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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

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Key words: Audiology, Aural rehabilitation, Internet, Clinical practice, Hearing loss

Abbreviations: AR=aural rehabilitation; CSS=Communication Strategy Scale; HADS=Hospital Anxiety and Depression Scale; HHIE=Hearing Handicap Inventory for the Elderly; IOI-HA=International Outcome Inventory for Hearing Aids; ITT=intention to treat; PTA=pure-tone average; SD=standard deviation.

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ABSTRACT

Objective: Guided internet-based intervention beyond hearing aid (HA) fitting has been shown to be efficacious in randomized controlled trials (RCT). However, until now, internet interventions have not been applied clinically as a part of regular aural rehabilitation (AR). Our aim was to evaluate the effectiveness of internet-based AR for HA users from a clinical population.

Outcome measures: The Hearing Handicap Inventory for the Elderly (HHIE) was used as the primary outcome measure, and the Communication Strategies Scale (CSS) and the Hospital Anxiety and Depression Scale (HADS) were used as secondary outcome measures. All questionnaires were administered before and directly after the intervention and at 6 months post-intervention.

Methods: We used a parallel group design (RCT). The data were collected in 2013-2014 at three different clinics. Seventy-four HA users were randomly assigned to receive either full internet-based AR (intervention group, n=37) or one element of the internet-based AR (control group, n=37).

Results: Data were analyzed following the intention-to-treat principle. Each group showed improved HHIE scores over time and did not differ significantly different from each other. The intervention group showed significantly greater improvement compared with the control group for the CSS total and the *Nonverbal* subscale scores.

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The intervention group and control group were also subdivided into two age groups: 20-59 years and 60-80 years. Significantly better improvement on the CSS total and *Nonverbal* subscale scores was found in the older group compared with the younger participants.

Conclusions: This study indicates that participants in an internet-based intervention applied in general clinical practice showed improved self-reported communication skills compared with a control group. Receiving a full intervention was not more effective in improving self-reported hearing problems than receiving just one element of the internet-based intervention.

Trial registration: This trial is registered at ClinicalTrals.gov, number NCT01837550.

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Strengths and limitations of this study:

- This is one of the first randomized controlled trials in Sweden to implement internet-based rehabilitation beyond conventional hearing aid fitting in a general clinical practice.
- The recruitment process used in the clinical trial will provide indications of the types of hearing aid users who are interested in this type of intervention.
- One limitation of this study is that the control group received an active intervention.

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INTRODUCTION

Hearing impairment influences communication in people's daily life. In agreement with the International Classification of Functioning, Disability, and Health[1], the objective of aural rehabilitation (AR) is to promote social participation for people with hearing impairment. Addressing this objective includes fitting the client with hearing aids (HA), educating him or her about the condition, and providing perceptual training and counseling[2]. To improve communication for people with hearing impairment, researchers recommend combining group AR with HA use [3-6]. This combination has shown to be more cost-effective than HA use alone[7]. However, despite the recommendations, the most common approach is the use of HAs alone[8]. This discrepancy could be explained by clinicians' lack of time and the difficulties of scheduling comprehensive AR in addition to HA fitting[9]. Moreover, HAs users with stressful life situations may have very limited time to spend on traveling to participate in rehabilitation courses offered by the clinic. Also, many HA users experience communication difficulties despite today's HA technology. This could cause patients to stop using their HAs[10], which can lead to withdrawal from and/or avoidance of interpersonal interactions or involvement in community life. A review of the literature showed that, HA users' self-perceived hearing difficulties can affect help seeking, HA uptake, HA use, and satisfaction[11]. Although combining group AR with HA use can be beneficial, the overall availability of and adherence to communication programs are still low[12].

Several studies have suggested that AR could be provided without in-person meetings[13-17]. Thorén et al[17], for example, significantly increased activity and participation in the intervention group by using Internet to provide AR in addition to HA fitting, while the control group did not improve. A recent systematic review indicated that such resources show benefits such as increased access to care, cost-effectiveness and improved quality of care in

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terms of user satisfaction[18]. Internet use is increasing among people with hearing impairment, which encourages including the Internet for AR in future research[19-21]. However, the literature regarding the clinical use of the Internet for AR is insufficient.

Our research group designed a randomized controlled trial (RCT) of internet-based AR in addition to HA fitting[17]. The study provided proof of concept that AR beyond HA fitting could be performed over the Internet [16-17]. However, participants were recruited through advertisements and articles in Swedish national daily newspapers and on the Internet, and the study did not indicate whether internet-based interventions could be feasible in a clinical setting. Nonetheless, we chose to use this study design[17] and supplement the trial with telephone support, and then implement the trial in a clinical setting at a later time. Our earlier research showed promising results for telephone-supported AR beyond HA fitting in general clinical practice (GCP)[22]. A study of self-help treatment for tinnitus in a clinical setting showed significant improvements pre- to post-treatment and at follow-up when internet-based treatments were used, indicating that self-help treatment can be transferred to the clinic[23]. Studies in other research fields, such as panic disorders, have shown that guided internet-based therapy is efficacious and effective when delivered as part of routine psychiatric care[24].

The first aim of this study was to evaluate whether internet-based AR for HA users will be effective in GCP. Our assumption is that the internet-based AR program would reduce residual hearing problems among HA users and improve the participants' communication strategies and psychosocial well-being, while participating in the control group would not. The second aim of the study was to analyze the effect of internet-based AR in GCP among two age-groups: 20-59 years and 60-80 years. Our hypothesis was that the 20- to 59-year age group may be more receptive to internet-based AR because of their presumably active- and stressful life situations.

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METHODS

The Consolidated Standards of Reporting Trials (CONSORT) checklist was followed when reporting the abstract, designing the study, and analyzing and interpreting the results [25-26]. A flowchart of the study procedure is presented in figure 1. The trial is registered at ClinicalTrals.gov, number NCT01837550.

– Figure 1 –

Recruitment and selection

The eligibility criteria targeted the most common patient category at three different clinics within the Hearing Organization, Södra Älvsborg, Sweden: patients who were 20-80 years old and who had mild to moderate conductive or sensorineural hearing loss, i.e., a 20-60 dB HL pure-tone average (500, 1000, and 2000 Hz). Additional eligibility criteria included patients who had completed a HA fitting 3 months before the study began (regardless of HA manufacturer or model), who had a HHIE score ≥20 points (HHIE: Hearing Handicap Inventory for the Elderly[27]; indicative of some residual hearing problems), and gave their informed consent to participate. The study was conducted in 2013-2014. The recruitment process was conducted in two sets, one for participants aged 20-59 years and one for those aged 60-80 years. All potential participants who fulfilled the criteria for age, hearing loss, and HA fitting received a recruitment letter that contained information about the study's purpose and structure and stressed that the participants' privacy would be protected and that participation was voluntary. The participants were prepared to allocate 1.5-2.0 hours each week to participate in the study and were informed that they would be placed into one of two groups. The participants were asked to visit the website www.iterapi.se/sites/hornet to read more about the study and to initiate participation.

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The first step of the participation required registering at the website and completing a screening form. Participants who registered at the website and completed the screening form (n=108) were called for an interview to assess their eligibility; of these, 104 agreed to participate in the study. The next step was for the participants to complete four questionnaires: the HHIE[27], the Communication Strategies Scale; the CSS (from the Communication Profile for the Hearing Impaired (CPHI)[28], the Hospital Anxiety and Depression Scale (HADS)[29] and International Outcome Inventory for Hearing Aids (IOI-HA)[30]. Consequently, 74 participants were included in the study as seen in Figure 1.

The study was a randomized controlled trial with a parallel group design and a simple randomization procedure. The 74 participants were randomly assigned to either an intervention group (group 1) or a control group (group 2) according to a computer-generated list of random numbers. An independent audiologist at the clinic generated the random allocation sequence, assigned the participants to different groups, and reported the allocation schedule to the project leader, who then enrolled the participants. The assigned participants were told which group they were allocated to (1 or 2) but were not informed whether the group was the intervention group or the control group. Thirty-seven participants were included in the intervention group, and 37 participants were included in the control group, as shown in table 1. No significant differences were found between the groups regarding the background variables age, age group, gender and hearing loss.

The study was reviewed and approved by the regional ethical review board in Gothenburg, Sweden (reference number 1018-11). The study website was programmed using Java Script, and information was available in hypertext markup language (HTML) format.

Table 1. Demographic and clinical characteristics of the participants. The data are reported as means (standard deviations (SD) unless stated otherwise.

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		Intervention group (n=37)	Control group (n=37)
20- to 59-year age group, n (%)		17 (46)	16 (43)
60- to 80-year age group, n (%)		20 (54)	21 (57)
Age, years (range 32-80 years)		61.8 (11.9)	62.1 (11.4)
	20- to 59-year age group	50.9 (7.2)	52.3 (9.1)
	60- to 80-year age group	71.1 (5.4)	69.6 (5.9)
Gender, n (%)			
	Men	24 (64.9)	20 (54.1)
	Woman	13 (35.1)	17 (45.9)
Pure-tone average (dB HL)			
	Right ear	37.5 (11.3)	38.0 (8.6)
	Left ear	37.8 (10.5)	36.5 (8.5)
HA, n (%)			
	Binaural	28 (75.7)	31 (83.,8)
	Monaural	9 (24.3)	6 (16.2)
Duration of HA use, years (range 0.5-55 years)		7.5 (9.6)	7.4 (6.3)
Computer experience*, n (%)		37 (100)	37 (100)
Computer access, n (%)		37 (100)	37 (100)
Able to have a telephone conversation without HA/s?, n (%)		32 (86.5)	35 (94.6)
IOI-HA	1. Daily use	4.1 (1.1)	4.4 (1.0)
	2. Benefit	3.8 (0.9)	4.1 (0.9)
	3. Remaining activity limitation	3.1 (0.8)	3.1 (0.8)
	4. Satisfaction	4.1 (1.1)	4.4 (0.8)
	5. Remaining participation restriction	3.8 (1.1)	4.1 (0.8)
	6. Impact on environment	3.6 (0.9)	3.9 (0.9)
	7. Quality of life	3.6 (0.8)	3.6 (1.0)

(*familiar with: able to log in, print information, complete a questionnaire on a website and read and send email); HA: hearing aid; IOI-HA: International Outcome Inventory for Hearing Aids.

Outcome Measures

The HHIE was the primary outcome measure. The HHIE includes two subscales; the *Social* subscale comprises 12 questions addressing the social effects of hearing loss, and the *Emotional* subscale comprises 13 questions addressing the emotional effects of hearing loss. Higher scores reflect a higher self-reported hearing problem.

The CSS and the HADS were used as secondary outcome measures. The CSS includes three subscales (*Maladaptive Behaviors, Verbal Strategies and Nonverbal Strategies*) and is designed to analyze participants' behavior in various communication situations. The *Maladaptive Behaviors* subscale includes 9 questions that analyze strategies that hinder communication. *Verbal Strategies* and *Nonverbal Strategies* address 16 items related to strategies that can enhance communication. Scoring for the CSS reflects how frequently a

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specific situation or behavior occurs. The HADS comprises 14 items separated into two subscales: *Anxiety* and *Depression*. Higher scores reflect more symptoms of anxiety and depression.

The IOI-HA includes seven questions measuring specific dimensions of HA outcomes: daily use, benefits, remaining activity limitations, satisfaction, remaining participation restrictions, impact on the environment, and quality of life; with higher scores indicating better outcomes. The IOI-HA was not used as an outcome measure in this study; rather, it was used to describe the demographic and clinical characteristics of the participants, as shown in table 1.

The HHIE, CSS and HADS were administered according to the methods described[27-29] and were available on the study website, in Swedish. The questionnaires were administered online before and directly after the study participation and 6 months after participation to evaluate self-reported hearing problems, communication strategies, and anxiety and depression. All of the questionnaires have a good internal consistency[31-32] and have been shown to be reliable when used with a Swedish population. Sundewall et al[33] stressed the importance of keeping the internet-based administration format of the HHIE and HADS stable across time points.

Intervention Group

The internet-based intervention program was partly tested in a previous study[17] and is based on four elements: reading, home training, interaction with an audiologist, interaction with peers in an internet-based discussion forum. The participants received information about the intervention program and access to the reading material on the study website; they also received a book about hearing and HAs[34] and the Swedish version of Active Communication Education, a compendium of communication strategies[5, 35-36]. The website information about

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the intervention program, along with the book and the compendium, were also mailed to all of the participants in the intervention group.

– Figure 2 –

The reading element is divided in to five modules, one module for each of the five weeks. The participants were instructed to read specific content each week based on the various chapters of the book and information from the compendium[17]. The weekly home assignments (week 1-5) were accessible to facilitate an understanding of the contents of the book and the compendium. For example, the weekly assignments could be to observe the benefits of using HA/s. The weekly home assignments were handed in on the Internet by the participants (week 1-5), and direct responses were provided by an audiologist. The weekly home assignments were also discussed with the audiologist over the phone at the end of each treatment week. The telephone consultations lasted approximately 10-15 minutes per participant and provided the participants with an opportunity to reflect on the assignment and discuss any concerns they might have. Weeks 1-4 ended with quiz questions on the content of the past weeks' readings.

The participants in the intervention group also attended a discussion forum on the study website. Weekly topics were presented for the participants[17] to discuss with one other, without any interaction with the audiologist. The participants were free to use the discussion forum with no restrictions from the audiologist. However, all activities where strictly observed, and if needed, inappropriate postings could be deleted. No inappropriate postings occurred.

Control Group

The control group received one reading element; i.e. the first four chapters of the book[34]; and the information about participation provided on the study website. The website information

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and book chapters were also mailed to the participants. The control group was asked to read the four chapters over a five-week period; no assignments were given in association with their participation. To minimize the impact of professional interaction, no monitoring was provided during the program to ensure that the participants actually read the chapters.

Follow-up

At the end of the treatment period, the HHIE, CSS and HADS were made available to all participants on the study website, and the participants were asked to complete them. Both groups' participation was evaluated using a post-study telephone interview. The post-study interviews for the intervention group were conducted by a different audiologist than the one who conducted the pre-study interviews and the telephone consultations during the study to minimize the influence of special attention on the participants' responses to the questionnaires. The post-study interviews for the control group were conducted by the same audiologist who conducted the pre-study interviews. For the telephone interview, the audiologists used a self-designed form that contained questions about the study process, including opportunities for the participants to provide their own comments. Different forms were designed for the intervention group and the control group. All of the participants were invited to keep their copy of the reading material.

Six months after the study participation, the participants in both groups were contacted via e-mail and asked to complete the HHIE, CSS and HADS online again.

Statistical Analyses

Statistical Package for the Social Sciences[37] software for Windows (SPSS, version 19.0) was used for the analysis of all data. Three measurement time points were examined: pre-treatment (T0), post-treatment (T1) and 6 months post-treatment (T2). To ensure a between-

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group effect of 80% at the 5% significance level, it was estimated that 60 participants needed to be included in the study. An effect size of Cohen's *d*=0.80 was expected. The expected standardized mean difference on the HHIE formed the basis of the obtained power. The within-group and between-group effect sizes of Cohen's *d* were calculated from T0-T1 and from T0-T2 and were categorized as small (≥0.2), moderate (≥0.5) and large (≥0.8).

Data that did not fulfill the assumptions for normal distribution (e.g., the HHIE-total and *Social* subscale for the intervention group, the *Emotional* subscale for the control group and CSS-total and *Maladaptive* and *Nonverbal* subscales for the intervention group) were transformed before the analysis using SPSS statistics for logarithmic transformations. No significant differences were found between the groups at T0 for all the outcome measures. All data from the participants who did not complete T1 and/or T2 measurements were treated on an *intention to treat* basis[38], meaning that the participants were included in the analysis (as missing data) regardless of their compliance or withdrawal from the study; see figure 1.

Given the ability to handle missing data[39], mixed effects models with compound symmetry as the covariance structure were used to analyze the HHIE, CSS and HADS. Differences between the intervention group and the control group were examined by modeling the interaction effects of group and time. Age was also included as a factor when modeling the interaction effects of group, of time and age. The age groups were categorized as age-group: 20-59 years and age-group: 60-80 years.

A sensitivity analysis was performed using mixed effects models for the HHIE, CSS and HADS, this time excluding subjects who did not complete all measurement time points (T1 and/or T2). Sensitivity analysis was performed to increase the understanding of the relationships between internet-based AR and the outcome measures, HHIE, CSS, and HADS.

