

# Aural rehabilitation programs for hearing aid users

Evaluating and clinically applying educational programs, supported via telephone and/or the internet and professionally guided by an audiologist

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By Ineko AB

*To Philip, Vincent & Elliot*



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## ABSTRACT

Many hearing aid users experience substantial communication difficulties that may affect their participation in daily life situations negatively. This experience can be addressed using follow-up rehabilitation programs, yet the overall availability of such programs in general clinical practice (GCP) is low.

The overall aim of this thesis was to evaluate, explore, and clinically apply aural rehabilitation (AR) programs administered from a remote location using randomized controlled trials (RCTs). In Papers I and II, each RCT evaluated programs for hearing aid users that were supported via telephone and/or the internet and professionally guided by an audiologist. The effectiveness of the programs was evaluated using a variety of outcome measures, and the results in an intervention group were compared with the results in a control group in each paper. Both RCTs were clinically applied. The process of implementing one of these RCTs in GCP is discussed in Paper III. Additionally, participants' views of participating in an internet-based AR program for hearing aid users were explored in Paper IV using a qualitative approach.

Providing the hearing aid users with follow-up rehabilitation programs reduced the self-reported hearing problems significantly more in the intervention group than in the control group, as presented in Paper I. Also, significant improvements in communication strategies for the intervention group compared with the control group were found in Paper II. Additionally, carrying out an internet-based RCT in GCP showed to be advantageous in several ways. Finally, overall positive experiences of participating in an internet-based rehabilitation program were revealed. Thus, providing AR programs for hearing aid users administered from a remote location and supported via telephone and/or the internet increases the possibilities for the audiologist in GCP to reach out to hearing aid users and offer an alternative cost-effective approach to AR.

**Keywords:** aural rehabilitation, hearing loss, counselling, hearing aids, internet interventions, randomized controlled trials, clinical practice, patient participation

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# SAMMANFATTNING PÅ SVENSKA

Hörseln är det viktigaste sinnet för kommunikation mellan människor. En hörselnedsättning påverkar t.ex. förmågan att uppfatta tal eller vissa ljud, men även det sociala samspelet mellan människor genom att bland annat leda till försämrad livskvalité, minskade sociala aktiviteter, känsla av utanförskap och därmed ökande förekomst av depressionssymptom. Mer än en miljon människor i Sverige har rapporterat någon form av hörselnedsättning. Förekomst av hörselnedsättning ökar med stigande ålder och p.g.a. människans stigande livslängd förväntas det totala antalet personer med hörselnedsättning öka ytterligare. En sådan ökning kan förväntas ställa större krav på den audiologiska rehabiliteringen inom klinisk verksamhet.

Målsättningen för audiologisk rehabilitering (hörselrehabilitering) är att minimera de negativa effekterna som en hörselnedsättning kan ha på socialt samspel och livskvalitet. För att nå detta mål krävs åtgärder och insatser inom en rad olika områden, och hörselrehabilitering bör utgå från ett psykosocialt synsätt. Hörapparat Anpassning är en metod för att nå ett eller flera mål inom hörselrehabilitering och är idag det mest förekommande förhållningssättet inom hörselvården. Trots hörapparat Anpassning och dagens avancerade hörapparatteknik är det många hörapparat användare som upplever kvarstående hörselproblem. Dessa kvarstående hörselproblem kan inverka negativt på hörapparat användarens sociala samspel och kan leda till att man slutar använda sin hörapparat.

Ett sätt att bemöta kvarstående hörselproblem som hörapparat användare kan uppleva är att erbjuda olika rehabiliteringsprogram. Dessa kan erbjudas i samband med eller efter hörapparat Anpassning, individuellt eller i grupp. Tidigare forskning har visat att sådana rehabiliteringsprogram kan minska upplevelsen av kvarstående hörselproblem, men även öka hörapparat användningen och nyttan med hörapparaterna. Trots de positiva effekterna av rehabiliteringsprogram erbjuds endast ett begränsat antal hörapparat användare sådana i klinisk verksamhet. Anledningen till detta kan vara tids- och resursbrist.

Syftet med denna avhandling var att utvärdera effekterna och möjligheterna av att applicera olika rehabiliteringsprogram för hörapparat användare inom klinisk verksamhet, samt att undersöka hörapparat användarnas egna upplevelser av sådana program. I avhandlingen ingår fyra olika delarbeten och totalt har 163 hörapparat användare bidragit till de presenterade resultaten.

Delarbete I och II är två randomiserade kontrollerade studier som utvärderar effekten av respektive pedagogiskt rehabiliteringsprogram, där insatsen förmedlades strukturerat och på distans inom klinisk verksamhet. Effekten av

respektive pedagogiskt rehabiliteringsprogram utvärderades med hjälp av olika utvärderingsmått, och resultat från deltagare i en interventionsgrupp jämfördes med resultat från deltagare i en kontrollgrupp i respektive delarbete. Erfarenheter av att använda Internet som ett verktyg inom klinisk verksamhet presenteras deskriptivt i Delarbete III. Hörapparat användare som har deltagit i ett internet-baserat rehabiliteringsprogram har intervjuats och resultat från datainsamlingen som analyserades med kvalitativa metoder presenteras i Delarbete IV.

Resultat från denna avhandling visar att rehabiliteringsprogram som användes i Delarbete I minskade kvarstående hörselproblem hos interventionsgruppen som fick ta del av programmet signifikant mer jämfört med kontrollgruppen som inte fick ta del av hela programmet. Vidare visar Delarbete II att hörapparat användare som har deltagit i ett internet-baserat rehabiliteringsprogram förbättrade sina kommunikationsstrategier signifikant mer än hörapparat användare som inte fick ta del av samma program. Resultaten från denna avhandling visar även att det är möjligt att använda Internet för att erbjuda rehabiliteringsprogram som ett alternativ inom klinisk verksamhet. Slutligen, hörapparat användarnas egna upplevelser av att ha deltagit i ett internet-baserat rehabiliteringsprogram var positiva.



# LIST OF PAPERS

This thesis is based on the following papers, referred to in the text by their Roman numerals.

- I. Lundberg, M., Andersson, G. & Lunner, T. (2011) A randomized, controlled trial of the short-term effects of complementing an educational program for hearing aid users with telephone consultations. *Journal of the American Academy of Audiology*, 22, 654-662.
- II. Malmberg, M., Lunner, T., Kähäri, K. & Andersson, G. (2017) Evaluating the short- and long-term effects of an internet-based aural rehabilitation program for hearing aid users in general clinical practice: a randomized, controlled trial. *Accepted for publication by BMJ Open*.
- III. Malmberg, M., Lunner, T., Kähäri, K., Jansson, G. & Andersson, G. (2015) Implementing internet-based aural rehabilitation in a general clinical practice. *American Journal of Audiology*, 24, 325-328.
- IV. Malmberg, M., Thorén, E.S., Öberg, M., Lunner, T., Andersson, G. & Kähäri, K. Experiences of an internet-based aural rehabilitation (IAR) program for hearing aid users: A qualitative study. *Submitted manuscript*.



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# ABBREVIATIONS

ACE	Active Communication Education
AR	Aural Rehabilitation
CONSORT	Consolidated Standards of Reporting Trials
COSI	Client-Oriented Scale of Improvement
CPhi	Communication Profile for the Hearing Impaired
CSS	Communication Strategies Scale
dB HL	Decibel Hearing Level
EBP	Evidence-Based Practice
GCP	General Clinical Practice
HADS	Hospital Anxiety and Depression Scale
HHIE	Hearing Handicap Inventory for the Elderly
Hz	Hertz
ICF	International Classification of Functioning, Disability and Health
ICIDH	International Classification of Impairments, Disabilities and Handicaps
IOI-HA	International Outcome Inventory for Hearing Aids
ITT	Intention To Treat
PTA	Pure-Tone Average measured across 500, 1000, and 2000Hz
RCT	Randomized Controlled Trial
SCB	Statistics Sweden
SD	Standard Deviation
SDT	Self-Determination Theory
SPSS	Statistical Package for the Social Sciences
VGR	Region Västra Götaland
WHO	World Health Organization



# 1 INTRODUCTION

Hearing is considered to be the most important sense for communication between people. Hearing impairment is one of the most common causes of disability globally and is listed as the third leading global cause of years lost due to disability (World Health Organization, WHO, 2008). Approximately 1.4 million adults in Sweden (Statistics Sweden, SCB, 2015) report varying degrees of hearing impairment that may affect their encounters in daily life situations. The inability to communicate with others is one of the main impacts of hearing impairment. Hearing impairment is positively related to age and the incidence of hearing impairment is expected to climb due to increasing life expectancy (World Health Organization, WHO, 2001; Stevens, Flaxman, Brunskill, Masacarenhas, Mathers & Finucane, 2013). This increase will in turn increase the stress on overall hearing health care services, especially in terms of quality and accessibility (Olusanya, Neumann & Saunders, 2014).

Communication failure caused by hearing impairment may lead to social withdrawal and reduced quality of life. Furthermore, hearing impairment may cause feelings of alienation and accordingly increase the presence of depression symptoms (Arlinger, 2003; Nachttegaal, Smit, Smits, Bezemer, van Beek, Festen & Kramer, 2009). Yet, hearing impairment often goes unnoticed or unaddressed. The most common approach to hearing impairment is hearing aid fitting as a part of aural rehabilitation (AR) (Chisolm et al., 2007; Kochkin, 2009). In Sweden, approximately 50% of those who could benefit from hearing aids are fitted with them, and nearly half of those use their hearing aids to a considerable extent every day. Despite addressing the hearing impairment with hearing aids, many hearing aid users experience substantial communication difficulties that can affect their performance in daily life situations (Arlinger, 2003; Hickson, Worrall & Scarinci, 2007). This could cause patients to stop using their hearing aids, which may negatively affect their interpersonal interactions and involvement in community life.

Adjusting to hearing impairment involves more than just hearing aid fitting, although hearing aid fitting is a step in the right direction (Hickson & Worall, 2003; Kramer, Allesie, Dondorp, Zekveld & Kapteyn, 2005; Chisolm et al., 2007). Additional steps within AR, such as learning about the condition and providing perceptual training and counseling, need to be included in order to minimize the negative effects of a hearing impairment on social interactions and quality of life (Kramer et al., 2005; Boothroyd, 2007). These additional steps can effectively be included variously throughout the AR (separately or in combination, and individually or in groups), they may increase hearing aid use and satisfaction, and can be performed as an adjunct to or a supplement for hearing aid fitting (Hickson & Worall, 2003;

Hawkins, 2005; Sweetow & Palmer, 2005; Hickson et al., 2007; Preminger, 2007). However, even though combining these additional steps with hearing aid use has proven to be beneficial, most hearing aid users are unaware of and are not offered any other rehabilitation measures than hearing aid fitting (Kochkin, 2009; Öberg Wänström, Hjertman, Lunner, & Andersson, 2009). Thus, the overall availability of comprehensive AR is low (Laplante-Lévesque, Hickson & Worall, 2010a).

Previous research has proposed employing telehealth (i.e., telephone and internet) in hearing health care to improve clinical care and increase access to hearing services (Swanepoel et al., 2010; Swanepoel & Hall, 2010). Telehealth offers a more cost-effective approach to AR and increases the possibilities for the audiologist in general clinical practice (GCP) to reach out to hearing aid users with persistent self-reported hearing problems.

The present thesis concerns the application of telephone and internet-based interventions (e.g., steps of AR) that may support the accessibility of comprehensive AR in addition to hearing aid fitting, as well as the individual audiologist. The present thesis includes studies that are conducted with experienced hearing aid users with self-reported hearing problems.

## 1.1 Theories of aural rehabilitation

In the 1970s, aural rehabilitation (AR) was described as a process that did not involve amplification. Instead it focused on lip-reading and auditory training (Alpiner, Hanse & Kaufman, 2000). Hearing aids were helpful but ponderous. Subsequently, improved technology positioned hearing aids as an integral part of rehabilitative audiology and their significance for people with hearing impairment was now inevitable. Several authors described the conceptual framework of AR in the literature, this time including hearing aids (e.g. Goldstein & Stephens, 1981).

At this point, the World Health Organization (WHO; ICIDH, International Classification of Impairments, Disabilities and Handicaps, 1980) used the terms “*impairment, disability and handicap*” when describing hearing impairment. These terms aimed to minimize the auditory and non-auditory effects of hearing impairment. The process of comprehensive AR was described by Goldstein and Stephens (1981), who developed a model highlighting different components of AR and considering the interactions of these components. The authors separated the process of AR into the concepts of *evaluation* and *remediation*. For example, they emphasized the individual’s attitude, personality, and intelligence as major psychological variables operating in AR (*evaluation*). One of the five concepts of



*remediation* included instrumental support, such as fitting hearing aids. The authors stressed that the purpose and goal of AR is centered in “communication training” as another concept of *remediation*. According to the authors, such communication training should be offered to every patient, and in order to increase the patient’s motivation, the authors recommend that the patient should be part of the planning process. The communication training consisted of four activities: a) provision of information (e.g., about hearing, hearing aids, and communication strategies), b) skill building (the audiologist enhancing effective communication by training the patient in the skills), c) “instrumental” (modifying amplification), and d) counseling (“*attitude and understanding which underpin one’s ability to adjust behavior to meet changing needs*”; Goldstein and Stephens, 1981, p.449).

