparatpassningen visade sig vara tillräcklig för att uppnå signifikant förbättrade effekter för hörapparatnytta, nöjdhet med hörapparaterna, psykosocialt välbefinnande, och aktivitets- och delaktighetsbegränsning. De flesta av dessa effekter, dock inte det psykiska välbefinnandet, förändrades över ett års tid. Dessa förändringar, som visade en viss reducering av uppnådda effekter ska dock ses som marginella jämfört med de förbättrade effekterna som uppmättes vid anpassningens slut.

De här studierna har visat att standardiserade internationella frågeformulär var giltiga och användbara även för en svensk befolkning. Förutbildningarna som prövades i dessa studier behöver undersökas vidare innan de kan rekommenderas för kliniskt bruk.

Telefonintervjuerna visade sig vara en bra metod för att bedöma hörselrehabiliteringens helhetseffekt. Denna utvärderingsmetod var enkel och tidsbesparande och har förutsättningar för att bli en använd metod för uppföljning och kvalitetssäkring inom hörselvården. Det är rekommenderat att frågeguiden och kategoriseringsskalan revideras innan den implementeras i klinik.

Appendix

Interview guide for the telephone interview in paper IV

- 1) Have the hearing aids (HAs) fulfilled your expectations?
- 2) What is the most positive/negative experience with your HAs?
- 3) To what extent have you reached your goals with the HAs?
- 4) How much do you use your HAs and in what situations?
- 5) How often do you change batteries?
- 6) Are there occasions when you do not use your HAs? If so, when, and where?
- 7) To what extent are you satisfied with your HAs (respond to a seven-point scale, not at all-complete)
- 8) What extent of benefit do you derive from the HAs (respond to a seven-point scale not at all-complete)
- 9) Does it happen that you use only one of your HAs? And if so, how often? (respond to a seven-point scale seldom-very often)
- 10) Have you changed your attitude to be a hearing aid wearer over time?
- 11) Have you given up any activities due to your hearing problems, and/or have you started (earlier) or new activities since you received your HAs?
- 12) Does it happen that you withdraw from social activities/ meeting etc. due to your hearing loss?
- 13) What is your experience of the audiological rehabilitation? Something particularly satisfactory or particularly unsatisfactory?
- 14) Do you think your HAs were worth the trouble?
- 15) If you can not follow the conversation, what is your most applied strategy?
- 16) Have you had any functional (practical) problems with your HA during the year? If so how did you solve it?

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