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RESULTS

Attrition and adherence

Eight participants in the intervention group and five in the control group completed the study program but did not provide all T1 and/or T2 measurements, without giving a specific reason. Six participants in the intervention group and seven in the control group withdrew from participation in the study, as shown in figure 1. Five of those who withdrew from the study provided T1 measurements; four provided T2 measurements. One participant who was lost to follow-up at T1 provided T2 measurements. Consequently, 12 participants (16%) did not provide T1 measurements (of which n=1 followed up only with the HHIE), and 22 participants did not provide T2 measurements (30%). No significant differences were found between those who discontinued the study program from T0-T1 and those who did not. Those who discontinued from T0-T2 had lower scores on HHIE-total (t(72)=-2.31, p=0.024) and the HHIE-*Social* (t(72)=-1.95, p=0.056) and -*Emotional* (t(72)=-2.05, p=0.044) subscales and lower points on HADS-total (t(72)=-2.73, p=0.008) and the HADS *Anxiety* (t(72)=-2.03, p=0.046) and *Depression* (t(72)=-2.38, p=0.020) subscales compared with those who continued with the study.

Some of the participants in the intervention group who completed the study did not answer all four of the weekly quizzes, and some of the participants in the intervention group did not provide all five of the online weekly responses to the audiologist. However, all of them were active participants in discussions during the weekly telephone follow-up, and some stated a wish for the discussion forum to be more active because they considered that part of the intervention very interesting. On average, the participants posted 0.4 contributions to the discussion forum.

Primary outcome measure

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Both groups showed decreased HHIE-total scores T0-T1 ($F_{(1, 65.6)}$=22.3, p<0.001) and T0-T2 ($F_{(2, 115.8)}$=12.00, p<0.001). The interaction effect for HHIE-total group and time T0-T1/T0-T2 was not significant. The results are presented in table 2, and the estimated marginal means (EMM) and standard errors of the outcome measures HHIE, CSS and HADS for both groups are presented as supplementary material in Complementary Appendix I. Both groups showed decreased scores for both of the HHIE subscales from T0-T1 (p<0.001) and T0-T2 (p<0.01 for *Social* and p<0.001 for *Emotional*). The interaction effect was not significant for models of group and time T0-T1 for the *Social* and *Emotional* subscales or for T0-T2 for the *Emotional* subscale. A borderline significant interaction effect emerged for the *Social* subscale T0-T2 ($F_{(2, 116.9)}$=2.9, p=0.061). Small to moderate between-group effect sizes were found for the HHIE, as shown in table 2.

Table 2. (n=74) Observed means (OM) and standard deviations (SD) of the outcome measures HHIE, CSS and HADS for both groups at pre-treatment (T0), post-treatment (T1) and 6-months post-treatment (T2). Cohen's pooled within-group and between-group small/moderate/large effect sizes (ES) and 95% confidence intervals (CI) for the intervention (I-group) and control groups (C-group) are presented. P-values illustrate the significance of the difference in estimated marginal means between the intervention and control groups. F-values illustrate the interaction effect for time^{x}group (t^{x}gr) and time^{x}group^{x}age (t^{x}gr^{x}a).

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Scale		T0	T1	T2	T0-T1	T0-T2	Age group	T0-T1	T0-T2	T0-T1	T0-T2
		OM (SD)	OM (SD)	OM (SD)	ES (95% CI) Within-group	ES (95% CI) Within-group		ES (95% CI) Between-group	ES (95% CI) Between-group	(*p-value*) (F-value)	(*p-value*) (F-value)
HHIE Total											
I-group	Total	42.0 (16.9)	35.8 (15.2)	36.0 (15.8)	S (-0.08 to 0.84)	S (-0.10 to 0.82)	**Total**	S (-0.16 to 0.76)		1.0 (*0.685*)	1.0 (*0.517*)
	20-59 years	44.7 (13.6)	40.8 (13.3)	43.4 (14.6)	S (-0.17 to 0.74)		**20-59**	M (0.01 to 0.93)	L (0.39 to 1.35)	1.1 (*0.657*)	1.0 (*0.918*)
	60-80 years	39.7 (19.3)	31.7 (15.8)	31.6 (15.2)	M (-0.01 to 0.91)	M (0.00 to 0.92)	**60-80**		S (-0.73 to 0.19)	1.0 (*0.837*)	1.0 (*0.413*)
C-group	Total	36.1 (11.8)	31.3 (14.3)	34.0 (13.2)	S (-0.10 to 0.82)						
	20-59 years	38.0 (12.7)	34.0 (15.3)	31.6 (13.5)	S (-0.18 to 0.74)	M (0.02 to 0.95)					
	60-80 years	34.7 (11.1)	29.0 (13.3)	35.5 (13.3)	M (0.00 to 0.92)						
HHIE Social											
I-group	Total	20.2 (8.8)	18.3 (7.1)	18.2 (7.8)	S (-0.22 to 0.69)	S (-0.22 to 0.69)	**Total**	S (-0.08 to 0.84)		1.1 (*0.080*)	1.0 (*0.061*)
	20-59 years	21.2 (7.9)	19.6 (6.6)	21.0 (7,6)	S (-0.24 to 0.68)		**20-59**	S (-0.03 to 0.89)	S (-0.08 to 0.86)	1.2 (*0.176*)	1.0 (*0.348*)
	60-80 years	19.3 (9.6)	17.2 (7.4)	16.6 (7.7)	S (-0.21 to 0.70)	S (-0.15 to 0.77)	**60-80**	S (-0.12 to 0.79)	S (-0.73 to 0.19)	1.2 (*0.273*)	1.0 (*0.181*)
C-group	Total	18.5 (6.6)	15.5 (7.3)	18.2 (7.1)	S (-0.03 to 0.89)						
	20-59 years	19.8 (7.0)	16.4 (8.0)	17.8 (8.9)	M (-0.01 to 0.91)	S (-0.21 to 0.71)					
	60-80 years	17.5 (6.2)	14.8 (6.8)	18.5 (6.0)	S (-0.04 to 0.87)						
HHIE Emotional											
I-group	Total	21.8 (9.5)	17.5 (9.4)	17.8 (9.5)	M (-0.01 to 0.91)	S (-0.04 to 0.88)	**Total**		S (-0.22 o 0.69)	1.0 (*0.356*)	1.0 (*0.602*)
	20-59 years	23.5 (7.8)	21.2 (8.2)	22.4 (10.0)	S (-0.02 to 0.74)		**20-59**	S (-0.04 to 0.88)	L (0.48 to 1.44)	1.1 (*0.443*)	1.0 (*0.605*)
	60-80 years	20.4 (10.7)	14.4 (9.3)	15.1 (8.3)	M (0.13 to 1.06)	M (0.08 to 1.01)	**60-80**		S (-0.66 to 0.25)	1.1 (*0.518*)	1.0 (*0.621*)
C-group	Total	17.6 (7.3)	15.8 (8.2)	15.7 (8.3)	S (-0.23 to 0.69)	S (-0.22 to 0.70)					
	20-59 years	18.3 (7.6)	17.6 (8.7)	13.8 (7.5)		M (0.12 to 1.06)					
	60-80 years	17.1 (7.3)	14.3 (7.7)	16.9 (8.9)	S (-0.09 to 0.83)						
CSS Total											
I-group	Total	68.1 (13.6)	74.7 (11.1)	70.9 (10.5)	M (-0.99 to -0.06)	S (-0.69 to 0.23)	**Total**	M (0.06 to 0.98)	S (-0.08 to 0.84)	1.1 (*0.019*) (t^xgr=5.8)*	1.0 (*0.044*) (t^xgr=3.2)*
	20-59 years	68.8 (12.0)	76.4 (8.3)	73.5 (8.6)	M (-1.20 to -0.26)	M (-0.91 to 0.02)	**20-59**	S (-0.08 to 0.84)	M (0.06 to 0.99)	1.0 (*0.477*)	1.0 (*0.773*)
	60-80 years	67.4 (15.1)	73.4 (10.6)	69.4 (11.4)	M (-0.92 to 0.01)		**60-80**	L (0.27 to 1.21)	S (-0.12 to 0.80)	1.1 (*0.006*) (t^xgr^{x}a=8.5)*	1.0 (*0.013*) (t^xgr^{x}a= 4.7)*
C-group	Total	67.2 (11.3)	68.5 (12.4)	66.7 (11.6)							
	20-59 years	67.7 (11.3)	72.3 (12.4)	69.2 (7.5)	S (-0.84 to 0.08)						
	60-80 years	66.8 (11.5)	65.1 (11.6)	65.0 (13.8)							
CSS Maladaptive											
I-group	Total	17.9 (4.5)	17.8 (5.7)	17.4 (4.3)			**Total**	S (-0.23 to 0.69)		1.0 (*0.873*)	1.0 (*0.954*)
	20-59 years	18.2 (4.1)	17.9 (5.8)	17.6 (2.5)			**20-59**	S (-0.25 to 0.67)	M (0.03 to 0.95)	1.1 (*0.248*)	1.0 (*0.428*)
	60-80 years	17.8 (5.0)	17.7 (5.8)	17.3 (5.1)			**60-80**	S (-0.24 to 0.68)		1.1 (*0.337*)	1.0 (*0.511*)
C-group	Total	17.2 (3.5)	16.7 (3.5)	17.3 (4.4)							
	20-59 years	16.7 (3.5)	16.9 (3.2)	16.1 (3.5)							
	60-80 years	17.7 (4.3)	16.6 (3.9)	18.1 (4.8)	S (-0.19 to 0.72)						
CSS Verbal											
I-group	Total	22.6 (6.7)	25.8 (6.1)	24.1 (4.8)	M (-0.96 to -0.03)	S (-0.71 to 0.20)	**Total**	S (-0.14 to 0.78)	S (-0.04 to 0.88)	1.0 (*0.299*)	1.0 (*0.309*)
	20-59 years	23.0 (8.0)	26.4 (6.8)	25.3 (4.8)	M (0.91 to 0.01)	S (-0.80 to 0.11)	**20-59**		S (-0.24 to 0.68)	0.5 (*0.756*)	1.0 (*0.820*)
	60-80 years	22.2 (5.5)	25.3 (5.5)	23.5 (4.8)	M (-1.02 to -0.09)	S (-0.71 to 0.21)	**60-80**	M (0.04 to 0.96)	M (0.13 to 1.06)	1.8 (*0.231*)	1.1 (*0.144*)

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C-group	Total	21.8 (5.6)	23.8 (6.4)	21.9 (5.5)	S (-0.79 to 0.13)						
	20-59 years	22.4 (5.5)	25.4 (6.6)	24.4 (3.2)	M (-0.95 to -0.03)	S (-0.90 to 0.02)					
	60-80 years	21.4 (5.6)	22.4 (6.0)	20.2 (6.1)		S (-0.25 to 0.66)					
CSS Nonverbal											
I-group	Total	27.6 (6.9)	31.2 (4.8)	29.3 (4.8)	M (-1.07 to -0.13)	S (-0.74 to 0.17)	**Total**	M (0.09 to 1.02)	S (-0.14 to 0.78)	1.2 (*0.003*) (t^xgr=9.2)**	1.0 (*0.007*) (t^xgr=5.2)**
	20-59 years	27.7 (5.6)	32.1 (4.1)	30.6 (4.9)	L (-1.36 to -0.41)	M (-1.01 to -0.08)	**20-59**	S (-0.01 to 0.84)	S (0.05 to 0.87)	1.1 (*0.098*)	1.0 (*0.293*)
	60-80 years	27.5 (8.0)	30.4 (5.2)	28.6 (4.8)	S (-0.89 to 0.03)		**60-80**	M (0.26 to 1.20)	S (-0.15 to 0.76)	1.2 (*0.014*) (t^xgr^{x}a=6.7)*	1.0 (*0.016*) (t^xgr^{x}a=4.4)*
C-group	Total	28.1 (6.2)	28.0 (6.5)	27.5 (6.2)							
	20-59 years	28.6 (5.5)	30.0 (6.5)	28.7 (4.2)	S (-0.69 to 0.23)						
	60-80 years	27.8 (7.3)	26.2 (6.1)	26.7 (7.3)	S (-0.22 to 0.69)						
HADS Total											
I-group	Total	8.5 (6.6)	7.5 (6.3)	4.8 (4.5)		M (0.18 to 1.12)	**Total**		S (-0.84 to 0.08)	1.0 (*0.603*)	1.0 (*0.233*)
	20-59 years	9.5 (5.8)	9.4 (4.9)	6.5 (4.5)		M (0.11 to 1.03)	**20-59**	S (-0.10 to 0.82)		1.1 (*0.477*)	0.5 (*0.720*)
	60-80 years	7.7 (7.3)	5.9 (7.0)	4.1 (4.4)	S (-0.21 to 0.71)	M (0.13 to 1.06)	**60-80**		M (-1.06 to -0.13)	1.2 (*0.383*)	0.5 (*0.204*)
C-group	Total	7.4 (4.8)	6.5 (5.2)	6.8 (5.9)							
	20-59 years	8.3 (4.3)	7.7 (4.5)	6.7 (7.4)		S (-0.20 to 0.72)					
	60-80 years	6.8 (5.2)	5.4 (5.7)	6.9 (4.9)	S (-0.20 to 0.71)						
HADS Anxiety											
I-group	Total	4.6 (3.8)	3.8 (3.4)	2.4 (2.0)	S (-0.24 to 0.68)	M (0.25 to 1.19)	**Total**		M (-0.94 to -0.02)	1.0 (*0.423*)	1.0 (*0.442*)
	20-59 years	5.2 (3.6)	4.8 (3.2)	3.1 (2.0)		M (0.24 to 1.18)	**20-59**		S (-0.80 to 0.12)	1.1 (*0.480*)	0.6 (*0.708*)
	60-80 years	4.1 (4.0)	2.9 (3.5)	2.0 (1.9)	S (-0.14 to 0.77)	M (0.20 to 1.13)	**60-80**		M (-1.07 to -0.14)	1.3 (*0.128*)	0.5 (*0.276*)
C-group	Total	4.3 (3.2)	3.7 (3.1)	3.7 (3.2)							
	20-59 years	5.1 (2.6)	4.7 (2.9)	4.2 (4.1)		S (-0.20 to 0.72)					
	60-80 years	3.7 (3.6)	2.8 (3.2)	3.4 (2.6)	S (-0.20 to 0.72)						
HADS Depression											
I-group	Total	3.9 (3.3)	3.7 (3.5)	2.6 (2.8)		S (-0.04 to 0.88)	**Total**	S (-0.16 to 0.75)		1.0 (*0.810*)	1.0 (*0.104*)
	20-59 years	4.3 (2.9)	4.6 (3.0)	3.4 (2.8)		S (-0.15 to 0.77)	**20-59**	M (0.15 to 1.09)	S (-0.21 to 0.70)	1.1 (*0.673*)	0.6 (*0.847*)
	60-80 years	3.6 (3.6)	3.0 (3.9)	2.1 (2.8)		M (-0.00 to 0.92)	**60-80**		S (-0.72 to 0.19)	1.1 (*0.618*)	0.6 (*0.069*)
C-group	Total	3.1 (2.5)	2.8 (2.4)	3.1 (2.9)							
	20-59 years	3.2 (2.2)	3.0 (2.0)	2.6 (3.6)		S (-0.26 to 0.66)					
	60-80 years	3.1 (2.7)	2.6 (2.8)	3.5 (2.4)							

S=small effect size (≥0.2), M=moderate effect size (≥0.5), L=large effect size (≥0.8); HHIE: Hearing Handicap Inventory for the Elderly; *Social* and *Emotional* subscales. CSS, Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI); *Maladaptive*, *Verbal* and *Nonverbal* subscales. HADS: Hospital Anxiety and Depression Scale; *Anxiety* and *Depression* subscales.

*$p<0.05$, **$p<0.01$.

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Secondary outcome measures

Both groups showed improved scores for the CSS-total T0-T1 ($F_{(1, 62.7)}$=9.5, p<0.01) and for the *Verbal* subscale T0-T1 ($F_{(1,61.7)}$=20.1, p<0.001) and the *Nonverbal* subscale T0-T1 ($F_{(1, 64.0)}$=6.7, p<0.05), as shown in table 2. This main effect of time persisted from T0-T2 (CSS-total; $F_{(2, 114.2)}$=4.6, p<0.05; *Verbal* $F_{(2,111.3)}$=7.8, p<0.01; *Nonverbal* $F_{(2, 116.2)}$=3.8, p<0.05). Furthermore, significantly greater improvement was found for the intervention group compared with the control group T0-T1 for the CSS-total ($F_{(1, 62.7)}$=5.8, p<0.05) and for the *Nonverbal* subscale ($F_{(1, 64.0)}$=9.2, p<0.01). This interaction effect persisted from T0-T2 for both the CSS-total ($F_{(2, 114.2)}$=3.2, p<0.05) and for the *Nonverbal* subscale ($F_{(2, 116.2)}$=5.2, p<0.01). Moderate within-group effect sizes from T0-T1 were observed for the intervention group for the CSS-total and for the *Verbal* and *Nonverbal* subscales. Moderate between-group effect sizes were shown for the CSS-total and for the *Nonverbal* subscale T0-T1, as shown in table 2.

The analyses for HADS showed that both the intervention group and the control group improved their total scores T0-T2 ($F_{(2, 113.7)}$=4.4, p<0.05), and the analyses identified no significant differences when modeling the interaction effects of group and time from T0-T1 or T0-T2, as shown in table 2. Moderate within-group effect sizes were found for the HADS-total T0-T2, as shown in table 2.