Later on, during the 1990s, several authors discussed and emphasized the importance of applying the WHO terms (WHO, 1980) when describing the process of AR, and many of them agreed on recognizing the absence of personal and environmental factors in the ICDH model. (e.g., Stephens & Hetú, 1991; Noble & Hetú, 1994; Gagné, Hetú, Getty & McDuff, 1995; Stephens, 1996). In the mid-1990s, the goal of AR is defined as “*to eliminate or reduce the situations of handicap experienced by individuals who have a hearing impairment...*” (Gagné, 1998, p.70).

In 2001, WHO redefined and renamed the ICDH as the International Classification of Functioning, Disability and Health (ICF; WHO, 2001). The ICF framework is now using terms such as impairments/functions/structures, activities/activity limitation, participation/participation restriction, and environmental and personal factors; all in the context of health. This new conceptual framework describes hearing impairment as complex interactions of these terms, and the WHO model is matched with developed AR models (e.g., Stephens & Hetú, 1991). Based on the ICF and on previous models of AR, Gagné redefined the goal of AR as: “*to restore or optimize participation in activities considered limitative by persons who have a hearing impairment or by other individuals who partake in activities that include persons with a hearing impairment*” (Gagné, 2000, p.65).

Boothroyd (2007) identified the goal of AR as to support the individual assets of the person with hearing impairment and minimize the negative effects of hearing impairment on social interaction and quality of life. Boothroyd suggests that effective rehabilitation can best be achieved by combining components such as: optimization of auditory function, instruction on the use of technology, improvement of speech perception and communication, and counseling (“*to enhance participation, and deal both emotionally and practically with residual limitations*”) (Boothroyd, 2007, p.63).

Furthermore, Stephens, and Kramer (2010) extended one model of AR (Goldstein & Stephens, 1981) in order to describe the process of AR in terms of *evaluation, integration and decision making, short-term remediation, and on-going remediation*. They argue that the rehabilitation process should be viewed as an enablement process, since it focuses on problem-solving, e.g., achieving improvements in patients' activities and participation, expectations, and quality of life. On-going remediation is the final stage in their model, before reaching optimal rehabilitation. This stage includes communication strategies and coping, and may require returning to earlier stages of the rehabilitation process. It may last from a few days to several years (Stephens & Kramer, 2010).

Despite the above AR models, hearing aids are still dominating the rehabilitative audiology. Fitting hearing aids is the most traditional approach to AR (Kochkin, 2009). Nevertheless, it is not unusual that hearing aid users continue to experience persistent communication difficulties after hearing aid fitting, and in turn they may stop using their hearing aids (Arlinger, 2003; Hickson et al., 2007; McCormack & Fortnum, 2013). In order to use hearing aids, persons with hearing impairment need to change their behavior accordingly. A positive attitude to hearing impairment and the advances of hearing aid technology may facilitate this adaptation phase (Southall, Gagné & Leroux, 2006; Hickson et al., 2007). A person's self-perceived hearing difficulties may also affect his or her hearing aid use and satisfaction (Vestergaard, Öberg, Nielsen, Naylor & Kramer, 2010; Ng & Loke, 2015). Further, patients who are permitted to borrow hearing aids from the clinic are more likely to increase their use and benefit of hearing aids (Compton, 2000). Consequently, adjusting to hearing impairment involves much more than just hearing aid fitting.

### 1.1.1 Counseling and education

In agreement with Boothroyd (2007), counseling should be performed continuously throughout the AR. It can be provided individually or in groups and before, during, or after hearing aid fitting. Counseling provided after the hearing aid fitting is the most common approach.

Counseling initially involves a delivery of essential information. In the beginning of the rehabilitation process, hearing aid users are usually informed of all aspects of their hearing impairment, for example the degree of hearing impairment, hearing aid options, and the use of communication strategies. Being knowledgeable about the hearing impairment helps hearing aid users in making rehabilitative decisions. The purpose of health related education is described as to: *"Provide a combination of knowledge, skills, and a heightened self-awareness regarding values and needs, so that patients can define and achieve their own goals"* (Feste & Anderson, 1995,

p.140), i.e., to provide empowerment. An increased understanding of the effects of hearing impairment facilitates acceptance of and adjustment to the impairment.

Accordingly, counseling involves helping a person adapt to the hearing impairment (Schum, 1994). The process of adapting to the hearing impairment involves problem-focused coping (to change the problem) and emotion-focused coping (to change one's attitudes or feelings). Changing behavior in order to adapt to the hearing impairment is a problem-solving process that the audiologist may address by counseling about social support, methods that could improve quality of life, and the limits of amplification (Erdman, 2000). A basic premise of the problem-solving approach in AR is that it should be individualized and inclusive (Stephens & Kramer, 2010).

Previous research indicates that accepting the hearing impairment is a continuous process that is critical to successful rehabilitation (Danermark, 1998; Backenroth & Ahlner, 2000; Jeram & Purdy, 2001), and if a person's acceptance of his or her hearing loss is poor, follow-up counseling may be beneficial. Competence or self-efficacy is one of three conditions within the theory of motivation called self-determination theory (SDT; Ridgway, Hickson & Lind 2013; Henshaw, McCormack & Ferguson, 2015), that potentially affect a person's acceptance of hearing impairment. SDT has previously been used for analyzing the role of motivation to adopt hearing aids (Ridgway et al., 2013; Ridgway, Hickson & Lind, 2015; Ridgway, Hickson & Lind, 2016). Besides competence, SDT refer to autonomy, i.e., a sense of control over one's actions and decisions, and relatedness, i.e., a sense of belonging (Ridgway et al., 2013). According to SDT, acting autonomously will help strengthen a person's motivation and further on influence long-term adherence to treatment. In addition, relatedness emphasizes the value of social relatedness as well as client-practitioner relatedness. All three conditions (autonomy, competence, and relatedness) need to be addressed within AR in order to achieve positive health outcomes.

Finally, inclusion of counseling in AR may be cost-effective in terms of increased hearing aid use and improved hearing aid benefit (Abrams, Hnath-Chisolm & McArdle, 2002; Vuorialho, Karinen & Sorri, 2006a). Also, the resulting increase in hearing aid use may in turn reduce self-perceived hearing difficulties (Newman & Weinstein, 1988; Malinoff & Weinstein, 1989a, 1989b; Erikson-Mangold, Ringdahl, Björklund & Wåhlin, 1990; Dillon, 2001; Chisolm et al., 2007).

## 1.2 Aural rehabilitation programs

The most cost- and time-effective counselling in AR takes place in a group setting and is provided after hearing aid fitting (Hawkins, 2005). Group AR programs for hearing aid users improve communication and may improve outcomes more than hearing aid use alone (Hickson & Woral, 2003; Hawkins, 2005; Hickson, Worrall & Scarinci, 2006; Chisolm & Arnold, 2012). Such group programs mainly focus on psychosocial counselling, provision of information, and training (Hickson et al., 2006, 2007; Preminger, 2007; Preminger & Yoo, 2010).

When designing intervention programs that are consistent with the goals of AR, a problem-solving approach to rehabilitation is recommended (Gagné, 1998; Gagné, 2000; Preminger & Yoo, 2010; Preminger & Rothpletz, 2016). Hickson et al. (2006) used a group program that targets communication difficulties in daily life among older people with hearing impairment, with promising results. The program, Active Communication Education (ACE), is based on a problem-solving, interactive approach. Later on, this program was translated to Swedish and a modified Swedish version of ACE has yielded significant improvements in the communication strategies of participants (Öberg, Bohn, & Larsson, 2014).

However, most hearing aid users are neither aware of nor offered group or communication programs (Kochkin, 2009; Öberg et al., 2009). The results of a study in which 62 initial AR consultations were filmed and analyzed indicated that the audiologists focused mainly on hearing aid-related issues (Grenness, Hickson, Laplante-Lévesque, Meyer & Davidson, 2015). This deficiency could be due to clinicians experiencing lack of time and difficulties scheduling comprehensive AR in addition to hearing aid fitting (Grenness et al., 2015). It could also be due to clinicians experiencing difficulties in recognizing hearing aid users' individual needs for the different steps of AR, or to the presumably increased costs of adding these steps to hearing aid fitting (Chisolm & Arnold, 2012). All these aspects could hinder clinicians in general clinical practice (GCP) from practicing comprehensive AR in addition to hearing aid fitting.

Several studies have shown that an intervention program could be carried out without in-person meetings. For example, Kramer et al. (2005) showed that a home education program has a positive long-term effect on quality of life. Laplante-Lévesque, Pichora-Fuller & Gagné (2006) showed that e-mail contact between the patient and the audiologist creates opportunities for a broader scope of AR. AR without in-person meetings is recommended to be concrete and easily accessible and to motivate participants to complete the study program (Sweetow & Henderson, 2007). Variables that may be related to treatment compliance have previously been discussed in relation to behavior prediction theories (Noh, Gagné &

Kaspar, 1994). The authors emphasize the importance of perceived self-efficacy when performing and engaging in behavioral change. Self-efficacy is described as “*beliefs in one’s capabilities to organize and execute the courses of action required to produce given levels of attainments*” (Bandura, 1998, p.3). In order to strengthen the self-efficacy, a person with hearing impairment needs to obtain the skill, ability, and knowledge to engage in a behavior (e.g., a rehabilitation program). Furthermore, previous research has shown that incorporating a self-efficacy framework in the AR process may improve the outcomes of a clinical intervention (Smith & West, 2006). Also, a major motivation for action is efficacy belief, i.e., a person believing she can produce the desired effect by means of her actions (Bandura, 1998). Engaging patients in their rehabilitation (Rankin & Stallings, 2001), e.g., by allowing patients to be involved in decision making may also increase their motivation for learning. Furthermore, the perceived benefits of taking part in the rehabilitation program need to exceed the perceived costs of participating. Hence, compliance may be interpreted as related to problem-focused counseling.

Hearing aid follow-up group programs comprising psychosocial counseling, provision of information, and training via the internet have been tested in several studies, with promising results (Thorén, Svensson, Törnqvist, Andersson, Carlbring & Lunner, 2011; Thorén, Öberg, Wänström, Andersson & Lunner, 2014; Ferguson, Brandreth, Brassington, Leighton & Wharrad, 2016). For example, Thoren et al. (2014) found significant improvements of self-perceived hearing difficulties in the intervention group, which completed an internet-based hearing aid follow-up program, while the control group did not improve. The use of the internet to provide interventions and health care information enables improvements of clinical encounters in a cost-effective manner (Swanepoel & Hall, 2010; Molini-Avejonas, Rondon-Melo, de La Higuera Amato & Samelli, 2015). This approach to hearing health care has increased in recent years and may be viewed as an empowering agent for persons with hearing impairment (Barak & Sadovsky, 2008). Studies indicate a high prevalence of internet use among people with hearing impairment (Henshaw, Clark, Kang & Ferguson, 2012; Sundewall, Öberg, Wänström, Andersson & Lunner, 2013). For example, elderly persons with hearing impairment have been found to use the internet more than the general Swedish population, on average (Sundewall et al., 2013).

A review of effective internet interventions proposes that four interactive design features should mediate intervention outcomes: “*social context and support, contacts with intervention, tailoring, and self-management*” (Morrison & Powell, 2015, p.142). Client participation is central for self-management to be successful (Laplante-Lévesque, Hickson & Worall, 2010b). For example, a person with hearing impairment can apply knowledge obtained through participation in a communication program to reduce hearing-related problems. Also, providing social

support using peer-to-peer-mediated communication or information about other hearing aid users may be associated with a more positive impact on behavior change. Thorén et al. (2011) showed that exchanging experiences in an online discussion forum for hearing aid users had positive effects. The role of a therapist or audiologist in delivering social contact and support, and contacts with the intervention seems to be of a particular importance in online audiology interventions (Greenwell & Hoare, 2016). Professional support and guidance in online interventions is very important in other research fields as well, including cognitive behavioral therapy, where numerous studies have demonstrated the effectiveness of internet interventions in reducing symptoms of anxiety, depression, and somatic problems (Andersson, Cuijpers, Carlbring, Riper & Hedman, 2014; Andersson, 2016).

### 1.2.1 Structured rehabilitation

Learning is an organized process that combines information, advice, action, change, feelings, and attitudes (van den Borne, 1998). Previous research reveals that 40 to 80% of the information presented to patients during a visit at a health clinic is forgotten after the visit (Kessels, 2003). Hearing aid follow-up group programs that include psychosocial counselling, provision of information, and training involve quite a substantial amount of information. Considering the learning process, and the patient's age, which in turn may affect the patient's memory, the information in an AR program should be presented clearly, using written text or images. (Dillon, 2001; Kessels, 2003; Reese & Hnath-Chisolm, 2005). Also, it may also be presented using visual or auditory presentations. This points to the importance of presenting information related to hearing impairment in a structured manner. The importance of structure in AR is emphasized by Öberg, Andersson, Wännström, & Lunner (2008).

Collaborative goal-setting (between the audiologist and the participant) adds structure to AR programs (Ridgway et al, 2013). Additionally, it fosters a capacity in the person with hearing impairment to master things, i.e., competence or self-efficacy as related to SDT. Considering SDT as a theoretical framework in future research may encourage engagement in and adherence to internet interventions.

## 1.3 Traditional aural rehabilitation

Traditional AR in Sweden differs across and within counties, in particular in terms of the number of visits and the content of comprehensive AR. The costs of amplification for the person with hearing impairment may also vary across counties.