Age analysis

Age was included as a factor in the model of the interaction effects of group, time and age for the HHIE, CSS and HADS scores from T0-T1 and T0-T2. No significant interaction effect was found for the outcome measures HHIE and HADS from T0-T1 or T0-T2 for the age groups 20-59 years and 60-80 years, as shown in table 2. Nevertheless, a large between-group effect was found from T0-T2 for the HHIE-total score among the participants in the 20- to 59-

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year age group, as shown in table 2. Medium to large effects were found for the HHIE-*Emotional* subscale, and medium effect sizes were found for the HADS-total outcome measure.

The CSS-total showed an interaction effect from T0-T1, indicating that the 60- to 80-year-olds ($F_{(1, 33.3)}$=8.5, p<0.01) in the intervention group showed significantly more improvement than the 20- to 59-year-olds in the intervention group. This effect persisted from T0-T2 ($F_{(2, 63.8)}$=4.7, p<0.05). There was also an interaction effect of age from T0-T1 for the *Nonverbal* subscale, with the 60- to 80-year-olds in the intervention group showing significantly greater improvement ($F_{(1, 33.9)}$=6.7, p<0.05) compared with the 20- to 59-year-olds in the same group. This effect persisted from T0-T2 ($F_{(2,64.4)}$=4.4, p<0.05). Moderate to large effects were found for the CSS, as shown in table 2.

Sensitivity analysis

A sensitivity analysis was performed for the HHIE, CSS and HADS by excluding all data from the participants who did not complete all three measurement time points (T0, T1 and T2; n=50). However, 50 participants are not sufficient to ensure a between-group effect of 80%. Nonetheless, the sensitivity analysis revealed an interaction effect for the HHIE-*Emotional* subscale from T0-T1 ($F_{(1, 48.0)}$=4.7, p<0.05) with the intervention group showing an advantage, as shown in the Complementary Appendix II. This interaction effect did not remain 6 months post-treatment.

The interaction effect for the CSS-total that was achieved when participants were treated on an *intention to treat* basis (n=74) was not apparent in the sensitivity analysis (n=50). The results for the CSS showed an interaction effect of time and group for the *Nonverbal* subscale from T0-T1 ($F_{(1, 48.0)}$=7.8, p<0.01) and from T0-T2 ($F_{(2, 96.0)}$=4.4, p<0.05), with the

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intervention group showing significantly greater improvement compared with the control group, similar to the results for the whole group (n=74).

Furthermore, the sensitivity analysis showed significant results for the HADS-*Depression* scale from T0-T2 ($F_{(2, 96.0)}$=3.3, p<0.05), indicating that the intervention group's scores had improved more than those of the control group. The sensitivity analysis for the remaining scales and subscales showed no changes in significance compared with the previous analysis (n=74), as shown in Complementary Appendix II.

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DISCUSSION

The aim of this study was to evaluate whether internet-based AR for HA users would be effective in GCP and whether the assumed positive effect of participating in the internet-based AR program would be maintained 6 months after the program was completed. Our aim was also to analyze the effect of the internet-based AR program in two age-groups.

Both the intervention group and the control group improved their HHIE scores from T0-T1 and from T0-T2; however, the improvements were not significantly different between groups, unlike the findings of our research group's previous study[17]. Differences in the results could be related to differences in the recruitment process. In our previous study[17], the participants were recruited through advertisements and articles in Swedish national daily newspapers and on the Internet; the recruited participants were well educated and had a higher education level than the general population. This indicated that the intervention program is well suited for educated patients, although education was not a significant predictor of intervention outcomes [40]. This recruitment strategy generated a broad range of background variables and recruited participants who actively sought involvement in research. The recruitment process used for the present study generated more narrow background variables, as shown in table 1, and indicates the types of HA users in GCP that are interested in this type of intervention. Another underlying explanation for the differences in improvement could be that the control group was more active in present study compared with our previous study[17], in which the participants read a book about the history of HAs, though not online. Participants being enrolled in a research study might generally be more positive afterward their participation[41], which could be considered research bias assuming that the full internet-based AR is more effective than one element of the program. A borderline significant interaction effect emerged for the HHIE *Social* subscale from T0-T2. As table 2 shows, both groups decreased their scores from T0-T1; this improvement persisted from T0-T2 in the intervention group, but not

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in the control group, indicating that the full internet-based AR could have had a positive impact on the social effects of the participants' hearing loss.

The sensitivity analysis that was performed (n=50) revealed an interaction effect for the HHIE-*Emotional* subscale from T0-T1, for the CSS-*Nonverbal Strategies* subscale from T0-T1 and from T0-T2, and for the HADS-*Depression* subscale from T0-T2; all interaction effects indicated an advantage for the intervention group. It appears that participants who are especially persistent and who participated in all aspects of the full internet-based AR or were just conscientious may show changes in the HHIE score and in their communications skills and may also be less depressed. Thus, the sensitivity analysis makes the study underpowered, and these interaction effects should be treated with caution.

The participants who did not provide T1/T2 measurements for present study had lower scores on the HHIE and HADS compared with those who continued in the study, indicating that insubstantial social and emotional effects of hearing loss and more pronounced anxiety and depression symptoms can influence the decision to drop out. Another potential influencing factor might be that it is easier to drop out when the intervention is internet-based, as discussed by Andersson et al[42].

In our earlier research, the HHIE was an applicable measure for the outcomes of telephone-supported AR beyond HA fitting in GCP[22]; in that study, the program for the intervention group did not include parts of the ACE program, which targets the communication difficulties experienced by older people with hearing impairment in everyday life[35-36]. In the clinical population of the present study, we found effects for the CSS-total and the *Nonverbal* subscale; thus, it seems that participating in the full internet-based AR program containing the ACE program has a larger effect on communication skills compared with partial participation. Determining the element responsible for the interaction improvement in the present study is challenging. The *reading* and *home training* elements of the full internet-based AR program

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might have contributed to improved communication skills, but so, too, might the telephone follow-up by the audiologist. Having personal phone contact with an audiologist may have encouraged the participants to try out the program's suggested strategies. The effect on the CSS, however, raises doubts about the applicability of the HHIE as a main outcome measure for the present study.

The intervention and control groups were also analyzed according to age groups. The 60- to 80-year-olds obtained significantly greater improvement compared with the 20- to 59-year-olds in the intervention group in terms of the CSS-total and the *Nonverbal* subscale, contradicting our hypothesis that the 20- to 59-year age group would be more receptive to internet-based AR. As mentioned, the ACE program targets the everyday life of older people, which may have been reflected in the results of the CSS age analysis.

Thorén et al[17] found significant improvements in the intervention group when measuring participants' psychosocial well-being using the HADS. Our results showed that both the intervention group and the control group showed improved HADS scores, although the difference between the groups was not significant. Preminger[43] reviewed the importance of taking psychosocial outcomes into account when implementing group adult aural rehabilitation and highlighted the importance of outcome studies. The HADS is believed to be sensitive enough to detect the effects of online education[16, 17].

Limitations

One limitation is that the participants in this study have been HA users for an average of 7.5 years. In our previous study in a GCP setting, that number was 6.5 years[22]; for Thorén et al, the average was 9.9 years[17]. Despite inclusion criteria that acknowledged the heterogeneity of a clinical population, the participants in the present study were experienced HA users. A systematic review[6] suggests that the short-term outcomes of group AR are important for

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encouraging new HA users to continue using amplification. Thus, although different aspects of AR may not suit every individual client, the study increases the confidence that the clinical use of group AR will likely have positive outcomes. Another limitation is that the control group received an active intervention. A more clear result would have been generated from a control group that received no intervention.

Conclusion

The internet-based approach expands the availability of AR in GCP, offering accessibility to many people, including hard-to-reach populations[44]. The present study shows that using the Internet for interactions between the audiologist and the HA user had a positive effect on communication skills for the intervention group compared with the control group. Furthermore, the full internet-based AR program was not more effective than one element of the internet-based AR program. Although, the advantages of an internet-based approach, both for the patient and the clinician, may inspire clinicians and operation managers in their future utilization of comprehensive AR in addition to HA fitting.

Further analysis is needed to examine the individual elements of the full internet-based AR program to evaluate which part of the internet-supported educational intervention had the greatest effect: the reading material, the weekly assignments, the discussion forum, or the contact with the audiologist. In addition, guided internet-based intervention should be compared with face-to-face AR to analyze whether the two approaches are equally effective. Additionally, the individual needs of the HA user should be taken into account when designing group AR, as should including significant others in the intervention.

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Contributors

GA, TL and MM contributed to the conception and design of the study, and to the acquisition of data for the study. MM contributed to data collection and analyzed the data. GA, TL, MM and KK contributed to the analysis of data and participated in interpretation of data for the study; in drafting the study and revising it critically for important intellectual content and in giving final approval of the version to be published. GA, TL and KK provided continuous supervision during the entire study.

Competing interest

The authors declare no competing interests.

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Data sharing statement

No additional data available.

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REFERENCES

1. World Health Organization. International Classification of Functioning, Disability and Health (ICF). Geneva: World Health Organization 2001.
2. Boothroyd A. Adult aural rehabilitation: what is it and does it work? *Trends in Amplif* 2007;11(2):63-71. doi: 10.1177/1084713807301073.
3. Hickson L, Worall L. Beyond hearing aid fitting: improving communication for older adults. *Int J Audiol* 2003;42(2):S84-91. doi:10.3109/14992020309074649.
4. Hawkins D. Effectiveness of Counselling-Based Adult Group Aural Rehabilitation Programs: A Systematic Review of Evidence. *J Am Acad Audiol* 2005;16:485-93. doi: http://dx.doi.org/10.3766/jaaa.16.7.8.
5. Hickson L, Worall L, Scarinci N. Measuring outcomes of a communication program for older people with hearing impairment using the International Outcome Inventory. *Int J Audiol* 2006;45:238-46. doi:10.1080/14992020500429625.
6. Chisolm T, Arnold M. Evidence about the effectiveness of aural rehabilitation programs for adults. In: Wong L, Hickson L, eds. Evidence-based practice in audiology: Evaluating interventions for children and adults with hearing impairment. San Diego, CA: Plural 2012:237-66.
7. Abrams H, Hnath-Chisolm T, McArdle R. A cost-utility of adult group audiologic rehabilitation: Are the benefits worth the cost? *J Rehabil Res Dev* 2002;39(5):549-58.
8. Kochkin S. Marke Trak VIII: 25-years in trends in the hearing health market. *Hearing review* 2009;16(11):12-31.
9. Grenness C, Hickson L, Laplante-Lévesque A. et al. Patient-centred care: A review for rehabilitative audiologists. *Int J Audiol* 2014;53(Suppl 1):P60-P67. doi:10.3109/14992027.2013.847286.

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10. McCormack A, Fortnum H. Why do people fitted with hearing aids do no wear them? *Int J Audiol* 2013;52:360-68. doi:10.3109/14992027.2013.769066.

11. Knudsen LV, Öber M, Nielsen C, et al. Factors Influencing Help Seeking, Hearing Aid Uptake, Hearing Aid Use and Satisfaction With Hearing Aids: A Review of the Litterature. *Trends in Amplification* 2010;14(3):127-54. doi: 10.1177/1084713810385712.

12. Laplante-Lévesque A, Hickson L, Worall L. Rehabilitation of older adults with hearing impairment: a critical review. *J Aging Health* 2010;22(2):143-53. doi:10.1177/0898264309352731.

13. Kramer SE, Allesie GHM, Dondorp AW, et al. A home education program for older adults with hearing impairment and their significant others: A randomized trial evaluating short- and long-term effects. *Int J Audiol* 2005;44:255-64. doi: 10.1080/14992020500060453.

14. Laplante-Lévesque A, Pichora-Fuller MK, Gagne JP. Providing an internet-based audiological counselling programme to new hearing aid users: a qualitative study. *Int J Audiol* 2006;45:697-706. doi:10.1080/14992020600944408.

15. Sweetow RW, Henderson SJ. Technologic advices in aural rehabilitation: applications and innovative methods of service delivery. *Trends in Amplification* 2007;11:101-11. doi: 10.1177/1084713807301321.

16. Thorén E, Svensson M, Törnqvist A, et al. Rehabilitative online education versus internet, discussion group for hearing aid users: a randomized controlled trial. *J Am Acad Audiol* 2011;22:274-85. doi: http://dx.doi.org/10.3766/jaaa.22.5.4.

17. Thorén ES, Öberg M, Wänström G, et al. A randomized controlled trial evaluating the effects of online rehabilitative intervention of adult hearing-aid users. *Int J Audiol* 2014;53:452-46. doi:10.3109/14992027.2014.892643.

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18. Molini-Avejonas DR, Rondon-Melo S, de la Higuera Amato CA, et al. A systematic review of the use of telehealth in speech, language and hearing sciences. *J Telemed Telecare* 2015;21:367-76. doi: 10.1177/1357633X15583215.

19. Barak A, Sadovsky Y. Internet use and personal empowerment of hearing-impaired adolescents. *Comput Human Behav* 2008;24:1802-15. doi:10.1016/j.chb.2008.02.007.

20. Henshaw H, Clark Daniel PA, Kang S, et al. Computer Skills and Internet Use in Adults Aged 50-74 Years: Influence of Hearing Difficulties. *J Med Internet Res* 2012;14(4):e113. doi:10.2196/jmir.2036.

21. Sundewall ET, Öberg M, Wänström E, et al. Internet Access and Use in Adults With Hearing Loss. *J Med Internet Res* 2013;15(5):e91. doi: 10.2196/jmir.2221.

22. Lundberg M, Andersson G, Lunner T. A randomized, controlled trial of the short-term effects of complementing an educational program for hearing aid users with telephone consultations. *J Am Acad Audiol* 2011;22(10):654-62. doi: 10.3766/jaaa.22.10.4.

23. Kaldo-Sandström V, Larsen HC, Andersson G. Internet-Based Cognitive-Behavioral Self-Help Treatment of Tinnitus: Clinical Effectiveness and Predictors of Outcome. *Am J Audiol* 2004;13:185-92. doi:10.1044/1059-0889(2004/023).

24. Hedman E, Ljótsson B, Rück C, et al. Effectiveness of Internet-based cognitive behaviour therapy for panic disorder in routine psychiatric care. *Acta Psychiatrica Scandinavica* 2013;128:457-67. doi: 10.1111/acps.12079.

25. Hopewell S, Clarke M, Moher D, et al. CONSORT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts: Explanation and Elaboration. *PLoS Med* 2008;5(1):e20. doi:10.1371/journal.pmed.0050020.

26. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *Int J of Surg* 2012;10(1):28-55. doi:10.1016/j.jclinepi.2010.03.004.

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27. Ventry IM, Weinstein BE. The Hearing Handicap Inventory for the Elderly: a new tool. *Ear Hear* 1982;3(3):128-34.

28. Demorest ME, Erdman SA. Development of the Communication profile for the hearing impaired. *J Speech Hear Disord* 1987;52(2):129-43. doi:10.1044/jshd.5202.129.

29. Zigmod AS, Snaith RP. The Hospital Anxiety Depression Scale. *Acta Psychiatr Scand* 1983;67:361-70. doi: 10.1111/j.1600-0447.1983.tb09716.

30. Cox R, Hyde M, Gatehouse S, et al. Optimal Outcome Measures, Research Priorities, and International Cooperation. *Ear Hear* 2000;21(4):106-15.

31. Öberg M, Lunner T, Andersson G. Psychometric evaluation of hearing specific self-report measures and their associations with psychosocial and demographic variables. *Audiol Med* 2007;5:188-99. doi:10.1080/16513860701560214.

32. Hallberg LRM, Eriksson-Mangold M, Carlsson SG. Psychometric evaluation of a Swedish version of the Communication Strategies Scale of the Communication Profile for the Hearing Impaired. *J Speech Hear Res* 1992;35:666-74. doi:10.1044/jshr.3503.666.

33. Sundewall ET, Andersson G, Lunner T. The use of research questionnaires with hearing impaired adults: online vs. paper-and pencil administration. *BMC Ear Nose Throat Disord* 2012;12:12. doi:10.1186/1472-6815-12-12.

34. Elberling C, Worsøe K. When the sounds are weaker - on hearing and hearing aids. Herlev: Bording A/S 2006.

35. Hickson L , Worrall L, Scarinci N. A randomized controlled trial evaluating the active communication education program for older people with hearing impairment. *Ear Hear* 2007;28:212-30. doi: 10.1097/AUD.0b013e31803126c8.

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36. Öberg M, Bohn T, Larsson U. Short- and Long-Term Effects of the Modified Swedish Version of the Active Communication Education (ACE) Program for Adults with Hearing Loss. *J Am Acad Audiol* 2014;25(9):848-58. doi: 10.3766/jaaa.25.9.7.