Figure 1 outlines the AR process in Hearing Organization Södra Älvsborg, which sorts under Region Västra Götaland (VGR). Hearing Organization in VGR comprises four areas; FyrBoDal, Göteborg och Södra Bohuslän, Skaraborg and Södra Älvsborg. Each area provides support and treatment for adults and children with hearing impairment. The population catchment area of Södra Älvsborg is approximately 400 000. Currently, hearing aids and assistive devices are free of charge for all patients in the entire Region.

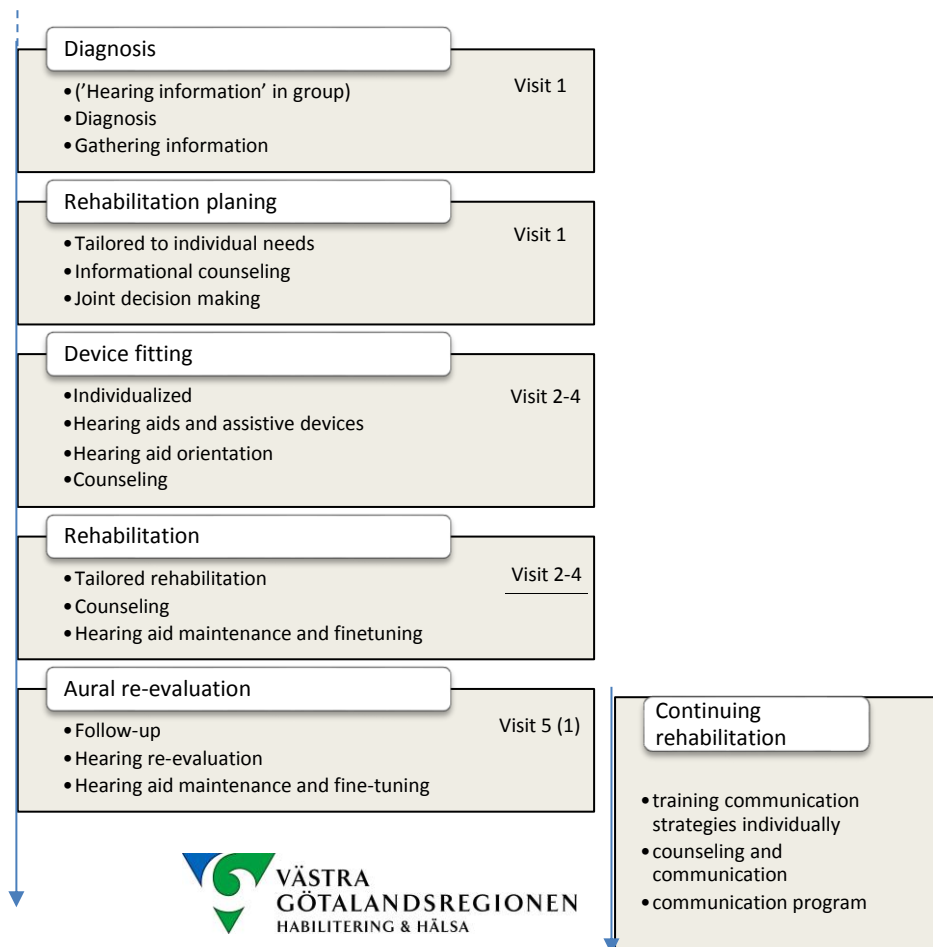


Figure 1. An example of the procedure of traditional aural rehabilitation (AR) at the Hearing Organization Södra Älvsborg.

At the initial visit to a clinic within Hearing Organization Södra Älvsborg, the patient receives information about basic anatomy and physiology, hearing aids, communication strategies, and assistive devices. Six to eight individual invitations are sent continuously to persons with hearing loss who are on the waiting list for visiting a hearing clinic. Invitations are sent by mail and inform the person with hearing impairment that he or she may bring 1 to 2 friends or family members. The first visit is also an opportunity for persons with hearing impairment to meet peers and discuss experiences or hearing related problems with them and with the audiologist leading the session. At the end of this session, all persons with hearing impairment receive an invitation for an individual *diagnosis* visit (Figure 1). However, not everybody on the waiting list participates in the introductory session (hence the parentheses in Figure 1 for *Hearing information in group*).

The diagnosis visit consists of necessary diagnostic tests, followed by gathering of relevant information about the person with hearing impairment. At this visit, the audiologist provides informational counseling and joint goals are formulated for the rehabilitation process. If required, earmold impressions are made.

The following 2 to 4 visits, approximately, center on device fitting, informational counseling, hearing aid maintenance, and fine-tuning. During these visits, a subjective evaluation is made regarding advantages and disadvantages of using the hearing aids. At this point, the rehabilitation is complete. The hearing aid user is encouraged to contact the clinic for example when experiencing problems with the devices or hearing deterioration.

The fifth visit is reserved for hearing aid maintenance and fine-tuning. It may take place anywhere from six months to five years after completion of rehabilitation. If the hearing aid user experiences hearing deterioration, a new diagnostic test is necessary in order to continue the rehabilitation. The fifth visit is then renamed visit one, and the rehabilitation process starts all over (Figure 1).

More comprehensive AR (*Continuing rehabilitation*, Figure 1) including training of communication strategies individually or in group, or participation in a communication program, is only offered to particular hearing aid users, such as users with profound hearing impairment or those diagnosed with Ménière's disease. Usually, such participation in group programs requires absence from work for the hearing aid user.



## 1.4 Evidence-based practice

When offering various interventions to persons with hearing impairment, the audiologist needs to use the best available research evidence and integrate it with clinical expertise and the client's preferences and goals (Wong & Hickson, 2012). This is in line with the Swedish code of ethics for audiologists (Gunnarsson, Lindström & Uhlin, 2001). In the literature it is referred to as evidence-based practice (EBP). EBP stresses the importance of the audiologists allowing the person with hearing impairment to make an informed choice about what action to take. The offered intervention options should reflect the evidence on how they perform in real-world conditions. Providing high-quality professional services and finding the "best" evidence helps clinicians improve the quality of life of their clients.

## 1.5 Randomized controlled trials

A randomized controlled trial (RCT) aims to reduce bias when testing the efficacy or effectiveness of health care interventions. The participants in the RCT are randomly allocated to either the intervention group or the control group (a group receiving placebo or standard treatment; Moher et al., 2012). According to the hierarchy of evidence, the best (Level 1) evidence comes from "*systematic reviews and meta-analysis of studies that are of high level or randomized controlled trials*" (Wong & Hickson, 2012, p. 12, Table 1-5). Level 2 evidence comes from well-designed RCTs. RCTs in the field of audiology have been tested in several studies, with promising results (Andersson, Green & Melin, 1997; Andersson, Strömberg, Ström & Lyttkens, 2002; Andersson, Porsaeus, Wiklund, Kaldo & Larsen, 2005; Öberg et al., 2008; Öberg, Andersson, Wännström, & Lunner, 2009; ; Thorén et al., 2011, 2014). Nevertheless, RCTs are considered costly and are uncommon within clinically implemented audiology interventions. Though, if clinically implemented, RCTs may help audiologists justify intervention decisions to policy makers/operation managers.

RCTs involve transparent reporting in order to enable the reader to judge the reliability and validity of the trial findings. In order to improve the quality of reporting of RCTs, the CONSORT statement (Consolidated Standards of Reporting Trials) was developed (Hopewell et al., 2008; Moher et al., 2012). CONSORT provides a checklist of essential items to include in RCT reports and a flowchart for documenting the participant performance in a trial. Following the checklist and the flowchart improves the reporting of the trial and ensures the achievement of structured RCTs. Furthermore, assessing structured work may be an essential component for quality assurance and continuous quality improvement of clinical practice in audiology.

## 1.6 Outcome measures for aural rehabilitation

The choice of outcome measures for a particular intervention should mirror the goals of the intervention, e.g., a change in behavior. When describing the importance of self-assessment for persons with hearing impairment, Noble (2013) writes: *“Even if the form of account making is reduced to numbers on a scaled questionnaire, those numbers are still the result of the person exercising discretion, hopefully with minimum distortion, in choosing a term that most closely matches his or her experience”* (Noble, 2013, p.13).

Outcome measures are important for the problem solving-process of AR and should resemble the conceptual framework proposed by the ICF (WHO, 2001) (Gagné, 2000). Although, important to notice is that measuring outcomes of hearing aid fitting is not alone reflecting improvements in activity, participation, and quality of life. Variables such as expectations regarding the value of hearing aids, individual personality and perspectives of friends and family members can influence hearing aid outcomes measured with self-report measures (Weinstein, 2000; Chisolm et al., 2007).

Psychosocial consequences of hearing impairment cannot be predicted from audiometric data alone (Hallberg, Hallberg & Kramer, 2008) and different age groups express different associations between psychosocial health and hearing status (Nachtegaal et al., 2009). Two instruments that reflect the domains of the ICF terminology (WHO, 2001) are the Hearing Handicap Inventory for the Elderly (HHIE, Ventry & Weinstein, 1982; Weinstein, Spitzer & Ventry, 1986; Weinstein & Ventry, 1983; Öberg, Lunner, & Andersson, 2007) and the International Outcome Inventory for Hearing Aids (IOI-HA, Cox et al., 2000; Cox, Stephens & Kramer, 2002) (Cox, 2003). The HHIE is widely used to measure the relationship between hearing impairment and psychological/emotional and social/communication variables. It is the most commonly used instrument when measuring psychosocial effects of group rehabilitation (Hawkins, 2005), change in participation restriction (Chisolm et al., 2007; Hawkins, 2005; Granberg, Dahlström, Möller, Kähäri & Danermark, 2014), and health-related quality of life (Chisolm et al., 2007). In contrast, other identified measures of quality of life lack sensitivity when applied on persons with hearing impairment (Vuorialho, Karinen & Sorri, 2006b; Bess, 2000). Benefits of hearing aids per se or influenced by counseling can also be quantified using the HHIE (Abrams, Hnath-Chisolm, Guerreiro & Ritterman, 1992; Weinstein, 2000; Cox, 2003). Hence, the HHIE is one of the chosen outcome measures for this thesis. Additionally, Sundewall, Andersson & Lunner (2012) present the possibilities of administering HHIE via the internet.

Although, there is a need for brief questionnaires that could be used in a clinical setting. IOI-HA is such a questionnaire that has been translated into various languages. Furthermore, the statements in IOI-HA lack cultural context, which is preferable in audiological research (Granberg et al., 2014). The IOI-HA is widely used for measuring hearing aid use, benefit, residual activity limitation, satisfaction, residual participation restriction, impact on others, and quality of life. There is a need for the outcome measures to address all possible outcomes of hearing aid fitting (Saunders, Chisolm & Abrams, 2005).

Another instrument that can be used is the Communication Strategies Scale (CSS, from the Communication Profile for the Hearing Impaired, CPHI, Demorest & Erdman, 1987; Hallberg, Eriksson-Mangold & Carlsson, 1992). The CSS is designed to analyze participant behavior in various communication situations, e.g., behavior that hinders or enhance communication (psychosocial outcomes). CSS is a form of standardized self-report that has previously been used in Swedish studies and targets the communication strategies that initially could be addressed by an AR program for hearing aid users.

The Hospital Anxiety and Depression Scale (HADS, Zigmond & Snaith, 1983) is a rare appearance in AR research. However, several researchers have found that hearing impairment often lead to emotions such as anxiety and negative self-image (e.g. Danermark, 1998; Garnefski & Kraaij, 2012). Furthermore, Gagné, Jennings & Southall, (2009) acknowledged that the emotional distress caused by hearing loss is not recognized in the domains of the ICF terminology (WHO, 2001). The HADS helps explore this area by measuring the presence or absence of anxiety and depression symptoms among persons with hearing impairment. Öberg et al. (2007) recommends including the HADS in research on AR as psychological factors strongly relate to hearing aid outcomes. HADS has previously been used online in AR programs for hearing aid users (Sundewall et al., 2012).

The challenge of identifying appropriate outcome measures for addressing the broad and comprehensive field of audiology has been acknowledged in previous research and the discussions of this challenge is still ongoing (Granberg et al., 2014; Vas, Akeroyd & Hall, 2016). As the reactions to hearing impairment could be multifaceted (e.g., emotional, cognitive, and interpersonal), the outcome measures should encompass each one of these reactions. This could for example be done by applying a combination of outcome measures in AR programs (Preminger, 2007), as presented in this thesis.

Also, individualized or customized questionnaires relating to these individual reactions to hearing impairment could be used. One such questionnaire is the Client Oriented Scale of Improvements (COSI; Dillon, James & Ginis, 1997). It is designed to

address individual problems related to one's hearing impairment. When used in treatment effectiveness research, such questionnaires help in overcoming some of the shortcomings related to the use of standardized questionnaires as outcome measures (Gagné, 2003).

## **1.7 Ethical considerations**

Whether participants in a study gave informed consent to participate is a crucial ethical issue in research. This issue will be addressed later in the Materials and Methods section.

Another important issue that needs to be addressed is the selection of subjects for a research study. Only participants who meet the criteria for a study are usually approached and, accordingly, all of them will have equal probability of being included in the sample group. Nevertheless, studies on AR programs conducted from a remote location (e.g., via telephone or/and the internet) may require the participants to, e.g., own a computer and have computer experience (usually self-perceived). These requirements may lead to an underrepresentation of populations with limited internet access. Furthermore, hearing aid users who are too busy to participate could be underrepresented if participating in AR programs requires the participant to allocate time for participating.

Also important in relation to studies conducted from a remote location is the physical absence of a researcher (Nosek, Banaji & Greenwald, 2002). This absence may eliminate the social demands for the participant to continue participation. This should be taken into account when designing AR programs that are conducted from a remote location.

Another issue that needs to be addressed is the completion of the outcome measures pre- and post-treatment. This can be done in several environments, e.g., at the clinic, at home, or online. When at home or online, the participants can answer the questionnaires influenced by other family members' opinions, if family members are present.

A further issue that needs attention is that completing outcome measures may require participants to answer questions about situations which are unimportant to him or her (or never actually occur in their life), while questions that are most critical situations for that participant might never be explored (Weinstein, 2000).

The benefits of conducting AR programs for hearing aid users with persistent hearing problems are recognized earlier in this thesis introduction/summary,

suggesting that such programs are valid and could be practically feasible (Emanuel, Wendler & Grady, 2000). This methodological rigor of such programs is important for the clinical research to be considered ethical. However, implementing such programs in GCP can be expensive. Conducting AR programs from a remote location could yield improved cost-effectiveness. It may improve clinical encounters and allow for hearing clinics to reach a substantial proportion of hearing aid users with persistent hearing problems. Consequently, the potential benefits of participating in AR programs from a remote location outweigh the potential risks of participating in such programs.

## **1.8 Rationale**

Many hearing aid users experience substantial communication difficulties that can negatively affect their interpersonal interactions or participation in daily life situations. This experience can be addressed with follow-up AR programs comprising psychosocial counselling, provision of information, and training. Such programs have proven to be effective in minimizing hearing related problems. Nevertheless, the overall availability of comprehensive AR in clinical practice is low. Evaluating and clinically applying educational programs administered from a remote location, supported via telephone and/or the internet, and professionally guided by an audiologist increases the possibilities for the audiologist in GCP to reach out to hearing aid users and offer a cost-effective approach to AR.



## 2 AIMS

The overall aim of this thesis was to evaluate, explore, and clinically apply educational AR programs administered from a remote location using randomized controlled trials, supported via telephone and/or the internet and professionally guided by an audiologist.

The specific aims of Papers I to IV:

- I. To evaluate the short-term effects of a telephone-supported educational program that focuses on hearing and hearing aids among hearing aid users.
- II. To evaluate the short- and long-term effects of implementing an internet-based AR program for hearing aid users, in general clinical practice.
- III. To share lessons learned in regarding to the process of implementing an internet-based randomized controlled trial in general clinical practice.
- IV. To identify and explore hearing aid users' individual experiences of an internet-based AR program using a qualitative method.





## 3 MATERIALS AND METHODS

### 3.1 General methods

In the present thesis, **Paper I** and **Paper II** report the results of two randomized controlled trials (RCTs), **Paper III** presents the process of implementing an internet-based RCT in general clinical practice (GCP), and **Paper IV** evaluates an internet-based AR program for hearing aid users using a qualitative approach.

RCTs involve a standardized intervention evaluated in terms of statistically measurable outcomes (Torpy, Lynn & Glass, 2005; Audrey, Holliday, Parry-Langdon & Campbell, 2006). The outcome measures used in **Paper I** are HHIE, IOI-HA, and HADS, all of which are self-assessment scales that were used pre-treatment (T0), and directly after the treatment (T1). The outcome measures used in **Paper II** are HHIE, HADS, and CSS. These are self-assessment scales as well, used: T0, T1, and six months post-treatment (T2). Table 1 shows the aims, designs, outcome measures used, and times of evaluation.

Table 1. Outline of *Papers I-IV*.

Paper	Aim	Design	Outcome measures	Time of evaluation
I	To evaluate the effects of a telephone-supported educational program for hearing aid users.	RCT	HHIE, IOI-HA & HADS	T0 & T1
II	To evaluate the effects of implementing an internet-based AR program for hearing aid users in GCP.	RCT	HHIE, HADS & CSS	T0, T1 & T2
III	To share lessons learned in regard to the process of Paper II.	Descriptive		
IV	To explore hearing aid users' individual experiences of an internet-based AR program.	Telephone interview		

## 3.2 Questionnaires/Outcome measures

Four standardized questionnaires were selected as outcome measures and used in **Papers I to II**: the Hearing Handicap Inventory for the Elderly (HHIE; Ventry & Weinstein, 1982), the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), the International Outcome Inventory for Hearing Aids (IOI-HA; Cox et al., 2000), and the CSS (from the Communication Profile for the Hearing Impaired, CPHI; Demorest & Erdman, 1987). All questionnaires are available in Swedish (Zigmond & Snaith, 1983; Cox et al., 2002; Öberg et al., 2007). They have good internal consistency (Hallberg et al., 1992; Öberg et al., 2007) and have been shown to be as reliable as the original versions when used with a Swedish population of young adults and old people (Öberg et al., 2007). The four questionnaires were used to evaluate self-reported hearing problems, anxiety and depression symptoms, hearing aid outcomes, and participants' communication strategies.

The HHIE was the primary outcome measure for both RCTs in **Paper I** and **Paper II**. It consists of two subscales: *social* and *emotional*. The former contains 12 questions addressing the social effects of hearing impairment, and the latter comprises 13 questions addressing the emotional effects of hearing impairment. For each of the 25 questions, there are three potential responses: "yes" (4 points), "sometimes" (2 points), and "no" (0 points). Higher scores reflect a higher self-reported hearing problem.

The HADS, IOI-HA, and CSS were selected as secondary outcome measures (HADS and IOI-HA for **Paper I** and HADS and CSS for **Paper II**). The HADS measures anxiety and depression symptoms using 14 items, divided into two subscales: *anxiety* and *depression*. Responses are scored from 0 to 3, with a higher score indicating more symptoms of anxiety and depression.

The IOI-HA comprises seven questions, each measuring a specific dimension of hearing aid outcomes: daily use, benefits, remaining activity limitations, satisfaction, remaining participation restrictions, impact on the environment, and quality of life. Responses are scored from 1 to 5, where a higher score indicates a better outcome.

The CSS is designed to analyze participants' behavior in various communication situations via three subscales: *maladaptive behaviors* (9 questions that analyze behaviors that hinder communication) and *verbal strategies and nonverbal strategies* (16 items related to strategies that can enhance communication). The 1 to 5 scoring reflects how frequently a specific situation or behavior occurs.

In **Paper I**, the HHIE, HADS, and IOI-HA were administered on paper before (T0) and directly after (T1) the program. In **Paper II**, the HHIE, HADS, and CSS were

administered via the internet before (T0), directly after (T1), and 6 months after the program (T2). Sundewall et al. (2012) stress the importance of keeping the internet-based administration format of the HHIE and HADS stable over time.

Furthermore, COSI was used to design part of the intervention in **Paper I**, although not as an outcome measure. The COSI is an individualized questionnaire in which participants list and rank problematic situations related to hearing impairment (Dillon et al., 1997). It requires participants to identify individual hearing problems that they feel affect their daily life in terms of, e.g., activity limitations and participation restrictions. Also, IOI-HA was used to describe the demographic and clinical characteristics of the participants in **Paper II**, but was not used as an outcome measure.

## 3.3 Participants

### 3.3.1 Inclusion criteria

In **Paper I**, the participants consisted of 69 hearing aid users. The inclusion criteria for the study were as follows: completion of a hearing aid fitting at least one year prior to the study, age 60 to 75 years, conductive or sensorineural hearing loss of a mild to moderate degree (20 to 60 Decibel hearing level (dB HL)), pure tone-average (PTA) measured across 500, 1000, and 2000Hz, and HHIE score of at least 20 points, which indicates some residual hearing problems.

In **Paper II**, the participants consisted of 74 hearing aid users. The inclusion criteria for the study were as follows: completion of a hearing aid fitting at least three months prior to the study, age 20 to 80 years old, conductive or sensorineural hearing loss of a mild to moderate degree (2060 dB HL, PTA measured across 500, 1000, and 2000Hz), and the HHIE to be equal to or more than 20 points, which indicates some residual hearing problems.

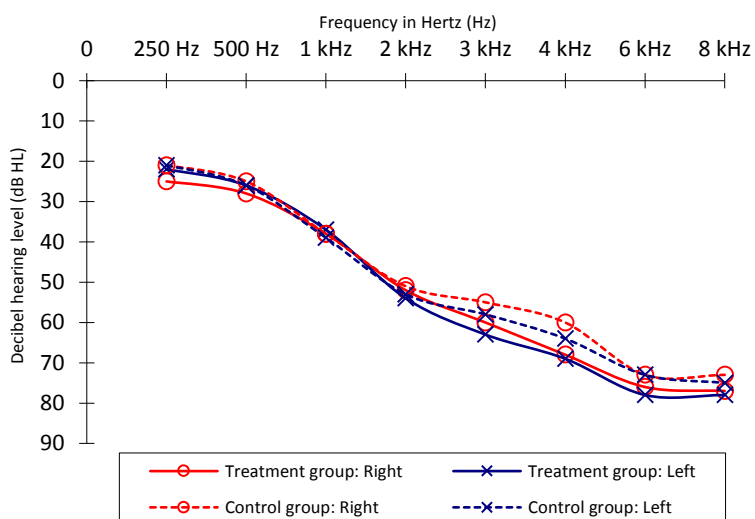
In **Paper III**, the authors present experiences of implementing an internet-based RCT in GCP.

In **Paper IV**, the participants consisted of 20 hearing aid users who had recently completed an internet-based AR program.

A total of 163 hearing aid users participated in the present thesis (67 females and 96 males), data on whom is presented in Table 2, Figure 2 and Figure 3.

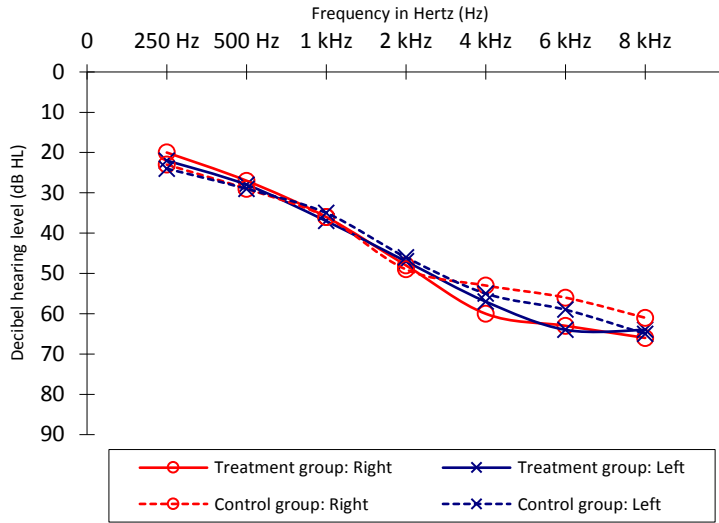
Table 2. Age, gender, and history of hearing aid use; participants in **Papers I, II, and IV.**

Paper	Group	N	Gender		Age (years)			Hearing aid use (years)	
			Female	Male	Mean	Range	SD	Mean	SD
I	Treatment	33	11	22	68.0	60–73	4.0	6.7	5.9
	Control	36	17	19	69.0	60–74	4.6	6.3	5.8
II	Treatment	37	13	24	61.8	32–79	11.9	7.5	9.6
	Control	37	17	20	62.1	31–80	11.4	7.4	6.3
IV	Interview	20	9	11	70.9	57–81	6.4	14.3	7.3



	250 Hz	500 Hz	1 kHz	2 kHz	3 kHz	4 kHz	6 kHz	8 kHz
Treatment group: Right	13.9	13.8	13.7	12.7	13.3	14.3	14.8	17.3
Treatment group: Left	13.9	15.4	15.3	11.6	15.0	14.3	16.7	18.5
Control group: Right	11.6	11.9	10.4	12.1	16.1	17.0	22.1	20.7
Control group: Left	11.4	12.3	11.9	11.6	16.8	19.8	20.9	19.1

Figure 2. **Paper I:** Means (graph) and standard deviations (SD; table) of Decibel hearing level (dB HL) for each frequency measured in Decibels (dB) presented for intervention and control group, as well as right and left ear.



	250 Hz	500 Hz	1 kHz	2 kHz	4 kHz	6 kHz	8 kHz
Treatment group: Right	12.8	12.8	13.3	17.1	23.1	26.0	27.6
Treatment group: Left	14.4	15.2	15.0	13.6	19.2	20.7	20.1
Control group: Right	12.6	13.0	13.7	13.1	15.8	19.5	22.8
Control group: Left	12.4	13.2	12.6	12.1	15.9	16.2	18.4

Figure 3. **Paper II:** Means (graph) and standard deviations (SD; table) of Decibel hearing level (dB HL) for each frequency measured in decibels (dB) presented for intervention and control group, as well as right and left ear.

## 3.4 Procedure

### 3.4.1 Paper I

For **Paper I**, all potential participants who fulfilled the criteria for age, hearing loss and hearing aid fitting received a recruitment letter describing the purpose of the study, procedures, and schedule. The participants were recruited from three clinics within Hearing Organization Södra Älvsborg. The recruitment letter also stated that the hearing aid users would be placed into one of two groups, that the participants' privacy would be protected, and that participation was voluntary. The HHIE questionnaire was included with the recruitment letter for the study reported in **Paper I**. Participants who agreed to participate in the study returned a completed HHIE questionnaire by mail and were then called in for an interview to assess their eligibility (Figure 4). This first visit at the clinic started with participants undergoing PTA in order to ensure there was no deterioration in hearing. After being interviewed, the participants completed the HADS, the IOI-HA, and the COSI (Figure 4) with the audiologist present in the room.