37. SPSS (data analysis software system) (2011) Statistical Package for the Social Sciences for Windows. Version 19.0. www.spss.com

38. Fergusson D, Aaron SD, Guyatt G, et al. Post-randomisation exclusions: the intention to treat principle and excluding patients from analysis. *BMJ* 2002;325:652-4. doi: http://dx.doi.org/10.1136/bmj.325.7365.652.

39. Gueorguieva R, Krystal JH. Move Over ANOVA. Progress in Analyzing Repeated-Measures Data and Its Reflection in Papers Published in the Archives of General Psychiatry. *Arch Gen Psychiatry* 2004;61:310-17. doi:10.1001/archpsyc.61.3.310.

40. Laplante-Lévesque A, Hickson L, Worall L. What makes adults with hearing impairment take up hearing aids or communication programs and achieve successful outcomes? *Ear Hear* 2011;32(5):1-15. doi: 10.1097/AUD.0b013e31822c26dc.

41. Linde L, Fässler M, Meissner K. Placebo interventions, placebo effects and clinical practice. *Phil Trans R Soc B* 2011;366:1905-12. doi: 10.1098/rstb.2010.0383.

42. Andersson G, Strömgren T, Ström L, et al. Randomized Controlled Trial of Internet-Based Cognitive Behavior Therapy for Distress Associated With Tinnitus. *Psychosom Med* 2002;64(5):810-16. doi: 10.1097/01.PSY.0000031577.42041.F8.

43. Preminger, J.E. Issues Associated With the Measurement of Psychosocial Benefits of Group Audiologic Rehabilitation Programs. *Trends in Amplification* 2007;11(2):113-23. doi: 10.1177/1084713807301084.

44. Swanepoel de W, Hall JW III. A systematic review of telehealth applications in audiology. *Telemedicine and e-health* 2010;16(2):181-200. doi:10.1089/tmj.2009.0111.

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Figure 1. Flowchart for the study procedure. Sets 1 + 2 of the recruitment process are presented in parentheses [n=set1+set2]. Set 1=20- to 59-year age group, set 2=60- to 80-year age group. *HHIE, Hearing Handicap Inventory for the Elderly; CSS, Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI); HADS, Hospital Anxiety and Depression Scale; IOI-HA, International Outcome Inventory for Hearing Aids.

Figure 2. The full internet-based program outlined for the intervention group and the element of the internet-based program outlined for the control group. The full internet-based program consisted of four elements: reading, home training, interaction with an audiologist, and interaction with peers in an internet-based discussion forum. Weeks 1-4 of the intervention concluded with a quiz. The small part of the internet-based program consisted of the reading element.

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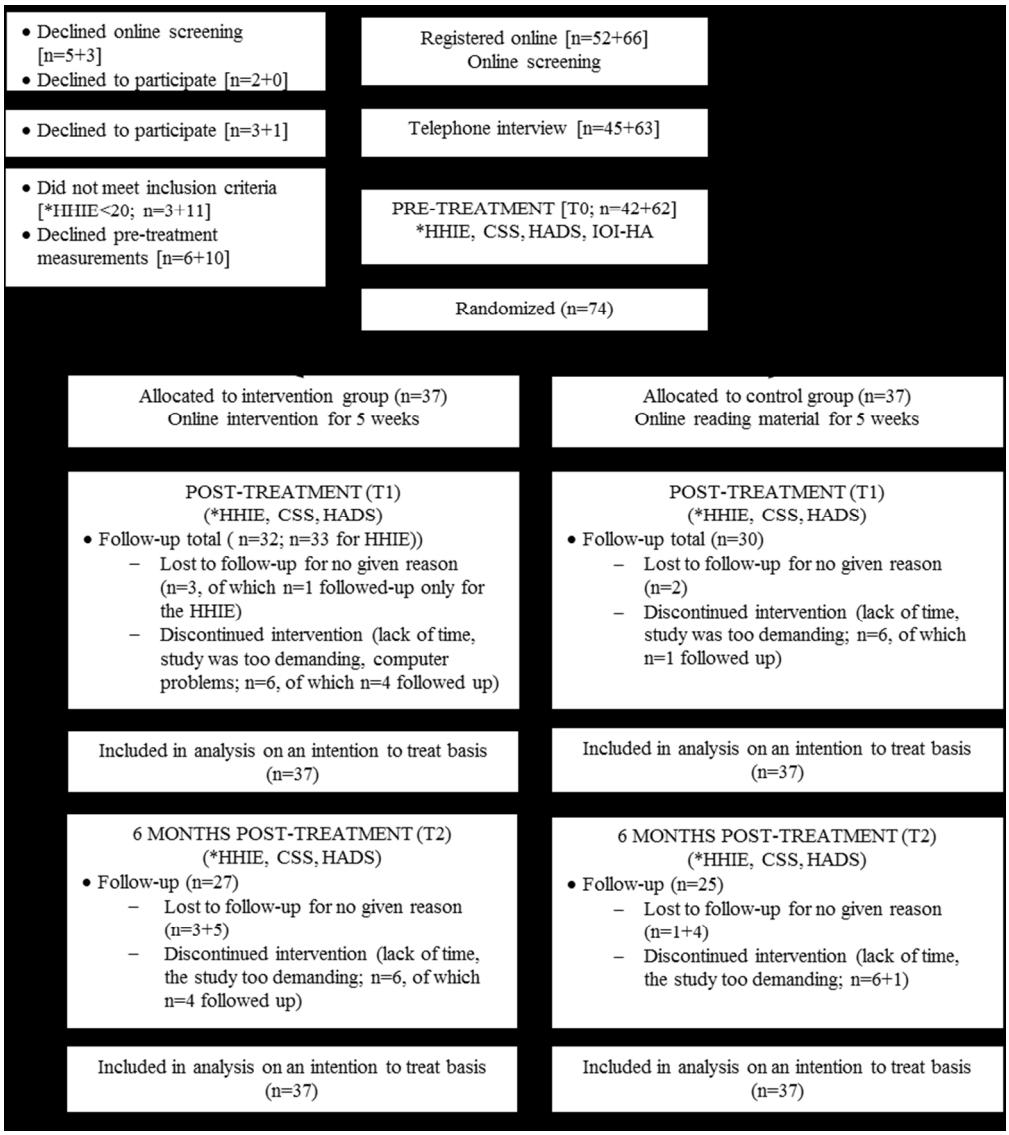

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160x180mm (150 x 150 DPI)

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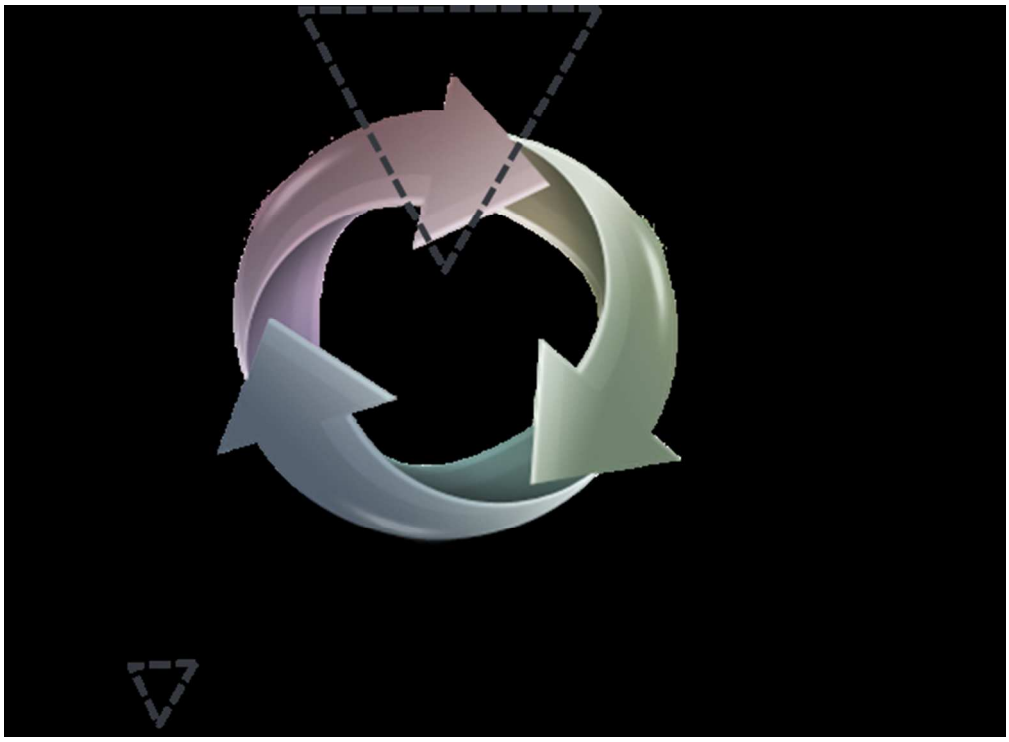

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Complementary Appendix I. (n=74) Estimated marginal means (EMM) and standard error (Std.Error) of the outcome measures HHIE, CSS and HADS for both groups at pre-treatment (T0), post-treatment (T1) and 6-months post-treatment (T2).

	EMM (Std. Error)					
	Intervention group			Control group		
Scale	T0	T1	T2	T0	T1	T2
HHIE-Total						
Total	40.0 (1.1)	33.4 (1.1)	35.3 (1.1)	35.3 (1.1)	28.7 (1.1)	33.4 (1.1)
20-59 years	43.7 (1.1)	38.3 (1.1)	41.6 (1.1)	37.1 (1.1)	31.1 (1.1)	34.1 (1.1)
60-80 years	37.1 (1.1)	29.9 (1.1)	31.2 (1.1)	34.1 (1.1)	26.9 (1.1)	32.8 (1.1)
HHIE-*Social*						
Total	19.4 (1.1)	17.9 (1.1)	18.3 (1.1)	18.4 (1.1)	14.6 (1.1)	18.5 (1.1)
20-59 years	21.0 (1.1)	19.1 (1.1)	20.1 (1.1)	19.5 (1.1)	15.1 (1.1)	19.2 (1.1)
60-80 years	18.2 (1.1)	17.0 (1.1)	17.0 (1.1)	17.5 (1.1)	14.3 (1.1)	18.0 (1.1)
HHIE-*Emotional*						
Total	20.9 (1.1)	15.8 (1.1)	17.2 (1.1)	17.2 (1.1)	14.4 (1.1)	15.2 (1.1)
20-59 years	23.2 (1.1)	19.7 (1.1)	20.8 (1.2)	17.8 (1.1)	16.3 (1.1)	15.0 (1.2)
60-80 years	19.1 (1.1)	13.1 (1.1)	14.9 (1.1)	16.8 (1.1)	12.9 (1.1)	15.2 (1.1)
CSS-Total						
Total	67.6 (1.0)	74.6 (1.0)	72.2 (1.0)	67.3 (1.0)	67.9 (1.0)	67.4 (1.0)
20-59 years	68.8 (1.0)	76.1 (1.0)	73.8 (1.1)	67.8 (1.0)	72.2 (1.0)	71.8 (1.1)
60-80 years	66.6 (1.0)	73.4 (1.0)	71.0 (1.0)	66.8 (1.0)	64.4 (1.0)	64.3 (1.0)
CSS-*Maladaptive*						
Total	18.4 (1.0)	18.0 (1.0)	18.5 (1.0)	17.9 (1.0)	17.2 (1.0)	17.8 (1.0)
20-59 years	18.7 (1.1)	17.6 (1.1)	18.4 (1.1)	17.3 (1.1)	17.5 (1.1)	17.1 (1.1)
60-80 years	18.2 (1.1)	18.3 (1.1)	18.6 (1.1)	18.3 (1.1)	16.9 (1.1)	18.2 (1.1)
CSS-*Verbal*						
Total	22.6 (1.0)	26.0 (1.0)	24.6 (1.0)	22.2 (1.0)	23.9 (1.0)	22.2 (1.0)
20-59 years	22.7 (1.1)	26.5 (1.1)	24.9 (1.1)	22.9 (1.1)	25.6 (1.1)	25.4 (1.1)
60-80 years	22.5 (1.1)	25.6 (1.1)	24.3 (1.1)	21.6 (1.1)	22.6 (1.1)	20.2 (1.1)
CSS-*Nonverbal*						
Total	27.5 (1.0)	31.8 (1.0)	30.4 (1.0)	28.3 (1.0)	28.0 (1.0)	28.5 (1.0)
20-59 years	28.1 (1.1)	32.8 (1.1)	31.8 (1.1)	29.0 (1.1)	30.4 (1.1)	30.9 (1.1)
60-80 years	27.0 (1.1)	30.9 (1.1)	29.5 (1.1)	27.9 (1.1)	26.1 (1.1)	26.9 (1.1)
HADS-Total						
Total	7.1 (1.2)	6.0 (1.2)	5.0 (1.2)	6.7 (1.2)	6.1 (1.2)	6.1 (1.2)
20-59 years	8.8 (1.2)	9.3 (1.2)	6.5 (1.3)	8.0 (1.2)	7.7 (1.2)	6.2 (1.2)
60-80 years	5.9 (1.2)	4.2 (1.2)	4.0 (1.2)	5.8 (1.2)	5.0 (1.2)	5.9 (1.2)
HADS-*Anxiety*						
Total	4.1 (1.1)	3.5 (1.1)	3.2 (1.2)	4.2 (1.1)	4.0 (1.1)	3.9 (1.2)
20-59 years	4.8 (1.2)	4.9 (1.2)	3.9 (1.2)	5.5 (1.2)	5.1 (1.2)	4.6 (1.2)
60-80 years	3.7 (1.2)	2.7 (1.2)	2.8 (1.2)	3.5 (1.2)	3.2 (1.2)	3.5 (1.2)
HADS-*Depression*						
Total	3.9 (1.1)	3.6 (1.1)	2.9 (1.1)	3.4 (1.1)	3.2 (1.1)	3.4 (1.1)
20-59 years	4.5 (1.2)	4.8 (1.2)	3.6 (1.2)	3.5 (1.2)	3.5 (1.2)	2.9 (1.2)
60-80 years	3.5 (1.2)	2.8 (1.2)	2.5 (1.2)	3.2 (1.2)	2.9 (1.2)	3.8 (1.2)

HHIE: Hearing Handicap Inventory for the Elderly, *Social* and *Emotional* subscales. CSS, Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI), *Maladaptive*, *Verbal* and *Nonverbal* subscales. HADS: Hospital Anxiety and Depression Scale, *Anxiety* and *Depression* subscales.

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Complementary Appendix II. Sensitivity analysis (n=50). Observed means (OM) and standard deviations (SD) of the outcome measures HHIE, CSS and HADS for both groups at pre-treatment (T0), post-treatment (T1) and 6-months post-treatment (T2). *P-values* illustrate the significance of the difference in estimated marginal means between the intervention and control group. F-values illustrate the interaction effect for time*group (t*gr).

	OM (SD)			T0-T1	T0-T2	T0-T1, (t*gr)	T0-T2, (t*gr)
Scale	T0	T1	T2	(*p-value*)	(*p-value*)	F-value	F-value
HHIE-Total							
I-group	40.2 (17.2)	33.5 (15.6)	36.0 (16.1)	1.0 (*0.643*)	1.0 (*0.460*)	0.2	0.8
C-group	33.8 (10.1)	30.4 (11.9)	34.2 (13.4)				
HHIE-*Social*							
I-group	19.4 (9.0)	17.6 (7.2)	18.3 (8.0)	1.1 (*0.203*)	1.0 (*0.089*)	1.7	2.5
C-group	17.3 (5.6)	15.2 (6.5)	18.5 (7.2)				
HHIE-*Emotional*							
I-group	20.8 (9.8)	15.9 (9.4)	17.7 (9.7)	1.0 (*0.034*)	1.0 (*0.114*)	4.7*	2.2
C-group	16.5 (7.0)	15.3 (7.2)	15.7 (8.5)				
CSS-Total							
I-group	67.2 (14.6)	72.5 (10.5)	70.5 (10.4)	1.0 (*0.103*)	1.0 (*0.247*)	2.8	1.4
C-group	66.8 (10.0)	68.2 (11.0)	67.8 (10.6)				
CSS-*Maladaptive*							
I-group	17.1 (3.6)	16.4 (3.5)	17.0 (3.6)	1.0 (*0.445*)	1.0 (*0.747*)	0.6	0.3
C-group	17.1 (3.6)	17.0 (3.4)	17.4 (4.4)				
CSS-*Verbal*							
I-group	23.0 (6.8)	25.6 (6.2)	24.2 (4.9)	1.0 (*0.494*)	1.0 (*0.623*)	0.5	0.5
C-group	22.0(4.9)	23.8 (5.9)	22.3 (5.3)				
CSS-*Nonverbal*							
I-group	27.1 (7.9)	30.6 (4.9)	29.3 (4.9)	1.1 (*0.007*)	1.0 (*0.014*)	7.8**	4.4*
C-group	27.6 (5.3)	27.3 (6.0)	28.1 (5.7)				
HADS-Total							
I-group	7.4 (5.8)	6.2 (5.4)	5.2 (4.5)	1.0 (*0.112*)	1.0 (*0.130*)	2.6	2.1
C-group	6.2 (4.5)	6.3 (5.2)	6.8 (6.0)				
HADS-*Anxiety*							
I-group	3.9 (3.4)	3.2 (3.1)	2.5 (2.0)	1.0 (*0.478*)	1.0 (*0.483*)	0.5	0.7
C-group	3.7 (2.7)	3.5 (3.1)	3.8 (3.3)				
HADS-*Depression*							
I-group	3.4 (2.8)	3.0 (2.7)	2.7 (2.9)	1.0 (*0.077*)	1.0 (*0.042*)	3.3	3.3*
C-group	2.5 (2.1)	2.8 (2.5)	3.0 (3.0)				

*$p<0.05$, **$p<0.01$; HHIE: Hearing Handicap Inventory for the Elderly, *Social* and *Emotional* subscales. CSS, Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI), *Maladaptive*, *Verbal* and *Nonverbal* subscales. HADS: Hospital Anxiety and Depression Scale, *Anxiety* and *Depression* subscales. I-group: intervention group; C-group: control group.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-5
	2b	Specific objectives or hypotheses	4-5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	na
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8,9,11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	na
Sample size	7a	How sample size was determined	12
	7b	When applicable, explanation of any interim analyses and stopping guidelines	na
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

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		assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	9-11
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11-13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11-13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Fig 1, p7, table 1&2, p14-15
	13b	For each group, losses and exclusions after randomisation, together with reasons	14
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6,7,11
	14b	Why the trial ended or was stopped	na
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	8
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	11-13
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	14-20
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	na
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	na
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	na
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	23-24
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	21-24
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	21-24
Other information			
Registration	23	Registration number and name of trial registry	3,6
Protocol	24	Where the full trial protocol can be accessed, if available	7
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	25

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Bilaga 7

Forskningsprotokoll

Randomiserad, kontrollerad studie av korttidseffekten av att komplettera en pedagogisk intervention för hörapparatanvändare med Internet support

Vetenskaplig frågeställning

Syftet är att undersöka korttidseffekten av att komplettera en pedagogisk insats med Internet support för personer med hörselnedsättning.