A pile of envelopes in numerical order was created, with the envelope with the lowest research number at the top. The envelopes contained allocations to one of two different groups (1 and 2). After ensuring the participants' eligibility for the study, the participants who agreed to participate received an envelope allocating them to an intervention (1) or a control group (2). The independent person who administered the envelopes and enrolled the participants was blinded to the content of the envelopes, and was not aware of the subjects' age, gender, degree of hearing loss, or fitting configuration. Finally, appointments were made for the second and final research visit.

The participants in the intervention group were given their COSI results, their most recent audiograms, and a letter describing the intervention. They were also provided with the book *When the Sounds Are Weaker – On Hearing and Hearing Aids* (Elberling & Worsøe, 2006). Each Monday (weeks 1 to 5), the participants received mail including weekly home assignments and the reading instructions needed to complete the assignments. See Table 3 for the content of weekly reading instructions.

Table 3. Reading instructions for the participants in the intervention group (*Paper I*).

WEEK	READING INSTRUCTIONS	READING CONTENT
1	Chapters 1 to 2	Basic information about hearing and audiometry.
2	Chapters 3 to 4	Explaining the hearing impairment, communication, and the audiogram.
3	Chapter 5	Explaining the inner ear function.
4	Chapters 6 to 7	Explaining the hearing aids, hearing aid limitations and benefits.
5	Chapter 8	Explaining various communication strategies.

At the end of each treatment week (1 to 5) weekly home assignments were discussed with the audiologist by phone. The purpose of this was for the audiologist to ensure that the participants had understood the information correctly and that any further questions or concerns could be addressed. These telephone consultations lasted approximately 10 to 15 min./participant. If considered necessary during these telephone consultations, the audiologist could introduce the individually tailored weekly tasks as defined according to the problem situations identified in the participant's COSI.

The participants in the control group received the same book as those in the intervention group and were asked to read and evaluate the book with no professional interaction. The book was sent to each participant's home in order to be read parallel to the intervention group's last two weeks of the program.

The HHIE, HADS, and IOI-HA questionnaires were mailed to all participants at the end of the treatment period. During both groups' second visit at the clinic, the participants were interviewed in order to evaluate the intervention or/and the book they had received (Figure 4).

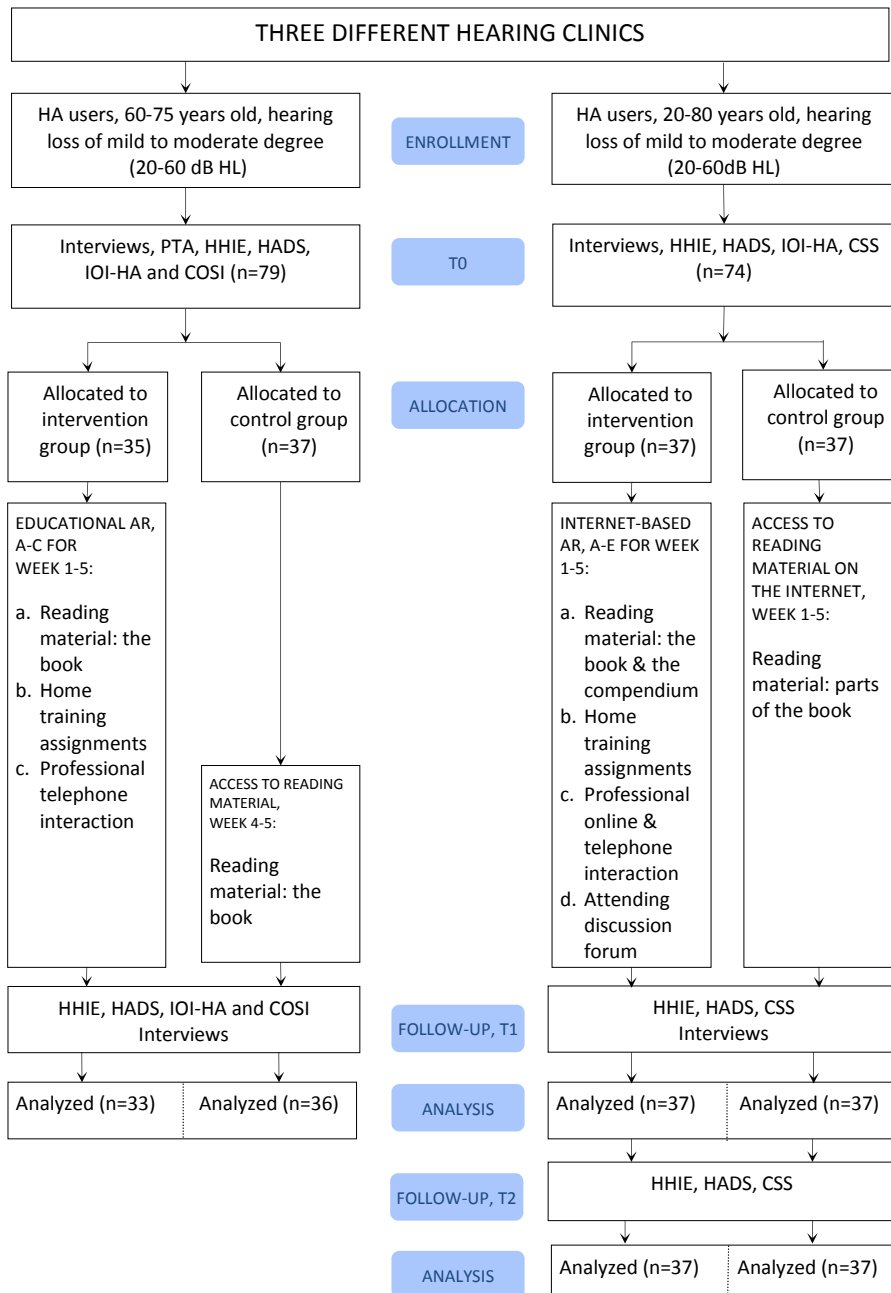


Figure 4. Flowchart of the procedure for **Paper I** (left) and **Paper II** (right).



### 3.4.2 Paper II

For **Paper II**, all potential participants who met the criteria for age, hearing loss, and hearing aid fitting received a recruitment letter describing the purpose of the study, procedures, and schedule. Once again, the participants were recruited from three clinics within Hearing Organization Södra Älvsborg. The recruitment letter also stated that hearing aid users would be placed into one of two groups, that the participants' privacy would be protected, and that participation was voluntary.

In **Paper II**, the first step of the participation required hearing aid users to register and complete a screening form on the study website. After completing and submitting the screening form, the participants were interviewed by phone to assess their eligibility. Further on, as a second step, the participants were asked to complete four questionnaires on the study website: the HHIE, the CSS, the HADS, and the IOI-HA (Figure 4). At this point, the IOI-HA was used to describe the demographic and clinical characteristics of the participants and was not used as an outcome measure.

A computer-generated list of random numbers was used to randomly assign the participants in **Paper II** to either an intervention group (group 1) or a control group (group 2) (Figure 4). An independent person generated the random allocation sequence and assigned the participants to different groups. The independent person disclosed the allocations for the project leader who then enrolled the participants in each group. The participants were informed about which group (1 or 2) they had been assigned to, but not about whether their group was the intervention or the control group.

The intervention group in **Paper II** had access to an internet-based AR program for five weeks. The program consisted of four elements (Figure 5): 1) reading material, i.e., a book titled *When the Sounds Are Weaker – On Hearing and Hearing Aids* (Elberling & Worsøe, 2006) and a compendium of communication strategies; 2) reading instructions and weekly assignments related to the reading material; 3) online and telephone interaction with a professional; and 4) access to an online discussion forum where new discussion topics were posted each week (without any interaction with the audiologist). See Table 4 for the content of weekly reading instructions. The control group only had access to a part of the intervention group's reading material (Figure 5).

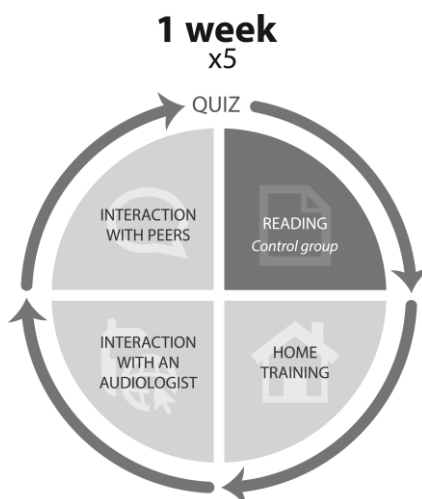


Figure 5. The full internet-based program for the intervention group and the element of the internet-based program that the control group participated in (Paper II).

Table 4. Reading instructions for the participants in the intervention group (Paper II).

WEEK	READING INSTRUCTIONS	READING CONTENT
1	Chapters 1 to 3 in the book	Basic information about hearing and audiometry.
2	Chapters 5 to 7 in the book	Explaining the inner ear function, hearing aids, and their limitations and benefits.
3	The compendium	Explaining disturbing background noise and communication in such environment. Problem-solving approach.
4	The compendium	Applying and practicing communication strategies using examples of daily life participation. Problem-solving approach.
5	The compendium	Information on assistive listening devices, maintenance of behavioral changes, and applied relaxation. Problem-solving approach.

The participants submitted weekly home assignments online each week and an audiologist provided direct responses in the same way. At the end of each treatment week (1 to 5), the weekly home assignments were discussed with the audiologist by phone.

The HHIE, CSS, and HADS were made available to all participants via the study website at the end of the treatment period (Figure 4). A post-study telephone interview was at that point conducted to evaluate the participation in both groups. Six months post-participation, the HHIE, CSS, and HADS were over again made available to all participants via the study website.

### 3.4.3 Paper III

The randomized controlled trial of internet-based AR for hearing aid users that is presented in **Paper II** was implemented in a clinical setting (GCP) by using the internet. Transferring RCTs into the clinic is challenging and there is no guarantee that a successfully performed RCT of internet-based AR for hearing aid users outside GCP can be as successfully performed in GCP. In order to maximize the chances of successfully implementing an RCT of internet-based AR in GCP, the project leader needed to engage clinicians in the implementation process and ensure that the sample of the recruited patients was as representative as possible of those in GCP.

Three clinicians were engaged in the GCP trial and were trained in administering the internet-based AR program. They were required to allocate approximately 15 to 20 min./participant/week. All three of them found the research question to be relevant enough for them to engage in the implementation process. The rewards for the participating clinicians included positive feedback and support from the project leader. Furthermore, clinician involvement required the operation managers to encourage their involvement in the implementation process without adventuring the clinicians' regular clinical practice and management duties.

The implemented recruitment strategy required participants to visit an internet site to read more about the trial and initiate participation. To allow for faster enrollment, the GCP trial used wide eligibility criteria. This also ensures that the trial population is representative. Various outcome measures were administered on the internet before and after the GCP trial.

### 3.4.4 Paper IV

In **Paper IV**, participants from an intervention/treatment group of an internet-based AR program for hearing aid users (Thorén et al., 2014) were interviewed using semi-structured telephone interviews. The 20 participants who agreed to participate received information about the study by mail. The participants were contacted by e-mail to decide a date and time for each interview. An interview guide addressing the participants' motivation to participate in the internet-based AR program, their

experiences of the program, and what they got out of the program was used. All interviews were audio recorded and later literally transcribed.

### 3.5 Ethical considerations

All participants included in this thesis participated on a voluntary basis by signing a written informed consent. The regional ethics committee of Gothenburg, Sweden reviewed and approved the studies presented in **Paper I** and **Paper II** (registration numbers: DR 253-07, DR 1018-11 + T112-14). The Research Ethics Group at the Department of Logopedics, Phoniatrics and Audiology, Lund University, Sweden approved the data collection for **Paper IV**. Research documents are archived according to University of Gothenburg's implementation decision in line with RA-FS (the Swedish National Archives regulations) 1999:1, modified 2002:1.

### 3.6 Analysis of data

All data for **Paper I** and **Paper II** were analyzed using the Statistical Package for the Social Sciences (SPSS; software for Windows 2007, version 16.0) for **Paper I** and software for Windows 2011 (SPSS, version 19.0) for **Paper II**. All questionnaires were administered according to the methods described by Ventry and Weinstein (1982), Zigmond and Snaith (1983), Cox et al. (2000), and Demorest and Erdman (1987).

It was estimated that 60 participants needed to be included in each RCT (**Paper I** and **Paper II**) in order to ensure a between-group effect of 80% at the 5% significance level. An effect size of Cohen's  $d=0.80$  was expected. The power for **Paper I** and **Paper II** was obtained based on the expected standardized mean difference on the HHIE total scale.