Kan en pedagogisk insats och professionellt Internet support minska kvarstående upplevd aktivitets- och delaktighetsbegränsning, upplevd oro och nedstämdhet samt öka hörapparatnyttan? Kan vi utveckla verktyg och metoder för att stödja den audiologiska rehabiliteringsprocessen genom att engagera patienten i den egna rehabiliteringen och genom att erbjuda Internet support?

Områdesöversikt

Tidigare studier beskriver olika psykologiska faktorer som varje audionom behöver kunna handskas med vid möte med patienter: bristen på motivation, passivitet, negativism samt orealistiska förväntningar. En undersökning vars syfte var att öka hörapparatanvändningen bland patienterna och ändra de orealistiska förväntningarna visade positiva effekter genom att bland annat, be patienterna föra dagbok mellan besökstiderna på sjukhuset. Patienterna var mer positiva till sina hörapparater och till sina hörapparatanpassningar samt kände sig mer säkra och hade mer realistiska förväntningar (Erikson- Mangold et al., 1990). Tidigare studie utförd av forskningsgruppen har visat att användningen av modern informationsteknologi i form av telefonsupport, tillsammans med en pedagogisk insats för hörapparatanvändaren resulterar i minskad upplevelse av aktivitets- och delaktighetsbegränsning för interventionsgruppen (Lundberg et. al., In press). Användning av hemuppgifter som patienten utförde i sin egen miljö, samt pedagogiskt stöd för att ge patienten egen kontroll över sitt liv gav patienten ett annat perspektiv på rehabiliteringsprocessen. Insatsen rekommenderades som en metod för att minska upplevd aktivitets- och delaktighetsbegränsning för personer med hörselnedsättning men även för att öka hörapparatanvändarnas delaktighet i den egna rehabiliteringen. Även Rankin and Stalling visade 2001 att engagemang av patienten i den egna rehabiliteringen visade sig öka självkänslan och även motivationen till det egna lärandet (Rankin and Stallings, 2001).

Modern informationsteknologi har idag blivit en del av de flesta människors vardag, med drygt 90 % användare av Internet i Sverige (www.internetworldstats.com). Det är vanligt att söka hälsorelaterad information på webben (Hesser och Andersson, In press), och det är även vanligt att anhöriga söker samma information om de är oroliga för sina föräldrar, partners m.m. Rehabilitering via Internet kan ses som ett nytt verktyg för den audiologiska rehabiliteringen. Thorén m.fl. har utfört en Internetbaserad studie för personer med hörselnedsättning med lovande resultat vilket inspirerar till fortsatt användning av det nya verktyget inom den audiologiska rehabiliteringen (Thorén et.al., 2011). Thorén m.fl. rekryterade sina deltagare via en tidningsannons. Det unika med den planerade studien blir att den Internet baserade rehabiliteringen för första gången tillämpas kliniskt som en del av den audiologiska rehabiliteringen, riktad mot hörapparatanvändare med kvarstående upplevd aktivitets- och delaktighetsbegränsning.

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Patientens förståelse för hörselnedsättningens konsekvenser och betydelsen av individuella insatser vid rehabiliteringen är viktiga aspekter inom audiologisk rehabilitering. Dessa aspekter kan även anses vara viktiga för att utveckla verktyg och metoder som kan stödja den audiologiska rehabiliteringsprocessen. Att bygga upp ett mer strukturerat och individuellt målinriktat arbetssätt kan underlätta den audiologiska rehabiliteringen.

Projektbeskrivning

Deltagare

60 vuxna randomiseras in till två grupper, 30 deltagare i testgruppen och 30 i kontrollgruppen. Patienterna finns inom Hörsel och Dövverksamheten inom Västragötalands regionen.

Inklusionskriterier

20-60 år, mild (TMV, tonmedelvärde; 20- 40) till måttlig (TMV, tonmedelvärde; 40- 60) hörselnedsättning, patienten har motivation till deltagande samt är nöjd med nuvarande hörapparatanpassningen. Patientenhar avslutat sin hörapparatanpassning och har använt hörapparat/er i minst tre månader. Patienten har kvarstående upplevd aktivitets- och delaktighetsbegränsning samt datorvana.

Procedur

Rekrytering utförs av doktoranden med hjälp av ett brev som skickas ihop med en svarsblankett (bilaga 4) till patienter som har avslutat sin hörapparatanpassning för cirka tre månader sedan och är nöjda med den. Brevet beskriver att patienten antigen kan hamna i kontrollgruppen eller i testgruppen, studiens upplägg samt tidsplan. Oavsett om patienten önskar delta i projektet eller inte blir han/hon ombedd att skicka in svarsblanketten till ansvarig doktorand. Brevet beskriver att deltagande i försöksverksamheten är frivillig. Deltagarna i projektet erhåller ingen ersättning för medverkande i projektet. Som forskningsperson har patienten alltid rätt att avbryta sitt deltagande i försöket utan att uppge någon anledning. Ett avbrutet deltagande har ingen påverkan på övrig behandling. De uppgifter som registrerats under projektet har sekretesskydd. Reseersättning utbetalas enligt gällande regler från sjukresekontoret. Rekryteringen kan även ske genom att fånga upp aktuella patienter på enheten för hörseldiagnostik och rehabilitering. Patienten deltar efter att ha lämnat sitt medgivande genom att fylla i samma svarsblankett.

Patienten intervjuas i början av projektet för att säkerställa motivationen och engagemanget till deltagandet i projektet. Därefter får patienten fylla i sina målformuleringar i frågeformuläret COSI, Client Oriented Scale of Improvement (Dillon et al, 1997; bil 5). Undersökningsgruppen kommer att bestå av hörapparatanvändare som av en oberoende person randomiseras in i två grupper, en interventionsgrupp och en kontrollgrupp. Båda grupper fyller i utvärderingsformulären IOI-HA, International Outcome Inventory for Hearing Aids (Cox et.al., 2000; bil 5), HADS, Hospital Anxiety Depression Scale (Zigmod and Snaith, 1983; bil 5) och HHIE, Hearing Handicap Inventory for the Elderly (Ventry and Weinstein, 1982; bil 5).

Interventionsgruppen kommer att få tillgång till information från boken ”När ljuden blir svagare - om hörsel och hörapparater” (Elberling and Worsøe, 2006; bil 13) via Internet och kommer få ämnesbaserade veckouppgifter relaterade till olika kapitel i boken, även de via Internet. Veckouppgifter kommer att ges i fem veckor och i veckoslutet utvärderas uppgifterna via Internet. Veckouppgifterna är uppdelade enligt följande:

Den första veckan handlar om att lära känna hörselsinnet och deltagaren ombeds att läsa kapitel 1 - 2 för att sedan registrera olika ljud i sin omgivning. Veckouppgifterna handlar om att förstå innebörden

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av hur ett ljust eller mörkt ljud låter samt om att börja uppmärksamma ljud runt omkring sig. Första veckans lärdom om ljud lägger grunden för andra veckans information om audiogram.

Den andra veckan handlar om att läsa kapitel 3 - 4 och därmed lära känna sitt audiogram (som deltagaren får med sig vid bedömningssamtalet), sin hörselnedsättning i jämförelse med bokens exempel på andra hörselnedsättningar samt innebörden av en talbanan (d. v. s. område i ett audiogram som står för normal talstyrka). Kunskapen om skillnaden mellan ljusa och mörka toner förväntas nu, utifrån audiogrammet och talbananen underlätta förståelsen för vilka ljud som deltagaren har en nedsättning på.

Tredje veckans uppgifter handlar om innehållet i kapitel 5 som beskriver hörselns fem dimensioner med bland annat dynamikområdet (d. v. s det ljudstyrkeområde som används av vår hörsel). För att lättare förstå innebörden av dynamikområdet samt hur det egna dynamikområdet återspeglas har deltagarna ett UCL- värde (Uncomfortable Loudness Level) på sina audiogram att jämföra med. Även under tredje veckan bidrar den tidigare kunskapen om audiogram och ljud till en ny förståelse för informationen presenterad i kapitel 5.

Fjärde veckan går ut på att lära känna hörapparater, dess möjligheter och begränsningar. Kapitel 6 och 7 som ska läsas inför den här veckan drar samband mellan hörapparater och tidigare beskrivna hörselns fem dimensioner.

Femte veckan återstår det sista kapitlet, kapitel 8, som tar upp olika kommunikationsstrategier. Deltagarna har nu lärt sig en del om ljud, hörapparater, samt möjligheter och begränsningar av dessa och får nu fundera över den egna hörselsituationen och reflektera över vilka begränsningar de upplever eller har upplevt under sin period med hörselnedsättning.

Interventionsgruppen kommer även att få tillgång till ett diskussionsforum via Internet där nya diskussionsämnen tas upp varje vecka. Diskussionsämnena kan exempelvis vara a) berätta för oss om vilka problem du upplever på grund av din hörselnedsättning?, b) hur påverkar din hörselnedsättning dina anhöriga? och c) berätta i vilken utsträckning din hörselnedsättning begränsar dig?.

Kontrollgruppen kommer enbart att få tillgång till bokens innehåll via Internet och kommer få i uppgift att läsa och utvärdera innehållet.

Utvärdering av interventionen sker sex veckor efter att patienten har fyllt i målformuleringarna i COSI formuläret, med hjälp av en slutlig intervju samt med hjälp av följande enkäter: IOI-HA, HAD och HHIE.

HHIE är ett frågeformulär som mäter upplevelsen av hörselnedsättningen hos äldre genom att fokusera på de psykosociala och emotionella effekterna av en hörselnedsättning. HADS är ett frågeformulär som mäter ångest och depression och IOI-HA är ett frågeformulär med sju frågor, där var och en belyser ett område för sig. Områden är: daglig användning av hörapparat, nytta av hörapparat, kvarstående aktivitetsbegränsning, belåtenhet, kvarstående delaktighetsbegränsning, inverkan på omgivningen och livskvalitet.

Betydelse

Olika människor påverkas och upplever sin hörselnedsättning på olika sätt. Patientens förståelse för hörselnedsättningens konsekvenser, betydelsen av individuella insatser vid rehabiliteringen och patientens eget bidrag till processen är viktiga aspekter inom audiologisk rehabilitering. Även för utvecklandet av verktyg och metoder som kan stödja den audiologiska rehabiliteringsprocessen.

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Bilaga 7

Att undersöka om användning av Internetbaserat support underlättar den audiologiska rehabiliteringen kan ge oss ett nytt perspektiv på den audiologiska rehabiliteringen.

Ett positivt utfall av projektet aktualiserar frågor som vilken rehabilitering personer med hörselnedsättning ska erbjudas i samband med hörapparatutprovning.

Tidigare erfarenheter av metoder, procedurer

Tidigare studier beskriver olika psykologiska faktorer som varje audionom behöver kunna handskas med vid möte med patienter: bristen på motivation, passivitet, negativism samt orealistiska förväntningar. En undersökning vars syfte var att öka hörapparatanvändningen bland patienterna och ändra de orealistiska förväntningarna visade positiva effekter genom att bland annat, be patienterna föra dagbok mellan besökstiderna på sjukhuset. Patienterna var mer positiva till sina hörapparater och till sina hörapparatanpassningar samt kände sig mer säkra och hade mer realistiska förväntningar (Erikson- Mangold et al., 1990). Tidigare studie utförd av forskningsgruppen har visat att användningen av modern informationsteknologi i form av telefonsupport, tillsammans med en pedagogisk insats för hörapparatanvändaren resulterar i minskad upplevelse av aktivitets- och delaktighetsbegränsning för interventionsgruppen (Lundberg et. al., In press). Användning av hemuppgifter som patienten utförde i sin egen miljö, samt pedagogiskt stöd för att ge patienten egen kontroll över sitt liv gav patienten ett annat perspektiv på rehabiliteringsprocessen. Insatsen rekommenderades som en metod för att minska upplevd aktivitets- och delaktighetsbegränsning för personer med hörselnedsättning men även för att öka hörapparatanvändarnas delaktighet i den egna rehabiliteringen. Även Rankin and Stalling visade 2001 att engagemang av patienten i den egna rehabiliteringen visade sig öka självkänslan och även motivationen till det egna lärandet (Rankin and Stallings, 2001).

Rehabilitering via Internet kan ses som ett nytt verktyg för den audiologiska rehabiliteringen. Thorén m.fl. har utfört en Internetbaserad studie för personer med hörselnedsättning med lovande resultat vilket inspirerar till fortsatt användning av det nya verktyget inom den audiologiska rehabiliteringen (Thorén et.al., 2011). Thorén m.fl. rekryterade sina deltagare via en tidningsannons. Det unika med den planerade studien blir att den Internet baserade rehabiliteringen för första gången tillämpas kliniskt som en del av den audiologiska rehabiliteringen, riktad mot hörapparatanvändare med kvarstående upplevd aktivitets- och delaktighetsbegränsning.

Tillgång till relevant säkerhet/personal

Forskningspersonen får ett löpande nummer, en kodsiffra. Endast kodsiffran kommer att kopplas till resultaten. Resultaten läggs in i ett Excel-ark för vidare statistik. Databearbetning kommer att göras av doktoranden.

Datamaterial som finns i doktorandens dator är endast tillgängligt vid personligt lösenord. Vid eventuell utskrift kommer dessa utskrifter endast att kopplas till deltagarnas kodsiffra. I övrigt behandlas projektdeltagarna med samma sekretess som om det hade varit fråga om vanligt patientbesök.

Etiska överväganden

Patienten deltar efter att ha lämnat sitt medgivande. Studien ska vara godkänd av forskningsetisk kommitté för att kunna bedrivas.

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Etikansökan för tidigare studie omnämnd under punkt 2:1 och utförd av forskningsgruppen omfattades inte av etikprövningslagen och ett rådgivande yttrande gavs (Dnr 253-07).

Deltagarna kommer att testas vilket är en bedömningssituation. Denna kan uppfattas negativt, men eftersom det är individuella kontakter räknar vi med att kunna bemöta och förklara ifall frågor uppstår. Slumpningen kan uppfattas negativt, men vi motverkar detta genom tydlig information om att lottning kommer att ske. Deltagarnas medverkande via Internet säkras med hjälp av hög datasäkerhet där säkerheten kan likställas med bankernas. Forskningsgruppen har tidigare arbetat med liknande projekt, godkända av etikprövningsnämnden och har lång erfarenhet i Internet rehabiliteringar. Medverkande sker i ett system separerat från ordinarie vårdkontakt.

Vår bedömning är att nyttan överstiger det eventuella obehaget av att fylla i formulär (bil nr 5) och bli slumpad till behandling. Projektet har som krav att deltagarna har grundkunskaper i datorhantering. Selekteringen kan medföra att vi missar en viktig grupp som inte får ta del av rehabiliteringen på grund av bristande kunskaper i datorhantering. Själva interventionerna i sig ser vi inga risker med.