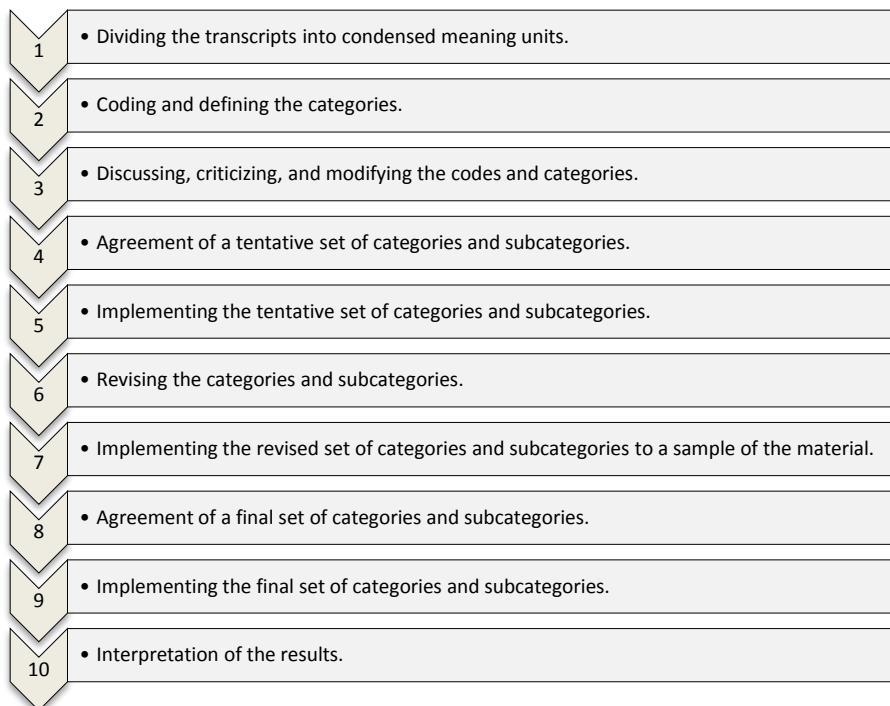
In **Paper I**, two measurement time points were examined: pre-treatment (T0) and post-treatment (T1). The analysis of variance (ANOVA) test was used to investigate the between-group difference (the main effect), the within-group difference, and the interaction effect between group and time. A significant interaction effect or main effect was followed by a Bonferroni-adjusted post hoc test. Participants who completed the outcome measures at T1 but eventually withdrew from the study were included in the data analysis on an "intention-to-treat" (ITT) basis (Fergusson, Aaron, Guyatt & Hébert, 2002).

In **Paper II**, three measurement time points were examined: pre-treatment (T0), post-treatment (T1), and 6 months post-treatment (T2). The within- and between-group effect sizes of Cohen's  $d$  were calculated from T0 to T1 and from T0 to T2. All

data for the participants who did not complete T1 and/or T2 measurements were included in the analysis (as missing data), and were treated on an ITT basis. The difference between and within groups, as well as interaction effects of group and time, were investigated with mixed effect models, allowing for handling of missing data (Gueorguieva & Krystal, 2004). Additionally, data was analyzed for two age groups (20 to 59 years and 60 to 80 years), and the data was analyzed after excluding participants who did not complete all measurement time points (T1 and/or T2).

In **Paper III**, no statistical analysis was carried out as this paper is of a descriptive nature. This paper may stimulate future research and provides useful information about an internet-based RCT implemented in GCP.

In **Paper IV**, all interviews were recorded, transcribed verbatim, and analyzed in accordance with content analysis (Graneheim & Lundman, 2004; Hsieh & Shannon, 2005; Knudsen et al., 2012). The interview transcripts were interpreted in line with Figure 6.



*Figure 6. The interview transcript interpretation process for the study presented in **Paper IV**.*



## 4 RESULTS

### 4.1 Paper I

The results for the study presented in **Paper I** show a significant interaction effect between group and time for the HHIE-total scores ( $p < 0.05$ ) and the HHIE-emotional subscale ( $p < 0.05$ ; Figure 7), indicating that providing the participants with a post hearing aid AR program reduced the self-reported hearing problems significantly more in the intervention group than in the control group.

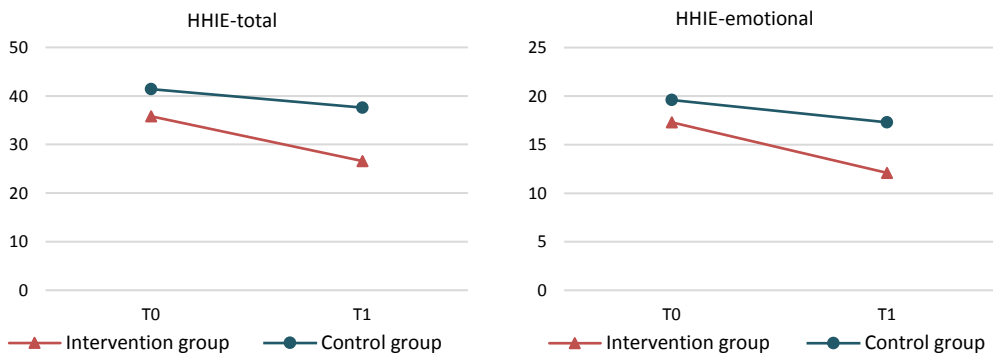


Figure 7. Means of the HHIE (Hearing Handicap Inventory for the Elderly) total scale and HHIE-emotional subscale, for both groups pre-treatment (T0) and post-treatment (T1) (**Paper I**).

Examining IOI-HA, the results show that the program had no effect on overall hearing aid outcomes, irrespective of participation in the intervention or the control group (Figure 8).

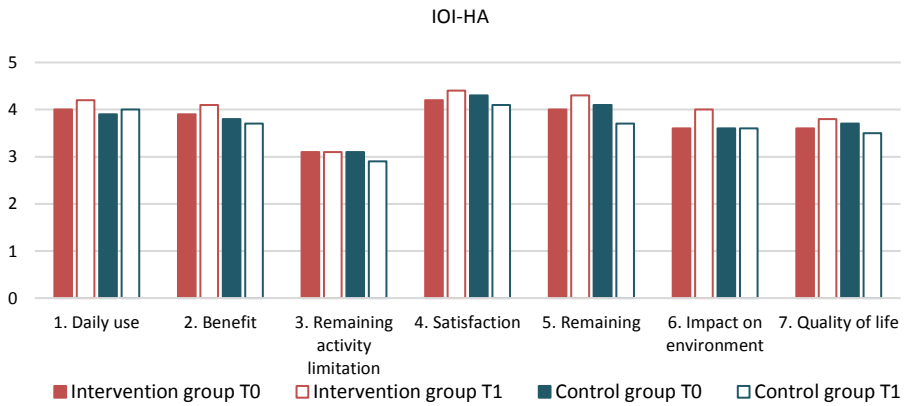


Figure 8. Means of the IOI-HA (International Outcome Inventory for Hearing Aids) item scores for both groups before (T0) and after the intervention (T1) in the study presented in Paper I.

Furthermore, examining HADS, the results reveal an interaction effect between group and time for the total scale ( $p < 0.05$ ) and the depression subscale ( $p < 0.05$ ; Figure 9), indicating that the intervention group improved significantly better than the control group.

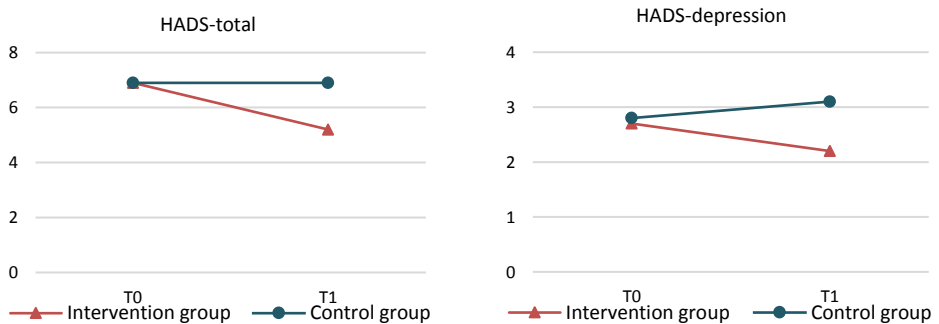


Figure 9. Means of the HADS (Hospital Anxiety and Depression Scale) total scale and HADS-depression subscale, for both groups pre-treatment (T0) and post-treatment (T1) (Paper I).



## 4.2 Paper II

The results for the study presented in **Paper II** show no significant interaction effect between group and time for the HHIE-total scores from T0 to T1 or T0 to T2 (Figure 10) and a borderline significant interaction effect for the emotional subscale from T0 to T1 ( $p=0.05$ ), indicating that providing the participants with a post hearing aid AR program reduced the self-reported hearing problems for both groups with no significant between-group difference found.

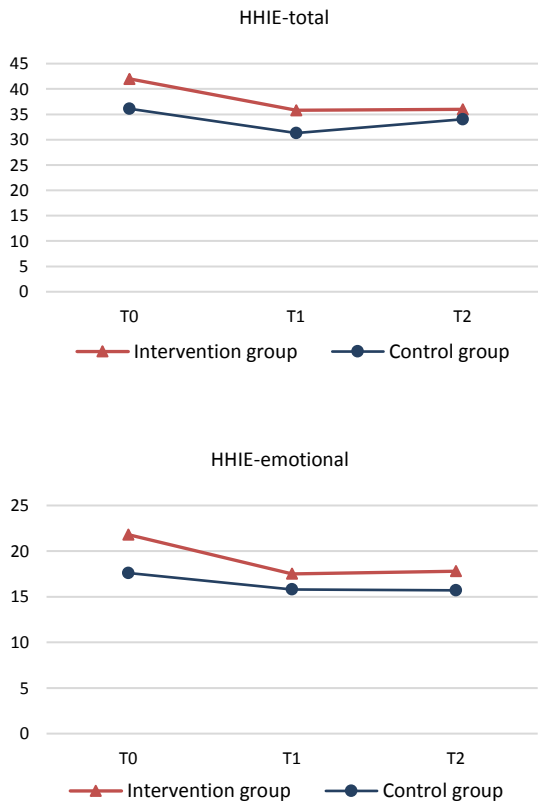


Figure 10. Means of the HHIE (Hearing Handicap Inventory for the Elderly) total scale and HHIE-emotional subscale, for both groups pre-treatment (T0), post-treatment (T1), and 6 months post-treatment (T2) (**Paper II**).

The analyses for HADS showed no significant differences when modeling the interaction effects of group and time for the intervention group and the control group from T0 to T1 or T0 to T2.

Examining CSS-total showed significantly greater improvement in the intervention group than in the control group T0 to T1 ( $p < 0.05$ ; Figure 11). This interaction effect almost persisted T0 to T2 ( $p = 0.06$ ). The nonverbal subscale showed significantly greater improvement for the intervention group than for the control group T0 to T1 ( $p < 0.01$ ), and this interaction effect persisted from T0 to T2 ( $p < 0.05$ ; Figure 11).

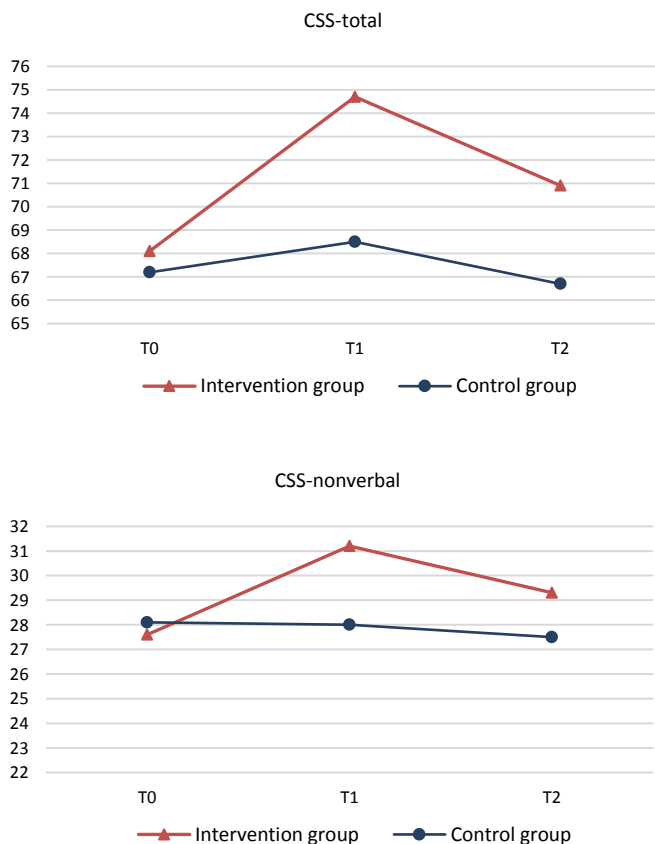


Figure 11. Means of the CSS (Communication Strategies Scale) total scale and nonverbal subscale, for both groups pre-treatment (T0), post-treatment (T1), and 6 months post-treatment (T2) (Paper II).

For the HHIE, CSS, and HADS scores T0 to T1 and T0 to T2, as presented in **Paper II**, different age groups were analyzed (20 to 59 years and 60 to 80 years). The results show no significant differences between the age dispositions in the intervention group compared to the ones in the control group for the HHIE and HADS T0 to T1 or T0 to T2. However, the 60 to 80 year olds in the intervention group showed significantly more improvement than the 60 to 80 year olds in the control group when examining CSS-total ( $p < 0.01$  T0 to T1;  $p < 0.05$  T0 to T2) and the nonverbal subscale ( $p < 0.05$  T0 to T1 and T0 to T2).

A sensitivity analysis was performed for all three outcome measures (HHIE, CSS, and HADS) including only data from the participants who completed all three measurement time points (T0, T1, and T2;  $n=50$ , not sufficient to ensure a between-group effect of 80%). The results show an interaction effect for the HHIE-emotional subscale T0 to T1 ( $p < 0.05$ ), and no interaction effect T0 to T2. Furthermore, the results reveal no interaction effect for the CSS-total scale, as was found for the whole group ( $n=74$ ). Meanwhile the nonverbal subscale showed similar results as presented for the whole group ( $p < 0.05$  T0 to T1 and T0 to T2). Also, the intervention group showed significantly greater improvements compared with the control group for the HADS-total scale T0 to T2 ( $p < 0.05$ ).

### 4.3 Paper III

The process of implementing an internet-based RCT in GCP is presented in **Paper III**. The results showed that it is possible to carry out an internet-based AR in addition to hearing aid fitting in GCP. By using an internet-based approach, we could overcome some of the challenges of implementing an RCT in GCP. For example, we could see advantages when collecting data, i.e. storing the registration responses directly in the database. Moreover, the internet-based approach used for the recruitment procedure required no effort from the clinicians. Furthermore, the GCP trial did not require effort in terms of recording questionnaire responses. The internet-based approach enabled the responses to be directly stored in a database and facilitated the participants' access to the questionnaires. Storing the responses directly in the database also facilitated the researchers' administration of the questionnaires.

The operation managers at the clinic where the trial was conducted encouraged clinician participation as a component of their regular clinical practice, which in turn encouraged the clinicians' participation in the implementation process of RCT in GCP.

## 4.4 Paper IV

In **Paper IV**, we aimed to explore participants' experiences of an internet-based AR program for hearing aid users and the possible subjective benefits provided by the program. The results presented in **Paper IV** concern three main categories: general experiences of the program, theoretical knowledge and benefits, and practical knowledge and benefits. Overall positive experiences of the internet-based program were revealed. The participants gained knowledge from participating in the program, which in turn contributed to an increased awareness of hearing impairment, hearing aids, and communication strategies as well as improved self-esteem. Further on, this gained knowledge, may have encouraged many of the participants to take actions that could improve their daily communication. The improvements shown in **Paper IV** emphasize the hearing aid users' ability to act and interact on their own, and to focus on what they can do instead of what they cannot do.

## 4.5 Summary of results

Table 5 represents a summary of the main findings in **Papers I to IV**.

*Table 5. Summary of main findings in Paper I to IV.*

PAPER	TIME FOR EVALUATIONS	OUTCOME MEASURES	MAIN FINDINGS
I	T0 & T1	HHIE, IOI-HA & HADS	Significant improvements for the intervention group compared with the control group in terms of HHIE-total scores, the HHIE-emotional subscale, the HADS-total scale, and the HADS-depression subscale.
II	T0, T1 & T2	HHIE, HADS & CSS	Significant improvements for the intervention group compared with the control group in terms of CSS-total and CSS-nonverbal subscale T0 to T1. The improvements for CSS-nonverbal subscale persisted from T0 to T2.
III			It is possible to carry out an internet-based AR program using RCT in GCP. The internet-based approach helps overcome some of the challenges of implementing a RCT in GCP.
IV			The overall results indicate positive experiences of the internet-based AR program. The participants gained knowledge from participating in the program, which in turn encouraged many participants to take actions that could improve their daily communication.

## 5 DISCUSSION

The overall aim of this thesis was to evaluate, explore, and clinically apply AR programs conducted from a remote location using randomized controlled trials (RCTs). The RCTs conducted in **Paper I** and **Paper II** consisted of clinically applied and evaluated AR programs for hearing aid users that were supported via telephone and/or the internet and professionally guided by an audiologist. The process of implementing one of these RCTs in general clinical practice (GCP) is discussed in **Paper III**. In **Paper IV**, participants' views of taking part in an AR program for hearing aid users were explored using a qualitative approach.

### 5.1 Aural rehabilitation programs and outcome measures

In **Paper I**, the results suggest that complementing an educational program with telephone consultations could be effective for reducing self-reported hearing problems and that audiologists may play an important role in applying the intervention. The intervention group improved significantly better T0 to T1 compared with the control group regarding HHIE-total scale and the HHIE-Emotional subscale. In **Paper II**, both the intervention group and the control group improved their HHIE scores T0 to T1 and T0 to T2; however, unlike the findings in **Paper I**, the improvements were not significantly different between groups. These differences in outcomes in terms of HHIE scores between **Paper I** and **Paper II** could be due to the differences in approach between the evaluated AR programs. In both papers, the programs were conducted from a remote location and followed up with telephone support. In **Paper I**, the participants were mailed weekly home assignments and reading instructions needed to accomplish the assignments. In **Paper II**, the participants had access to an internet-based rehabilitation program that was an extended version of the program in **Paper I** including evidence-based tools (Wong & Hickson, 2012), and the participants were encouraged by e-mail each week to log into the study website and access the reading material and the weekly home assignments. It is possible that the extra effort required of the participants in **Paper II** (e.g. logging into the study website) could be affected by peoples' extrinsic and intrinsic motivation. These different types of motivation are presented in the literature as related to self-determination theory (SDT; Ridgway et al., 2013; Henshaw et al., 2015). According to Henshaw et al. (2015), both extrinsic (important for accepting the value of a task) and intrinsic (important for completing a task) motivation may influence engagement in and adherence to an online program. Thus, the extra effort required of the participants could have affected the

engagement in and adherence to the program and subsequently the outcomes of the program.

Another underlying explanation for the differences in improvements measured by the HHIE could be that the control group in **Paper II** was more active, in contrast to the control group in **Paper I**. Participants in the control group in **Paper II** were encouraged to log in online and read about hearing and hearing aids. This encouragement could be considered an activity that requires more effort than the requirements of the control group in **Paper I**, where the participants were asked to read a book (on paper). Though, when enrolled in a research study the participants might generally be more positive (Linde, Fässler & Meissner, 2011). The enrollment in the control group, in both **Paper I** and **Paper II**, could be considered a research bias assuming that being enrolled in the intervention group is more effective than being enrolled in the control group.

Similarity of improvements measured by the HHIE could be seen in the HHIE-emotional subscale. A significant interaction effect and a borderline significant interaction effect were found in **Paper I** and **Paper II**, respectively, for the emotional subscale, indicating that taking part in a follow-up AR program could reduce emotional effects of hearing impairment. The improvements measured by the HHIE emotional subscale could be due to the participants feeling more knowledgeable due to reading and home training elements of the programs. Feeling knowledgeable may raise participants' abilities, which in turn can lead to increased self-esteem or confidence. Confidence is crucial for a person's ability to engage in effective communication (Sweetow & Henderson, 2010). According to Sweetow and Henderson (2010), a lack of confidence may lead to disuse of hearing aids, anxiety, and avoidance behavior. In addition, the increased self-esteem/confidence may be acknowledged by the audiologist during the weekly telephone consultations. This is in line with the results in **Paper IV**, where the participants were interviewed regarding their participation in an internet-based AR program. Participants in **Paper IV** expressed that being knowledgeable improved their self-esteem and encouraged them to take actions that could improve their communication in daily life. Knowledge as a result of educational guidance can generate competence or self-efficacy, a condition that, according to SDT is needed in order to achieve positive health outcomes.

The guidance provided by the audiologist throughout the AR programs in **Paper I** and **Paper II** is important for the maintenance and enhancement of motivation. A study by Laplante-Léveque et al. (2012), on the views of individuals with hearing impairment regarding AR revealed that patients valued the guidance they received on hearing aid use and care (i.e., daily life aspects) more than they value the initial hearing aid fitting. Maintenance and enhancement of motivation require supportive

conditions (Henshaw et al., 2015), which brings attention to the important role of the audiologists in AR programs. It is the audiologists' clinical experience and skills combined with knowledge of the clinical significance of the respective AR programs that strengthen the guidance provided by the audiologists in **Paper I** and **Paper II**. Audiologists spend a lot of time teaching hearing aid users to manage their hearing aids, but hearing aid users also need to acquire skills that support self-management of practical, emotional, and psychosocial aspects of a life with hearing impairment (Convery, Keidser, Hickson & Meyer, 2016).

When performing and engaging in a behavior change, such as for example learning new communications strategies, inclusion of reading material and weekly tasks in AR programs is important for a person's perceived self-efficacy. These elements of examined AR programs are relevant in order for participants to believe that they can produce an effect by their actions. According to SDT (Ridgway et al., 2013), one's need of a sense of control and affirmation of personal actions will help enable intrinsic motivation and further on influence long-term adherence to treatment. Further on, the confidence that comes with self-efficacy leads to a sense of competence, which is a critical element for intervention success (Sweetow & Henderson, 2010). In **Paper IV**, participants report increased awareness of hearing impairment and improved self-esteem/confidence from participating in the program. This is in line with previous research on educational programs for hearing aid users, where participants reported increased confidence in dealing with hearing impairment (Kramer et al., 2005; Ferguson et al., 2016). Confidence may additionally be fostered using shared goal-setting. The weekly tasks performed by the participants in **Paper I** and **Paper II** could be considered shared goals that are renewed each week, which, according to van den Borne (1998), can help increase patients' motivation for continued learning. Shared goal-setting is also crucial component of client centeredness (Laplante-Levésque et al., 2010b). In line with the WHO (2001), client centeredness adopts a biopsychosocial perspective and emphasizes the clients' unique experience and a good clinician-client relationship. COSI is recommended for these purposes and was used, though not statistically addressed, in **Paper I**. A client centeredness approach in hearing rehabilitation programs may improve the quality of life of hearing aid users and should be addressed in a broader manner in future research on internet interventions.

Emotions such as anxiety and negative self-image could be one of several consequences of hearing impairment and this was the reason for including HADS in **Paper I** and **Paper II**, i.e. to measure the participants' self-reported symptoms of anxiety and depression. In **Paper I**, the intervention group showed some significant improvements on the HADS-Total scale and the HADS-Depression subscale compared with the control group. Although, neither the participants in **Paper I** nor those in **Paper II** expressed initial symptoms of anxiety or depression. HADS is

considered to be sensitive enough to detect changes in psychological factors related to hearing aid outcomes (Öberg et al., 2007). Nevertheless, HADS has rarely been studied in relation to hearing impairment and additional research is needed to further analyze in what way HADS addresses the psychosocial factors related to hearing problems, and AR programs address the anxiety and depression symptoms often experienced by persons with hearing impairments. Also, future use of HADS in AR programs needs to consider the consequences participants may experience when answering questions about for example anxiety, thus it could be so that the participant never previously has related anxiety to the experience of hearing impairment. Additionally, future use of HADS should take into account possible co morbidity or hearing aid users cognitive abilities, and the effects of such presence on the outcomes of HADS.

IOI-HA was used in **Paper I** to measure possible improvements in hearing aid outcomes after participating in an AR program, and in **Paper II** to describe the demographic and clinical characteristics of the participants prior to participation in the study. In **Paper I**, the participants initially report using their hearing aids on average “4–8 hours a day” (response 4 in IOI-HA; Cox et al., 2000). No improvements in hearing aid use were detected in **Paper I**. It is possible that it is hard to improve already “good” daily hours of hearing aid use. As seen in **Paper IV**, taking part in AR programs may increase hearing aid satisfaction rather than increase daily hours of hearing aid use. Increased hearing aid satisfaction may in turn lead to substantial everyday communication (Lockey, Jennings & Shaw, 2010; Laplante-Lévesque et al., 2012). Furthermore, Brännström & Wennerström (2010) found that the outcomes of the Swedish version of IOI-HA could depend on differences in hearing aid type, a finding that may apply also in the current thesis since all participants were recruited regardless of hearing aid type.

Furthermore, including CSS in **Paper II** helped measure changes in participants’ use of communications strategies. The results show that participating in the internet-based AR program containing the ACE program significantly improved communication strategies measured by CSS-total and the nonverbal subscale compared with being in the control group. Once again, in line with the results presented in **Paper IV**, being knowledgeable as a result of educational guidance can generate self-efficacy and confidence, which may have contributed to the improvements in **Paper II** measured by the CSS. If hearing aid users lack confidence in their communication performance, they could develop maladaptive strategies and even stop using their hearing aids (Sweetow & Henderson, 2010). In **Paper IV**, participants expressed that being knowledgeable further encouraged them to take actions that could improve their daily life communication. These actions could for example be considered to be communication strategies.



## 5.2 Methodological considerations

RCTs are widely considered the “gold standard” for evaluating the effectiveness of interventions, as they are considered the type of trials that provide the most robust external evidence of intervention effectiveness. Despite the obvious advantages of RCTs there is a negative aspect that needs to be addressed. In RCTs participants typically do not represent the population as a whole due to the randomized process of assigning participants to either an intervention or a control group. It is therefore difficult to tell which subset of participants actually benefited from the evaluated intervention. In the current thesis, **Paper I** and **Paper II** reveal what types of hearing aid users in GCP are interested in this type of interventions and the results are not generalizable. Also, people who seek help with lifestyle changes could be more likely to enter internet-delivered interventions (Mohr, Siddique, Ho, Duffecy, Jin & Fokuo, 2010). Assessing how representative a sample volunteering to take part in research interventions is of a typical clinical sample may give us a bigger picture. Moreover, the inclusion criterion for age in **Paper II** had a wider range than in **Paper I**. This is due to the internet-based approach in **Paper II** and the assumption that younger hearing aid users possess presumably greater digital literacy skills (Moore, Rothpletz & Preminger, 2015). Also, Sundevall et al. (2013) showed that use of the internet in a group of Swedish adults with hearing impairment was higher among younger participants (25 to 64 years) compared to the older participants (75 to 96). Same study revealed that more hearing impaired men than women used the internet. These findings may explain why more men than women were interested in participating in **Paper II**. But then again, more men than women participated in **Paper I** as well. This over representativeness of men in **Paper I** and **Paper II** could be explained by the fact that more men than women in Sweden are using hearing aids (SCB, 2015).