Referenser

Cox R, Hyde M, Gatehouse S, et al. (2000) Optimal Outcome Measures, Research Priorities, and International Cooperation. Ear Hear 21(4):106-15.

Dillon H, James A, Ginis J. (1997) Client Oriented Scale (COSI) and its relationship to several other measures of benefit and satisfaction provided by hearing aids. J Am Acad Audiol 8:27-43.

Elberling C, Worsøe K. När ljuden blir svagare - om hörsel och hörapparater. Herlev: Bording A/S; 2006.

Eriksson- Mangold M, Ringdahl A, Björklund A-K, Wåhlin B. (1990) The active fitting (AF) programme of haring aids: a psychological perspective. Br J Audiol 24:277-85.

Hesser, H., & Andersson, G. (in press). The role of anxiety sensitivity and behavioral avoidance in tinnitus disability. Int J Audiol.

Lundberg M, Andersson G, Lunner T. (in press). A randomized, controlled trial of the short-term effects of complementing an educational program for hearing aid users with telephone consultations. J Am Acad Audiol.

Rankin SH, Stallings KD. (2001) Patient education: principles & practice. 4th ed. Philadelphia: Lippincott Williams & Wilkins.

Thorén E, Svensson M, Törnqvist A, Andersson G, Carlbring P, Lunner T. (2011). Rehabilitative online education versus Internet discussion group for hearing aid users: a randomized controlled trial. J Am Acad Audiol 22:274-85.

Ventry IM, Weinstein BE. The Hearing Handicap Inventory for the Elderly: a new tool. Ear Hear 1982;3(3):128-34.

Zigmod AS, Snaith RP (1983) The Hospital Anxiety Depression Scale. Acta Psychiatr Scand 67:361-70.

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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

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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

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Key words: Audiology, Aural rehabilitation, Internet, Clinical practice, Hearing loss

Abbreviations: AR=aural rehabilitation; CSS=Communication Strategy Scale; CPHI=Communication Profile for the Hearing Impaired; HA=hearing aid/s; HADS=Hospital Anxiety and Depression Scale; HHIE=Hearing Handicap Inventory for the Elderly; IOI-HA=International Outcome Inventory for Hearing Aids; ITT=intention to treat; PTA=pure-tone average; RCT=randomized controlled trial; SD=standard deviation.

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ABSTRACT

Objective: Guided internet-based intervention beyond hearing aid (HA) fitting has been shown to be efficacious in randomized controlled trials (RCT). However, until now, internet interventions have not been applied clinically as a part of regular aural rehabilitation (AR). Our aim was to evaluate the effectiveness of internet-based AR for HA users from a clinical population.

Outcome measures: The Hearing Handicap Inventory for the Elderly (HHIE) was used as the primary outcome measure, and the Communication Strategies Scale (CSS) and the Hospital Anxiety and Depression Scale (HADS) were used as secondary outcome measures. All questionnaires were administered before and directly after the intervention and at 6 months post-intervention.

Methods: We used a parallel group design (RCT). The data were collected in 2013-2014 at three different clinics. Seventy-four HA users were randomly assigned to receive either full internet-based AR (intervention group, n=37) or one element of the internet-based AR (control group, n=37).

Results: Data were analyzed following the intention-to-treat principle. Each group showed improved HHIE scores over time and did not differ significantly from each other. The intervention group showed significantly greater improvement compared with the control group for the CSS total and the *Nonverbal* subscale scores.

The intervention group and control group were also subdivided into two age groups: 20-59 years and 60-80 years. Significantly better improvement on the CSS total and *Nonverbal* subscale scores was found in the older group compared with the younger participants.

Conclusions: This study indicates that participants in an internet-based intervention applied in general clinical practice showed improved self-reported communication skills compared

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with a control group. Receiving a full intervention was not more effective in improving self-reported hearing problems than receiving just one element of the internet-based intervention.

Trial registration: This trial is registered at ClinicalTrals.gov, number NCT01837550.

Strengths and limitations of this study:

- This is one of the first randomized controlled trials in Sweden to implement internet-based rehabilitation beyond conventional hearing aid fitting in a general clinical practice.
- The recruitment process used in the clinical trial will provide indications of the types of hearing aid users who are interested in this type of intervention.
- One limitation of this study is that the control group received an active intervention.

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INTRODUCTION

Hearing impairment influences communication in people's daily life. In agreement with the International Classification of Functioning, Disability, and Health[1], the objective of aural rehabilitation (AR) is to promote social participation for people with hearing impairment. Addressing this objective includes fitting the client with hearing aids (HA), educating him or her about the condition, and providing perceptual training and counseling[2]. To improve communication for people with hearing impairment, researchers recommend combining group AR with HA use [3-6]. This combination has shown to be more cost-effective than HA use alone[7]. However, despite the recommendations, the most common approach is the use of HAs alone[8]. This discrepancy could be explained by clinicians' lack of time and the difficulties of scheduling comprehensive AR in addition to HA fitting[9]. Moreover, HAs users with stressful life situations may have very limited time to spend on traveling to participate in rehabilitation courses offered by the clinic. Also, many HA users experience communication difficulties despite today's HA technology. This could cause patients to stop using their HAs[10], which can lead to withdrawal from and/or avoidance of interpersonal interactions or involvement in community life. A review of the literature showed that, HA users' self-perceived hearing difficulties can affect help seeking, HA uptake, HA use, and satisfaction[11]. Although combining group AR with HA use can be beneficial, the overall availability of and adherence to communication programs are still low[12].

Several studies have suggested that AR could be provided without in-person meetings[13-17]. Thorén et al[17], for example, significantly increased activity and participation in the intervention group by using Internet to provide AR in addition to HA fitting, while the control group did not improve. A recent systematic review indicated that such resources show benefits such as increased access to care, cost-effectiveness and improved quality of care in

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terms of user satisfaction[18]. Internet use is increasing among people with hearing impairment, which encourages including the Internet for AR in future research[19-21]. However, the literature regarding the clinical use of the Internet for AR is insufficient.

Our research group designed a randomized controlled trial (RCT) of internet-based AR in addition to HA fitting[17]. The study provided proof of concept that AR beyond HA fitting could be performed over the Internet [16-17]. However, participants were recruited through advertisements and articles in Swedish national daily newspapers and on the Internet, and the study did not indicate whether internet-based interventions could be feasible in a clinical setting. Nonetheless, we chose to use this study design[17] and supplement the trial with telephone support, and then implement the trial in a clinical setting at a later time. Our earlier research showed promising results for telephone-supported AR beyond HA fitting in general clinical practice (GCP)[22]. A study of self-help treatment for tinnitus in a clinical setting showed significant improvements pre- to post-treatment and at follow-up when internet-based treatments were used, indicating that self-help treatment can be transferred to the clinic[23]. Studies in other research fields, such as panic disorders, have shown that guided internet-based therapy is efficacious and effective when delivered as part of routine psychiatric care[24].

The first aim of this study was to evaluate whether internet-based AR for HA users will be effective in GCP. Our assumption is that the internet-based AR program would reduce residual hearing problems among HA users and improve the participants' communication strategies and psychosocial well-being, while participating in the control group would not. The second aim of the study was to analyze the effect of internet-based AR in GCP among two age-groups: 20-59 years and 60-80 years. Our hypothesis was that the 20- to 59-year age group may be more receptive to internet-based AR because of their presumably active- and stressful life situations.

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METHODS

The Consolidated Standards of Reporting Trials (CONSORT) checklist was followed when reporting the abstract, designing the study, and analyzing and interpreting the results [25-26]. A flowchart of the study procedure is presented in figure 1. The trial is registered at ClinicalTrals.gov, number NCT01837550.

– Figure 1 –

Recruitment and selection

The eligibility criteria targeted the most common patient category at three different clinics within the Hearing Organization, Södra Älvsborg, Sweden: patients who were 20-80 years old and who had mild to moderate conductive or sensorineural hearing loss, i.e., a 20-60 dB HL pure-tone average (500, 1000, and 2000 Hz). Additional eligibility criteria included patients who had completed a HA fitting 3 months before the study began (regardless of HA manufacturer or model), who had a HHIE score ≥20 points (HHIE: Hearing Handicap Inventory for the Elderly[27]; indicative of some residual hearing problems), and gave their informed consent to participate. The study was conducted in 2013-2014. The recruitment process was conducted in two sets, one for participants aged 20-59 years and one for those aged 60-80 years. All potential participants who fulfilled the criteria for age, hearing loss, and HA fitting received a recruitment letter that contained information about the study's purpose and structure and stressed that the participants' privacy would be protected and that participation was voluntary. The participants were prepared to allocate 1.5-2.0 hours each week to participate in the study and were informed that they would be placed into one of two groups. The participants were asked to visit the website www.iterapi.se/sites/hornet to read more about the study and to initiate participation.

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The first step of the participation required registering at the website and completing a screening form. Participants who registered at the website and completed the screening form (n=108) were called for an interview to assess their eligibility; of these, 104 agreed to participate in the study. The next step was for the participants to complete four questionnaires: the HHIE[27], the Communication Strategies Scale; the CSS (from the Communication Profile for the Hearing Impaired (CPHI)[28], the Hospital Anxiety and Depression Scale (HADS)[29] and International Outcome Inventory for Hearing Aids (IOI-HA)[30]. Consequently, 74 participants were included in the study as seen in Figure 1.

The study was a randomized controlled trial with a parallel group design and a simple randomization procedure through the recruitment process that was conducted in two sets. The 74 participants were randomly assigned to either an intervention group (group 1) or a control group (group 2) according to a computer-generated list of random numbers. An independent audiologist at the clinic generated the random allocation sequence, assigned the participants to different groups, and reported the allocation schedule to the project leader, who then enrolled the participants. The assigned participants were told which group they were allocated to (1 or 2) but were not informed whether the group was the intervention group or the control group. Thirty-seven participants were included in the intervention group, and 37 participants were included in the control group, as shown in table 1. No significant differences were found between the groups regarding the background variables age, age group, gender and hearing loss.

The study was reviewed and approved by the regional ethical review board in Gothenburg, Sweden (reference number 1018-11). The study website was programmed using Java Script, and information was available in hypertext markup language (HTML) format.

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Table 1. Demographic and clinical characteristics of the participants. The data are reported as means (standard deviations, SD) unless stated otherwise.

		Intervention group (n=37)	Control group (n=37)
20- to 59-year age group, n (%)		17 (46)	16 (43)
60- to 80-year age group, n (%)		20 (54)	21 (57)
Age, years (range 31-80 years)		61.8 (11.9)	62.1 (11.4)
	20- to 59-year age group	50.9 (7.2)	52.3 (9.1)
	60- to 80-year age group	71.1 (5.4)	69.6 (5.9)
Gender, n (%)			
	Men	24 (64.9)	20 (54.1)
	Woman	13 (35.1)	17 (45.9)
Pure-tone average (dB HL)			
	Right ear	37.5 (11.3)	38.0 (8.6)
	Left ear	37.8 (10.5)	36.5 (8.5)
HA, n (%)			
	Binaural	28 (75.7)	31 (83.8)
	Monaural	9 (24.3)	6 (16.2)
Duration of HA use, years (range 0.5-55 years)		7.5 (9.6)	7.4 (6.3)
Computer experience*, n (%)		37 (100)	37 (100)
Computer access, n (%)		37 (100)	37 (100)
Able to have a telephone conversation without HA/s?, n (%)		32 (86.5)	35 (94.6)
IOI-HA	1. Daily use	4.1 (1.1)	4.4 (1.0)
	2. Benefit	3.8 (0.9)	4.1 (0.9)
	3. Remaining activity limitation	3.1 (0.8)	3.1 (0.8)
	4. Satisfaction	4.1 (1.1)	4.4 (0.8)
	5. Remaining participation restriction	3.8 (1.1)	4.1 (0.8)
	6. Impact on environment	3.6 (0.9)	3.9 (0.9)
	7. Quality of life	3.6 (0.8)	3.6 (1.0)

(*familiar with: able to log in, print information, complete a questionnaire on a website and read and send email); HA: hearing aid; IOI-HA: International Outcome Inventory for Hearing Aids.

Outcome Measures

The HHIE was the primary outcome measure. The HHIE includes two subscales; the *Social* subscale comprises 12 questions addressing the social effects of hearing loss, and the *Emotional* subscale comprises 13 questions addressing the emotional effects of hearing loss. Higher scores reflect a higher self-reported hearing problem.

The CSS and the HADS were used as secondary outcome measures. The CSS includes three subscales (*Maladaptive Behaviors, Verbal Strategies and Nonverbal Strategies*) and is designed to analyze participants' behavior in various communication situations. The *Maladaptive Behaviors* subscale includes 9 questions that analyze strategies that hinder

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communication. *Verbal Strategies* and *Nonverbal Strategies* address 16 items related to strategies that can enhance communication. Scoring for the CSS reflects how frequently a specific situation or behavior occurs. The HADS comprises 14 items separated into two subscales: *Anxiety* and *Depression*. Higher scores reflect more symptoms of anxiety and depression.

The IOI-HA includes seven questions measuring specific dimensions of HA outcomes: daily use, benefits, remaining activity limitations, satisfaction, remaining participation restrictions, impact on the environment, and quality of life; with higher scores indicating better outcomes. The IOI-HA was not used as an outcome measure in this study; rather, it was used to describe the demographic and clinical characteristics of the participants, as shown in table 1.

The HHIE, CSS and HADS were administered according to the methods described[27-29] and were available on the study website, in Swedish. The questionnaires were administered online before and directly after the study participation and 6 months after participation to evaluate self-reported hearing problems, communication strategies, and anxiety and depression. All of the questionnaires have a good internal consistency[31-32] and have been shown to be as reliable as the original versions when used with a Swedish population of young adults and elderly[31]. Sundewall et al[33] stressed the importance of keeping the internet-based administration format of the HHIE and HADS stable across time points.

Intervention Group

The internet-based intervention program was partly tested in a previous study[17] and is based on four elements: reading, home training, interaction with an audiologist, and interaction with peers in an internet-based discussion forum. The participants received information about the intervention program and access to the reading material on the study website; they also

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received a book about hearing and HAs[34] and the Swedish version of Active Communication Education, a compendium of communication strategies[5, 35-36]. The website information about the intervention program, along with the book and the compendium, were also mailed to all of the participants in the intervention group.

– Figure 2 –

The reading element is divided in to five modules, one module for each of the five weeks. The participants were instructed to read specific content each week based on the various chapters of the book and information from the compendium[17]. The weekly home assignments (week 1-5) were accessible to facilitate an understanding of the contents of the book and the compendium. For example, the weekly assignments could be to observe the benefits of using HA/s. The weekly home assignments were handed in on the Internet by the participants (week 1-5), and direct responses were provided by an audiologist. The weekly home assignments were also discussed with the audiologist over the phone at the end of each treatment week. The telephone consultations lasted approximately 10-15 minutes per participant and provided the participants with an opportunity to reflect on the assignment and discuss any concerns they might have. Weeks 1-4 ended with quiz questions on the content of the past weeks' readings.

The participants in the intervention group also attended a discussion forum on the study website. Weekly topics were presented for the participants[17] to discuss with one other, without any interaction with the audiologist. The participants were free to use the discussion forum with no restrictions from the audiologist. However, all activities where strictly observed, and if needed, inappropriate postings could be deleted. No inappropriate postings occurred.

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Control Group

The control group received one reading element; i.e. the first four chapters of the book[34]; and the information about participation provided on the study website. The website information and book chapters were also mailed to the participants. The control group was asked to read the four chapters over a five-week period; no assignments were given in association with their participation. To minimize the impact of professional interaction, no monitoring was provided during the program to ensure that the participants actually read the chapters.

Follow-up

At the end of the treatment period, the HHIE, CSS and HADS were made available to all participants on the study website, and the participants were asked to complete them. Both groups' participation was evaluated using a post-study telephone interview. The post-study interviews for the intervention group were conducted by a different audiologist than the one who conducted the pre-study interviews and the telephone consultations during the study to minimize the influence of special attention on the participants' responses to the questionnaires. The post-study interviews for the control group were conducted by the same audiologist who conducted the pre-study interviews. For the telephone interview, the audiologists used a self-designed form that contained questions about the study process, including opportunities for the participants to provide their own comments. Different forms were designed for the intervention group and the control group. All of the participants were invited to keep their copy of the reading material.

Six months after the study participation, the participants in both groups were contacted via e-mail and asked to complete the HHIE, CSS and HADS online again.

Statistical Analyses

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Statistical Package for the Social Sciences[37] software for Windows (SPSS, version 19.0) was used for the analysis of all data. Three measurement time points were examined: pre-treatment (T0), post-treatment (T1) and 6 months post-treatment (T2). To ensure a between-group effect of 80% at the 5% significance level, it was estimated that 60 participants needed to be included in the study. An effect size of Cohen's d=0.80 was expected. The expected standardized mean difference on the HHIE formed the basis of the obtained power. The within-group and between-group effect sizes of Cohen's d were calculated from T0-T1 and from T0-T2 and were categorized as small ($0.2 \leq d < 0.5$), moderate ($0.5 \leq d < 0.8$) and large ($0.8 \leq d$).

No significant differences were found between the groups at T0 for all the outcome measures. All data from the participants who did not complete T1 and/or T2 measurements were treated on an *intention to treat* basis[38], meaning that the participants were included in the analysis (as missing data) regardless of their compliance or withdrawal from the study; see figure 1.

Given the ability to handle missing data[39], mixed effects models with compound symmetry as the covariance structure were used to analyze the HHIE, CSS and HADS. Differences between the intervention group and the control group were examined by modeling the interaction effects of group and time. A subgroup analysis was performed including two groups categorized as age-group: 20-59 years and age-group: 60-80 years.

A sensitivity analysis was performed using mixed effects models for the HHIE, CSS and HADS, this time excluding subjects who did not complete all measurement time points (T1 and/or T2). Sensitivity analysis was performed to increase the understanding of the relationships between internet-based AR and the outcome measures, HHIE, CSS, and HADS.

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RESULTS

Attrition and adherence

Eight participants in the intervention group and five in the control group completed the study program but did not provide all T1 and/or T2 measurements, without giving a specific reason. Six participants in the intervention group and seven in the control group withdrew from participation in the study, as shown in figure 1. Five of those who withdrew from the study provided T1 measurements; four provided T2 measurements. One participant who was lost to follow-up at T1 provided T2 measurements. Consequently, 12 participants (16%) did not provide T1 measurements (of which n=1 followed up only with the HHIE), and 22 participants did not provide T2 measurements (30%). No significant differences were found when comparing the baseline values between those who discontinued the study program from T0-T1 and those who did not. Those who discontinued from T0-T2 had lower scores on baseline values for HHIE-total ($t(72)=-2.31$, $p=0.024$) and the *Emotional* subscale ($t(72)=-2.05$, $p=0.044$), and lower points on HADS-total ($t(72)=-2.73$, $p=0.008$) and the *Anxiety* ($t(72)=-2.03$, $p=0.046$) and *Depression* ($t(72)=-2.38$, $p=0.020$) subscales compared with those who continued with the study.

Some of the participants in the intervention group who completed the study did not answer all four of the weekly quizzes, and some of the participants in the intervention group did not provide all five of the online weekly responses to the audiologist. However, all of them were active participants in discussions during the weekly telephone follow-up, and some stated a wish for the discussion forum to be more active because they considered that part of the intervention very interesting. On average, the participants posted 0.4 contributions to the discussion forum.

Primary outcome measure

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Both groups showed decreased HHIE-total scores T0-T1 ($F_{(1, 64.0)}$=22.1, p<0.000) and T0-T2 ($F_{(2, 114.4)}$=11.5, p<0.000). The interaction effect for HHIE-total group and time T0-T1/T0-T2 was not significant. The results are presented in table 2, and the estimated marginal means (EMM) and standard errors of the outcome measures HHIE, CSS and HADS for both groups are presented as supplementary material in Complementary Appendix I. Both groups showed decreased scores for both of the HHIE subscales from T0-T1 (p<0.001) and T0-T2 (p<0.001). The interaction effect was not significant for models of group and time T0-T1 for the *Social* subscale or for T0-T2 for the *Social* and *Emotional* subscale. A borderline significant interaction effect emerged for the *Emotional* subscale T0-T1 ($F_{(1,64.3)}$=3.8, p=0.054). Small to moderate between-group effect sizes were found for the HHIE, as shown in table 2.

Table 2. (n=74) Observed means (OM) and standard deviations (SD) of the outcome measures HHIE, CSS and HADS for both groups at pre-treatment (T0), post-treatment (T1) and 6-months post-treatment (T2). Cohen's pooled within-group and between-group small/moderate/large effect sizes (ES) and 95% confidence intervals (CI) for the intervention (I-group) and control groups (C-group) are presented. *P-values* illustrate the significance of the difference in estimated marginal means between the intervention and control groups. F-values illustrate the interaction effect for time^{x}group (t^{x}gr).

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Scale		T0	T1	T2	T0-T1	T0-T2	Age group	T0-T1	T0-T2	T0-T1	T0-T2
		OM (SD)	OM (SD)	OM (SD)	ES (95% CI) Within-group	ES (95% CI) Within-group		ES (95% CI) Between-group	ES (95% CI) Between-group	(*p-value*) (F-value)	(*p-value*) (F-value)
HHIE Total											
I-group	Total	42.0 (16.9)	35.8 (15.2)	36.0 (15.8)	S (-0.08 to 0.84)	S (-0.10 to 0.82)	**Total**	S (-0.16 to 0.76)		2.5 (*0.297*)	3.8 (*0.306*)
	20-59 years	44.7 (13.6)	40.8 (13.3)	43.4 (14.6)	S (-0.17 to 0.74)		**20-59**	M (0.01 to 0.93)	L (0.39 to 1.35)	1.3 (*0.681*)	1.0 (*0.919*)
	60-80 years	39.7 (19.3)	31.7 (15.8)	31.6 (15.2)	M (-0.01 to 0.91)	M (0.00 to 0.92)	**60-80**		S (-0.73 to 0.19)	3.5 (*0.344*)	5.5 (*0.282*)
C-group	Total	36.1 (11.8)	31.3 (14.3)	34.0 (13.2)	S (-0.10 to 0.82)						
	20-59 years	38.0 (12.7)	34.0 (15.3)	31.6 (13.5)	S (-0.18 to 0.74)	M (0.02 to 0.95)					
	60-80 years	34.7 (11.1)	29.0 (13.3)	35.5 (13.3)	M (0.00 to 0.92)						
HHIE Social											
I-group	Total	20.2 (8.8)	18.3 (7.1)	18.2 (7.8)	S (-0.22 to 0.69)	S (-0.22 to 0.69)	**Total**	S (-0.08 to 0.84)		0.4 (*0.732*)	1.8 (*0.224*)
	20-59 years	21.2 (7.9)	19.6 (6.6)	21.0 (7,6)	S (-0.24 to 0.68)		**20-59**	S (-0.03 to 0.89)	S (-0.08 to 0.86)	1.1 (*0.570*)	1.3 (*0.604*)
	60-80 years	19.3 (9.6)	17.2 (7.4)	16.6 (7.7)	S (-0.21 to 0.70)	S (-0.15 to 0.77)	**60-80**	S (-0.12 to 0.79)	S (-0.73 to 0.19)	0.1 (*0.954*)	2.1 (*0.381*)
C-group	Total	18.5 (6.6)	15.5 (7.3)	18.2 (7.1)	S (-0.03 to 0.89)						
	20-59 years	19.8 (7.0)	16.4 (8.0)	17.8 (8.9)	M (-0.01 to 0.91)	S (-0.21 to 0.71)					
	60-80 years	17.5 (6.2)	14.8 (6.8)	18.5 (6.0)	S (-0.04 to 0.87)						
HHIE Emotional											
I-group	Total	21.8 (9.5)	17.5 (9.4)	17.8 (9.5)	M (-0.01 to 0.91)	S (-0.04 to 0.88)	**Total**		S (-0.22 o 0.69)	3.0 (*0.054*) (t^xgr=3.8)	1.9 (*0.132*)
	20-59 years	23.5 (7.8)	21.2 (8.2)	22.4 (10.0)	S (-0.02 to 0.74)		**20-59**	S (-0.04 to 0.88)	L (0.48 to 1.44)	2.4 (*0.190*)	0.4 (*0.340*)
	60-80 years	20.4 (10.7)	14.4 (9.3)	15.1 (8.3)	M (0.13 to 1.06)	M (0.08 to 1.01)	**60-80**		S (-0.66 to 0.25)	3.4(*0.158*)	3.5 (*0.212*)
C-group	Total	17.6 (7.3)	15.8 (8.2)	15.7 (8.3)	S (-0.23 to 0.69)	S (-0.22 to 0.70)					
	20-59 years	18.3 (7.6)	17.6 (8.7)	13.8 (7.5)		M (0.12 to 1.06)					
	60-80 years	17.1 (7.3)	14.3 (7.7)	16.9 (8.9)	S (-0.09 to 0.83)						
CSS Total											
I-group	Total	68.1 (13.6)	74.7 (11.1)	70.9 (10.5)	M (-0.99 to -0.06)	S (-0.69 to 0.23)	**Total**	M (0.06 to 0.98)	S (-0.08 to 0.84)	5.2 (*0.021*) (t^xgr=5.6)*	3.5 (*0.064*) (t^xgr=2.8)
	20-59 years	68.8 (12.0)	76.4 (8.3)	73.5 (8.6)	M (-1.20 to -0.26)	M (-0.91 to 0.02)	**20-59**	S (-0.08 to 0.84)	M (0.06 to 0.99)	2.5 (*0.504*)	1.5 (*0.806*)
	60-80 years	67.4 (15.1)	73.4 (10.6)	69.4 (11.4)	M (-0.92 to 0.01)		**60-80**	L (0.27 to 1.21)	S (-0.12 to 0.80)	7.8 (*0.004*) (t^xgr=9.3)**	5.5 (*0.017*) (t^xgr=4.3)*
C-group	Total	67.2 (11.3)	68.5 (12.4)	66.7 (11.6)							
	20-59 years	67.7 (11.3)	72.3 (12.4)	69.2 (7.5)	S (-0.84 to 0.08)						
	60-80 years	66.8 (11.5)	65.1 (11.6)	65.0 (13.8)							
CSS Maladaptive											
I-group	Total	17.9 (4.5)	17.8 (5.7)	17.4 (4.3)			**Total**	S (-0.23 to 0.69)		0.3 (*0.739*)	0.2 (*0.893*)
	20-59 years	18.2 (4.1)	17.9 (5.8)	17.6 (2.5)			**20-59**	S (-0.25 to 0.67)	M (0.03 to 0.95)	1.0 (*0.426*)	0.1 (*0.631*)
	60-80 years	17.8 (5.0)	17.7 (5.8)	17.3 (5.1)			**60-80**	S (-0.24 to 0.68)		1.3 (*0.337*)	0.4 (*0.543*)
C-group	Total	17.2 (3.5)	16.7 (3.5)	17.3 (4.4)							
	20-59 years	16.7 (3.5)	16.9 (3.2)	16.1 (3.5)							
	60-80 years	17.7 (4.3)	16.6 (3.9)	18.1 (4.8)	S (-0.19 to 0.72)						
CSS Verbal											
I-group	Total	22.6 (6.7)	25.8 (6.1)	24.1 (4.8)	M (-0.96 to -0.03)	S (-0.71 to 0.20)	**Total**	S (-0.14 to 0.78)	S (-0.04 to 0.88)	1.2 (*0.299*)	1.4 (*0.455*)
	20-59 years	23.0 (8.0)	26.4 (6.8)	25.3 (4.8)	M (0.91 to 0.01)	S (-0.80 to 0.11)	**20-59**		S (-0.24 to 0.68)	0.6 (*0.756*)	0.6 (*0.875*)
	60-80 years	22.2 (5.5)	25.3 (5.5)	23.5 (4.8)	M (-1.02 to -0.09)	S (-0.71 to 0.21)	**60-80**	M (0.04 to 0.96)	M (0.13 to 1.06)	1.8 (*0.231*)	2.8 (*0.190*)

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C-group	Total	21.8 (5.6)	23.8 (6.4)	21.9 (5.5)	S (-0.79 to 0.13)						
	20-59 years	22.4 (5.5)	25.4 (6.6)	24.4 (3.2)	M (-0.95 to -0.03)	S (-0.90 to 0.02)					
	60-80 years	21.4 (5.6)	22.4 (6.0)	20.2 (6.1)		S (-0.25 to 0.66)					
CSS Nonverbal											
I-group	Total	27.6 (6.9)	31.2 (4.8)	29.3 (4.8)	M (-1.07 to -0.13)	S (-0.74 to 0.17)	**Total**	M (0.09 to 1.02)	S (-0.14 to 0.78)	3.7 (*0.004*) (t^xgr=9.2)**	1.9 (*0.011*) (t^xgr=4.7)*
	20-59 years	27.7 (5.6)	32.1 (4.1)	30.6 (4.9)	L (-1.36 to -0.41)	M (-1.01 to -0.08)	**20-59**	S (-0.01 to 0.84)	S (0.05 to 0.87)	2.8 *(0.106)*	1.9 *(0.318)*
	60-80 years	27.5 (8.0)	30.4 (5.2)	28.6 (4.8)	S (-0.89 to 0.03)		**60-80**	M (0.26 to 1.20)	S (-0.15 to 0.76)	4.7 (*0.010*) (t^xgr=7.4)*	2.2 (*0.019*) (t^xgr=4.2)*
C-group	Total	28.1 (6.2)	28.0 (6.5)	27.5 (6.2)							
	20-59 years	28.6 (5.5)	30.0 (6.5)	28.7 (4.2)	S (-0.69 to 0.23)						
	60-80 years	27.8 (7.3)	26.2 (6.1)	26.7 (7.3)	S (-0.22 to 0.69)						
HADS Total											
I-group	Total	8.5 (6.6)	7.5 (6.3)	4.8 (4.5)		M (0.18 to 1.12)	**Total**		S (-0.84 to 0.08)	0.7 (*0.463*)	2.4 (*0.070*)
	20-59 years	9.5 (5.8)	9.4 (4.9)	6.5 (4.5)		M (0.11 to 1.03)	**20-59**	S (-0.10 to 0.82)		0.3 *(0.804)*	2.1 *(0.300)*
	60-80 years	7.7 (7.3)	5.9 (7.0)	4.1 (4.4)	S (-0.21 to 0.71)	M (0.13 to 1.06)	**60-80**		M (-1.06 to -0.13)	1.4 *(0.257)*	2.7 *(0.178)*
C-group	Total	7.4 (4.8)	6.5 (5.2)	6.8 (5.9)							
	20-59 years	8.3 (4.3)	7.7 (4.5)	6.7 (7.4)		S (-0.20 to 0.72)					
	60-80 years	6.8 (5.2)	5.4 (5.7)	6.9 (4.9)	S (-0.20 to 0.71)						
HADS Anxiety											
I-group	Total	4.6 (3.8)	3.8 (3.4)	2.4 (2.0)	S (-0.24 to 0.68)	M (0.25 to 1.19)	**Total**		M (-0.94 to -0.02)	0.6 (*0.198*)	1.4 (*0.071*)
	20-59 years	5.2 (3.6)	4.8 (3.2)	3.1 (2.0)		M (0.24 to 1.18)	**20-59**		S (-0.80 to 0.12)	0.1 *(0.858)*	1.5 *(0.198)*
	60-80 years	4.1 (4.0)	2.9 (3.5)	2.0 (1.9)	S (-0.14 to 0.77)	M (0.20 to 1.13)	**60-80**		M (-1.07 to -0.14)	1.0 *(0.117)*	1.3 *(0.254)*
C-group	Total	4.3 (3.2)	3.7 (3.1)	3.7 (3.2)							
	20-59 years	5.1 (2.6)	4.7 (2.9)	4.2 (4.1)		S (-0.20 to 0.72)					
	60-80 years	3.7 (3.6)	2.8 (3.2)	3.4 (2.6)	S (-0.20 to 0.72)						
HADS Depression											
I-group	Total	3.9 (3.3)	3.7 (3.5)	2.6 (2.8)		S (-0.04 to 0.88)	**Total**	S (-0.16 to 0.75)		0.0 (*0.984*)	1.1 (*0.171*)
	20-59 years	4.3 (2.9)	4.6 (3.0)	3.4 (2.8)		S (-0.15 to 0.77)	**20-59**	M (0.15 to 1.09)	S (-0.21 to 0.70)	0.5 *(0.556)*	0.7 *(0.501)*
	60-80 years	3.6 (3.6)	3.0 (3.9)	2.1 (2.8)		M (-0.00 to 0.92)	**60-80**		S (-0.72 to 0.19)	0.4 *(0.678)*	1.3 *(0.278)*
C-group	Total	3.1 (2.5)	2.8 (2.4)	3.1 (2.9)							
	20-59 years	3.2 (2.2)	3.0 (2.0)	2.6 (3.6)		S (-0.26 to 0.66)					
	60-80 years	3.1 (2.7)	2.6 (2.8)	3.5 (2.4)							

S=small effect size ($0.2 \leq d < 0.5$), M=moderate effect size ($0.5 \leq d < 0.8$), L=large effect size ($0.8 \leq d$); HHIE: Hearing Handicap Inventory for the Elderly; *Social* and *Emotional* subscales. CSS: Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI); *Maladaptive*, *Verbal* and *Nonverbal* subscales. HADS: Hospital Anxiety and Depression Scale; *Anxiety* and *Depression* subscales.
*$p<0.05$, **$p<0.01$.