RCTs are generally more costly and time consuming than other types of methods. **Paper III** shows that the costs of conducting RCT in GCP can be minimized by using an internet-based approach. Also, according to Mohr et al. (2010), administration of interventions via telephone or the internet rather than face-to-face is a good way to reduce the time constraint problem.

An intervention itself and the process of an intervention program can influence intervention effectiveness. Factors related to the participant or to persons other than the participants who are directly or indirectly involved in an intervention program may affect the success of the program (Gagné, 2003). Considering the above, researchers need to supplement the potential objective findings with evidence from studies using other methods. Thus, the subjective outcomes of a program in **Paper IV** complement the objective findings related to internet interventions. Furthermore, prior knowledge of an intervention program may have

influenced the data collection and the procedure used to analyze the collected data in **Paper IV** (Krippendorf, 2013). In **Paper IV**, the interviewer's prior knowledge of the internet-based AR program was limited. However, the researchers conducting the coding process had some familiarity with the obtained information, which could clearly influence the coding process.

Furthermore, the participants who agreed to participate in the study presented in **Paper IV** could be overrepresented by the participants of the intervention program who were satisfied with taking part in the internet-based program. This, too, could clearly influence the results in **Paper IV**.

### 5.3 Ethical considerations

Andersson et al. (2002) and Nosek et al. (2002) argue that it may be easier to drop out of an internet intervention than a face-to-face program. Participation in clinical trials is affected by patients' opinions about the health care and caregivers and by how patients regard their health situation (Verheggen, Nieman & Jonkers, 1998). Verheggen et al. (1998) point out that informed consent is not enough for entering a trial and that the researcher needs to consider psychosocial factors as well. Those who participate in a trial do so related to their so-called personal balance account; e.g. their physical and emotional values of their belief in gaining from participating in the intervention compared to not participating. In order to determine such values of participating in a trial, maybe the participants need to have some kind of treatment experience or hearing aid experience. This consideration may explain the substantial hearing aid experience measured in years of use among participants entering the trials/studies in the current thesis. Also, a difference in motivation is found between patients who are satisfied with their treatment prior to participating in a clinical trial and patients who are dissatisfied with their previous treatment (Verheggen et al., 1998). Those who are dissatisfied with their previous treatment may have higher expectations of completing a clinical trial.

Another ethical consideration that needs to be addressed is requiring participants to complete the outcome measures. It is possible that participants are asked to answer questions about situations that have never actually occurred in their life (Weinstein, 2000) and such questions (e.g. questions about anxiety) could evoke consequential feelings. For example, a hearing aid user may feel uncomfortable about relating experienced hearing impairment to feelings of anxiety and depression measured by HADS. This should be taken into account in future internet interventions/AR programs.

## 5.4 Clinical applications and evidence-based practice

Implementing an RCT in GCP using the internet, as in **Paper III**, showed advantages in data collection and clinician participation in terms of personnel, training, time, and cost. Clinical trials usually require the clinicians to recruit eligible patients. This could enterprize typical clinical practice and management duties. In **Paper III**, the recruitment process required no effort from the clinicians. Additionally, implementing an RCT in GCP as shown in **Paper III** indicates a possibility to minimize the costs of conducting an RCT in GCP by using an internet-based approach. Such advantages may reinforce clinicians and operation managers in their future utilization of AR programs.

However, it is important to point out that the internet is not available to all patients. In a study by Ferguson and Henshaw (2015), accessibility showed to be a barrier to internet interventions if the hearing aid user does not have the skills to use a computer, or does not have access to one. On the other hand, the same study found that computer skills had no influence on the use of or adherence to internet interventions.

Relating the evidence to the client is one of the steps in EBP and includes shared decision making between the client and the clinician (Wong & Hickson, 2012). A client-centered approach is recommended for shared decision making regarding rehabilitation decisions of persons with hearing impairment (Laplante-Levésque, Hickson & Worrall, 2010c). Nevertheless, little is known about the audiologists' intention to clinically implement EBP. Implementation research is dependent on clinicians, policy makers, operation managers, and possibly also demands for a quick fix (Eccles, Grimshaw, Walker, Johnston & Pitts, 2005). Time-constrained practitioners may not be willing to add services to their workload unless it provides them with immediately relevant information that is helpful in treatment planning. The attitudes of the health care professionals or their perceived ability to control the content of an intervention may mediate the effectiveness of an intervention (Eccles et al., 2005). For example, although many audiologists have positive attitudes to computer and telecommunication technologies within AR, a recent worldwide study revealed that less than 25% of audiologists use these facilitators (Eikelboom & Swanepoel, 2016). According to the authors, the reason for this could be that the audiologists are overloaded with work, which limits their possibility to provide additional services. As shown in **Paper III**, it was of essential value for the outcomes of the studied internet intervention that the operation managers encouraged participation. Improved outcomes for individual hearing aid users may inspire clinicians and operation managers in their future utilization of internet-based AR programs.

A further issue that needs special attention is that the participants in **Paper I**, **Paper II**, and **Paper IV** had been hearing aid users for an average of 6.5, 7.5, and 14.3 years. The inclusion criteria for **Paper I** and **II** aimed for recruiting hearing aid users who completed a hearing aid fitting at least one year prior to the study participation in **Paper I** and at least three months prior to the study participation in **Paper II**. However, the participants were on average value experienced hearing aid users. This is in line with previous research. In a study examining a home education program in a clinical setting, more than half of the participants were experienced hearing aid users (Kramer et al., 2005). Almost half of the participants who actively applied for participation in another internet-based AR program had been using their hearing aids for more than 10 years (Thorén et al., 2011), and on average for 10.5 years in an additional internet-based AR program for hearing aid users (Thorén et al., 2014). Thus, could it be that it is impossible to recruit entirely new hearing aid users (0–1 year) from a clinical population to distance-based AR programs? As mentioned previously, participating in a trial requires an expectation of gaining from the intervention compared with not participating. In order to expect gain from an intervention, perhaps hearing aid users need to have more than one year of hearing aid experience. Nevertheless, as seen in **Paper IV**, participants taking part in an internet-based AR program explicitly recommend such programs to new hearing aid users. This is in line with Kramer et al. (2005), where the most common negative experience of a home education program concerned the limited relevance of the program for experienced hearing aid users. Moreover, in line with the results in **Paper IV**, experienced hearing aid users in Kramer et al. (2005) had acquired communication strategies by trial and error prior to participating in the AR programs. Participating in an AR program brought confirmation of appropriate behavior and made the hearing aid users more confident in dealing with their hearing impairment. In order to benefit from the AR programs, perhaps there is a need for the hearing aid users to learn by trial and error in everyday communication for a period of time before they participate in a distance-based AR program (i.e. realizing that there is a problem in order to create an interest in solving that same problem). After all, the results in **Paper IV** show that the program might increase hearing aid satisfaction rather than daily hours of hearing aid use, which may be due to the participants being experienced hearing aid users. According to Kramer et al. (2005) emotional functioning is positively influenced by hearing aid fitting per se while daily life interactions and communication is positively influenced by extra AR programs.

## 5.5 Limitations

Some identified limitations of the included papers need to be addressed. First, a lower limit of 20 points was set for the outcome measure HHIE as a participant selection criterion. According to Weinstein and Ventry (1983), indication of self-reported hearing problem on the HHIE starts at 18 points. Since the intention was to target the interventions in **Paper I** and **Paper II** to hearing aid users who experience residual self-reported hearing problems, a 20-point limit was considered reasonable. This limit allows the included participants to have a chance of improving self-reported hearing problems.

Second, differences in treatment presented in **Paper I** and **Paper II** could have influenced the participants' responses to the questionnaires. The intervention groups in **Paper I** and **Paper II** may have built a stronger relationship with the audiologist, which could have affected the outcomes of the studies.

Third, the questionnaires in **Paper I** and **Paper II** were completed at home, at the clinic, or online. When completed for example at home, responses may have been influenced by the family's opinion if family members were present. However, we assume that this arrangement did not affect the outcomes of the questionnaires.

Fourth, the participants in **Paper I**, **Paper II** and **Paper IV** were on average value experienced hearing aid users. New hearing aid users are more likely than experienced hearing aid users to benefit from educational programs (Kramer et al., 2005).

Fifth, the control groups in **Paper I** and **Paper II** received an active intervention. Clearer results may have been obtained had the control groups not received an intervention.

Lastly, mostly participants with self-generated motivation to participate were included in **Paper IV**, which could have affected the outcome of the program. Also, the interviews in **Paper IV** rely on what the participants remember of the program as the interviews took place a couple of months post-participation. This could certainly also affect the results presented in **Paper IV**.



## 6 CONCLUSIONS

Experiences of substantial communication difficulties as a hearing aid user can negatively affect one's interpersonal interactions and participation in daily life situations. Addressing these experiences with follow-up AR programs that comprise elements such as perceptual training and counseling and learning about the condition has previously proven to be effective in minimizing hearing-related problems. After addressing communication difficulties and self-reported hearing problems with such AR programs in the present thesis, the following conclusions can be drawn:

- Clinically applying a follow-up AR program conducted from a remote location using an RCT, supported via telephone, and professionally guided by an audiologist can reduce self-reported hearing problems and improve emotional well-being in hearing aid users.
- Implementing internet-based follow-up AR programs for hearing aid users in GCP using an RCT, supported via telephone and the internet and professionally guided by an audiologist, had a positive effect on self-reported hearing problems and communication skills in hearing aid users.
- The process of implementing an internet-based RCT in GCP showed that internet-based AR in addition to hearing aid fitting can be carried out in GCP such as Hearing Organization Södra Älvsborg. This process showed advantages in overcoming some of the challenges of implementing an RCT in GCP.
- Finally, exploring hearing aid users' individual experiences of an internet-based follow-up AR program revealed overall positive experiences in relation to the studied program. Many participants gained knowledge from the program and experienced increased awareness of hearing impairment, hearing aid benefits, and communication strategies. These benefits encouraged many participants to take further actions that could improve their daily communication.

In a broader perspective, these findings add knowledge to what type of hearing aid user is interested in participating in distance-based AR. Additionally, they add knowledge regarding the possibilities of clinically implementing AR programs, which may inspire clinicians and operation managers in their future utilization of distance-based AR programs. Furthermore, the examined approaches to AR for hearing aid users increase the availability of the educational programs in GCP, which in turn increases the possibilities for clinicians to offer more comprehensive AR to hearing aid users. Improved outcomes for individual patients may lead to greater hearing aid satisfaction and lower return rates.





## 7 FUTURE PERSPECTIVES

Telehealth (i.e., telephone and internet) in hearing health care expands the availability of AR in GCP, offering access to AR to many people. Using telehealth in hearing health care may help audiologists respond to the expected increase in the incidence of persons with hearing impairment. In agreement with Sweetow, Corti, Edwards, Moodie and Sabes (2007), AR programs should be viewed as integral components of the holistic approach within audiology, and not as something we add on to hearing aid fitting.

Moreover, future studies should evaluate AR programs similar to those presented in this thesis administered to new hearing aid users. Also, when delivered exclusively to new hearing aid users, the outcome should be compared with that for a matched group that only receives traditional AR, in order to explore the relative efficacy of the AR programs. Additionally, there is a lack of studies of long-term effects (more than 6 months) of AR programs (Chisolm, Abrams & McArdle, 2004; Barker, Mackenzie, Elliot, Jones & de Lusignan, 2016) and this should be included in future perspectives of AR programs. Also, it would be interesting to examine the individual benefits hearing aid users derive of AR programs, e.g. perhaps there is a difference in the benefits of the AR programs related to daily hours of hearing aid use prior to program participation.

It would also be desirable to apply AR programs that involve friends or family members. Friends or family members could then be guided in understanding communication breakdowns experienced by the hearing aid users, and may be involved in both the reading of the material and the application of tasks. Including friends or family members in an online self-help group for people with hearing impairment has been predicted to yield better outcomes than not including them (Cummings, Sproull & Kiesler, 2002). Also, social support is related to compliance (Noh et al., 1994), and social relationships are important determinants of health (Kawachi & Berkman, 2001). Thus, including friends or family members may improve intervention compliance for persons with hearing impairment. Furthermore, including a client-centered approach in future internet-based interventions or educational AR programs may improve intervention adherence. The need for client-centered AR in order to achieve satisfaction with hearing aids is emphasized by Laplante-Lévesque et al. (2012).

Understanding what makes evaluated AR programs work is a challenge for future research that involves investigating the mediators of outcomes. The AR programs presented in **Paper I** and **Paper II** could be optimized by identifying the predictors and mediators of change by testing the interactive elements individually or in

combinations. Also, because different aspects of AR require different forms of behavioral change, the motivation for behavioral change should be taken into account in future perspectives of internet interventions/AR programs.

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