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Secondary outcome measures

Both groups showed improved scores for the CSS-total T0-T1 ($F_{(1, 62.9)}$=10.7, p<0.01) and for the *Verbal* subscale T0-T1 ($F_{(1,61.7)}$=20.1, p<0.001) and the *Nonverbal* subscale T0-T1 ($F_{(1, 63.8)}$=7.1, p<0.05), as shown in table 2. This main effect of time persisted from T0-T2 (CSS-total; $F_{(2, 114.4)}$=4.9, p<0.05; *Verbal* $F_{(2,112.3)}$=9.1, p<0.01; *Nonverbal* $F_{(2, 115.8)}$=3.6, p<0.05). Furthermore, significantly greater improvement was found for the intervention group compared with the control group T0-T1 for the CSS-total ($F_{(1, 62.9)}$=5.6, p<0.05) and for the *Nonverbal* subscale ($F_{(1, 63.8)}$=9.2, p<0.01). This interaction effect persisted from T0-T2 for the *Nonverbal* subscale ($F_{(2, 115.8)}$=4.7, p<0.05), and was on the borderline for CSS-total ($F_{(2,114.4)}$=2.8, p=0.064). Moderate within-group effect sizes from T0-T1 were observed for the intervention group for the CSS-total and for the *Verbal* and *Nonverbal* subscales. Moderate between-group effect sizes were shown for the CSS-total and for the *Nonverbal* subscale T0-T1, as shown in table 2.

The analyses for HADS showed that both the intervention group and the control group improved their total scores over the time, and the analyses identified no significant differences when modeling the interaction effects of group and time from T0-T1 or T0-T2, as shown in table 2. Moderate within-group effect sizes were found for the HADS-total T0-T2, as shown in table 2.

Subgroup analysis

A subgroup analysis for different age groups was performed for the HHIE, CSS and HADS scores from T0-T1 and T0-T2. No significant interaction effect of group and time was found for the outcome measures HHIE and HADS from T0-T1 or T0-T2 for the age groups 20- to 59-years and 60- to 80-years, as shown in table 2. Nevertheless, a large between-group effect was found from T0-T2 for the HHIE-total score and for the *Emotional* subscale among the

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participants in the 20- to 59-year age group, as shown in table 2. The participants in the 60- to 80-year age group showed medium between-group effect sizes for the HADS-total scale and *Anxiety* subscale.

The CSS-total showed an interaction effect from T0-T1, indicating that the 60- to 80-years old ($F_{(1, 33.2)}$=9.3, p<0.01) in the intervention group showed significantly more improvement than the 60- to 80-year-olds in the control group. This effect persisted from T0-T2 ($F_{(2, 63.7)}$=4.3, p<0.05). There was also an interaction effect from T0-T1 for the *Nonverbal* subscale, with the 60- to 80-year-olds in the intervention group showing significantly greater improvement ($F_{(1, 33.7)}$=7.4, p<0.05) compared with the 60- to 80-year-olds in the control group. This effect persisted from T0-T2 ($F_{(2,64.1)}$=4.2, p<0.05). It may be noted that the participants of the age 60-80 years in the control group declined over time as measured by CSS-total and *Nonverbal* subscale, and that improvements in the intervention group were of effect size small or moderate. However, the younger subgroup (20-59 years of age), was improving over time in both the control (small effect sizes) and the intervention group (moderate or large effect sizes).

Sensitivity analysis

A sensitivity analysis was performed for the HHIE, CSS and HADS by excluding all data from the participants who did not complete all three measurement time points (T0, T1 and T2; n=50). However, 50 participants are not sufficient to ensure a between-group effect of 80%. Nonetheless, the sensitivity analysis revealed an interaction effect for the HHIE-*Emotional* subscale from T0-T1 ($F_{(1, 48.0)}$=4.3, p<0.05) with the intervention group showing an advantage, as shown in the Complementary Appendix II. This interaction effect did not remain 6 months post-treatment.

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The interaction effect for the CSS-total that was achieved when participants were treated on an *intention to treat* basis (n=74) was not apparent in the sensitivity analysis (n=50). The results for the CSS showed an interaction effect of time and group for the *Nonverbal* subscale from T0-T1 ($F_{(1, 48.0)}$=6.8, p<0.05) and from T0-T2 ($F_{(2, 96.0)}$=3.5, p<0.05), with the intervention group showing significantly greater improvement compared with the control group, similar to the results for the whole group (n=74).

Furthermore, the sensitivity analysis showed significant results for the HADS-total scale from T0-T2 ($F_{(2, 96.0)}$=3.1, p<0.05), indicating that the intervention group's scores had improved more than those of the control group. The sensitivity analysis for the remaining scales and subscales showed no changes in significance compared with the previous analysis (n=74), as shown in Complementary Appendix II.

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DISCUSSION

The aim of this study was to evaluate whether internet-based AR for HA users would be effective in GCP and whether the assumed positive effect of participating in the internet-based AR program would be maintained 6 months after the program was completed. Our aim was also to analyze the effect of the internet-based AR program in two age-groups.

Both the intervention group and the control group improved their HHIE scores from T0-T1 and from T0-T2; however, the improvements were not significantly different between groups, unlike the findings of our research group's previous study[17]. Differences in the results could be related to differences in the recruitment process. In our previous study[17], the participants were recruited through advertisements and articles in Swedish national daily newspapers and on the Internet; the recruited participants were well educated and had a higher education level than the general population. This indicated that the intervention program is well suited for educated patients, although education was not a significant predictor of intervention outcomes[40]. This recruitment strategy generated a broad range of background variables and recruited participants who actively sought involvement in research. The recruitment process used for the present study generated more narrow background variables, as shown in table 1, and indicates the types of HA users in GCP that are interested in this type of intervention.

Another underlying explanation for the differences in improvement could be that the control group was more active in present study compared with our previous study[17], in which the participants read a book about the history of HAs, though not online. Participants being enrolled in a research study might generally be more positive afterward their participation[41], which could be considered research bias assuming that the full internet-based AR is more effective than one element of the program. A borderline significant interaction effect emerged for the HHIE *Emotional* subscale from T0-T1, indicating that the full internet-based AR could have had a positive impact on the emotional effects of the participants' hearing loss.

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The sensitivity analysis that was performed (n=50) revealed an interaction effect for the HHIE-*Emotional* subscale from T0-T1, for the CSS-*Nonverbal Strategies* subscale from T0-T1 and from T0-T2; and for the HADS-total scale from T0-T2; all interaction effects indicated an advantage for the intervention group. It appears that participants who are especially persistent and who participated in all aspects of the full internet-based AR or were just conscientious may show changes in the HHIE score and in their communications skills and may also have less symptoms of anxiety and depression. Thus, the sensitivity analysis makes the study underpowered, and these interaction effects should be treated with caution. The participants who did not provide T1/T2 measurements for present study had lower baseline scores on the HHIE and HADS compared with those who continued in the study, indicating that insubstantial social and emotional effects of hearing loss and more pronounced anxiety and depression symptoms can influence the decision to drop out. Another potential influencing factor might be that it is easier to drop out when the intervention is internet-based, as discussed by Andersson et al[42].

In our earlier research, the HHIE was an applicable measure for the outcomes of telephone-supported AR beyond HA fitting in GCP[22]; in that study, the program for the intervention group did not include parts of the ACE program, which targets the communication difficulties experienced by older people with hearing impairment in everyday life[35-36]. In the clinical population of the present study, we found effects for the CSS-total and the *Nonverbal* subscale; thus, it seems that participating in the full internet-based AR program containing the ACE program has a larger effect on communication skills compared with partial participation. Determining the element responsible for the interaction improvement in the present study is challenging. The *reading* and *home training* elements of the full internet-based AR program might have contributed to improved communication skills, but so, too, might the telephone follow-up by the audiologist. Having personal phone contact with an audiologist may have

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encouraged the participants to try out the program's suggested strategies. The effect on the CSS, however, raises doubts about the applicability of the HHIE as a main outcome measure for the present study.

The intervention and control groups were also analyzed using subgroups. The 60- to 80-year-olds in the intervention group obtained significantly greater improvement compared with the 60- to 80-year-olds in the control group in terms of the CSS-total and the *Nonverbal* subscale, contradicting our hypothesis that the 20- to 59-year age group would be more receptive to internet-based AR. As mentioned, the ACE program targets the everyday life of older people, which may have been reflected in the results of the CSS subgroup analysis. However, it might be that the decline in scores as measured by CSS-total and the *Nonverbal* subscale for the 60-80 year-olds in the control group contributes to that the small effect in the intervention group becomes more pronounced in this subgroup than the differences in the improvements seen in both control and intervention group in the younger subgroup (20-59 years). However, the subgroup analysis includes small groups and these results should be treated with caution.

Thorén et al[17] found significant improvements in the intervention group when measuring participants' psychosocial well-being using the HADS. Our results showed that both the intervention group and the control group showed improved HADS scores, although the difference between the groups was not significant. Preminger[43] reviewed the importance of taking psychosocial outcomes into account when implementing group adult aural rehabilitation and highlighted the importance of outcome studies. The HADS is believed to be sensitive enough to detect the effects of online education[16, 17].

Limitations

One limitation is that the participants in this study have been HA users for an average of 7.5 years. In our previous study in a GCP setting, that number was 6.5 years[22]; for Thorén et al,

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the average was 9.9 years[17]. Despite inclusion criteria that acknowledged the heterogeneity of a clinical population, the participants in the present study were experienced HA users. A systematic review[6] suggests that the short-term outcomes of group AR are important for encouraging new HA users to continue using amplification. Thus, although different aspects of AR may not suit every individual client, the study increases the confidence that the clinical use of group AR will likely have positive outcomes. Another limitation is that the control group received an active intervention. A more clear result would have been generated from a control group that received no intervention.

Another concern that needs to be mentioned is that the observed standardized mean difference on the HHIE between the intervention and control group was much lower than what was expected when comparing with previous research and anticipated in the sample size calculation; also, the standard deviation was larger than expected. Thus, increasing the sample size initially could maybe result in statistically significant difference between the groups; nevertheless, it is not certain that the standardized mean difference between the groups in a larger sample would lead to clinically meaningful difference for the participants.

Conclusion

The internet-based approach expands the availability of AR in GCP, offering accessibility to many people, including hard-to-reach populations[44]. The present study shows that using the Internet for interactions between the audiologist and the HA user had a positive effect on communication skills for the intervention group compared with the control group. Furthermore, the full internet-based AR program was not more effective than one element of the internet-based AR program. Although, the advantages of an internet-based approach, both for the patient and the clinician, may inspire clinicians and operation managers in their future utilization of comprehensive AR in addition to HA fitting.

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More research is needed to examine the efficacy and applicability of this type of intervention. This study is one of the first RCTs in Sweden to implement internet-based rehabilitation beyond conventional HA fitting in a GCP; and is explicitly at the beginning of exploring the possible clinical applicability of this type of intervention. Further analysis is needed to examine the individual elements of the full internet-based AR program to evaluate which part of the internet-supported educational intervention had the greatest effect: the reading material, the weekly assignments, the discussion forum, or the contact with the audiologist. In addition, guided internet-based intervention should be compared with face-to-face AR to analyze whether the two approaches are equally effective. Also, this type of internet-based intervention delivered exclusively to new HA users should be compared to a matched group who only receive HA in order to know the relative efficacy of the internet-based AR program. Additionally, the individual needs of the HA user should be taken into account when designing group AR, as should including significant others in the intervention.

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Contributors

GA, TL and MM contributed to the conception and design of the study, and to the acquisition of data for the study. MM contributed to data collection and analyzed the data. GA, TL, MM and KK contributed to the analysis of data and participated in interpretation of data for the study; in drafting the study and revising it critically for important intellectual content and in giving final approval of the version to be published. GA, TL and KK provided continuous supervision during the entire study.

Competing interest

The authors declare no competing interests.

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Data sharing statement

No additional data available.

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REFERENCES

1. World Health Organization. International Classification of Functioning, Disability and Health (ICF). Geneva: World Health Organization 2001.
2. Boothroyd A. Adult aural rehabilitation: what is it and does it work? *Trends in Amplif* 2007;11(2):63-71. doi: 10.1177/1084713807301073.
3. Hickson L, Worall L. Beyond hearing aid fitting: improving communication for older adults. *Int J Audiol* 2003;42(2):S84-91. doi:10.3109/14992020309074649.
4. Hawkins D. Effectiveness of Counselling-Based Adult Group Aural Rehabilitation Programs: A Systematic Review of Evidence. *J Am Acad Audiol* 2005;16:485-93. doi: http://dx.doi.org/10.3766/jaaa.16.7.8.
5. Hickson L, Worall L, Scarinci N. Measuring outcomes of a communication program for older people with hearing impairment using the International Outcome Inventory. *Int J Audiol* 2006;45:238-46. doi:10.1080/14992020500429625.
6. Chisolm T, Arnold M. Evidence about the effectiveness of aural rehabilitation programs for adults. In: Wong L, Hickson L, eds. Evidence-based practice in audiology: Evaluating interventions for children and adults with hearing impairment. San Diego, CA: Plural 2012:237-66.
7. Abrams H, Hnath-Chisolm T, McArdle R. A cost-utility of adult group audiologic rehabilitation: Are the benefits worth the cost? *J Rehabil Res Dev* 2002;39(5):549-58.
8. Kochkin S. Marke Trak VIII: 25-years in trends in the hearing health market. *Hearing review* 2009;16(11):12-31.
9. Grenness C, Hickson L, Laplante-Lévesque A, et al. Patient-centred care: A review for rehabilitative audiologists. *Int J Audiol* 2014;53(Suppl 1):P60-P67. doi:10.3109/14992027.2013.847286.

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10. McCormack A, Fortnum H. Why do people fitted with hearing aids do no wear them? *Int J Audiol* 2013;52:360-68. doi:10.3109/14992027.2013.769066.

11. Knudsen LV, Öber M, Nielsen C, et al. Factors Influencing Help Seeking, Hearing Aid Uptake, Hearing Aid Use and Satisfaction With Hearing Aids: A Review of the Litterature. *Trends in Amplification* 2010;14(3):127-54. doi: 10.1177/1084713810385712.

12. Laplante-Lévesque A, Hickson L, Worall L. Rehabilitation of older adults with hearing impairment: a critical review. *J Aging Health* 2010;22(2):143-53. doi:10.1177/0898264309352731.

13. Kramer SE, Allesie GHM, Dondorp AW, et al. A home education program for older adults with hearing impairment and their significant others: A randomized trial evaluating short- and long-term effects. *Int J Audiol* 2005;44:255-64. doi: 10.1080/14992020500060453.

14. Laplante-Lévesque A, Pichora-Fuller MK, Gagne JP. Providing an internet-based audiological counselling programme to new hearing aid users: a qualitative study. *Int J Audiol* 2006;45:697-706. doi:10.1080/14992020600944408.

15. Sweetow RW, Henderson SJ. Technologic advices in aural rehabilitation: applications and innovative methods of service delivery. *Trends in Amplification* 2007;11:101-11. doi: 10.1177/1084713807301321.

16. Thorén E, Svensson M, Törnqvist A, et al. Rehabilitative online education versus internet, discussion group for hearing aid users: a randomized controlled trial. *J Am Acad Audiol* 2011;22:274-85. doi: http://dx.doi.org/10.3766/jaaa.22.5.4.

17. Thorén ES, Öberg M, Wänström G, et al. A randomized controlled trial evaluating the effects of online rehabilitative intervention of adult hearing-aid users. *Int J Audiol* 2014;53:452-46. doi:10.3109/14992027.2014.892643.

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18. Molini-Avejonas DR, Rondon-Melo S, de la Higuera Amato CA, et al. A systematic review of the use of telehealth in speech, language and hearing sciences. *J Telemed Telecare* 2015;21:367-76. doi: 10.1177/1357633X15583215.

19. Barak A, Sadovsky Y. Internet use and personal empowerment of hearing-impaired adolescents. *Comput Human Behav* 2008;24:1802-15. doi:10.1016/j.chb.2008.02.007.

20. Henshaw H, Clark Daniel PA, Kang S, et al. Computer Skills and Internet Use in Adults Aged 50-74 Years: Influence of Hearing Difficulties. *J Med Internet Res* 2012;14(4):e113. doi:10.2196/jmir.2036.

21. Sundewall ET, Öberg M, Wänström E, et al. Internet Access and Use in Adults With Hearing Loss. *J Med Internet Res* 2013;15(5):e91. doi: 10.2196/jmir.2221.

22. Lundberg M, Andersson G, Lunner T. A randomized, controlled trial of the short-term effects of complementing an educational program for hearing aid users with telephone consultations. *J Am Acad Audiol* 2011;22(10):654-62. doi: 10.3766/jaaa.22.10.4.

23. Kaldo-Sandström V, Larsen HC, Andersson G. Internet-Based Cognitive-Behavioral Self-Help Treatment of Tinnitus: Clinical Effectiveness and Predictors of Outcome. *Am J Audiol* 2004;13:185-92. doi:10.1044/1059-0889(2004/023).

24. Hedman E, Ljótsson B, Rück C, et al. Effectiveness of Internet-based cognitive behaviour therapy for panic disorder in routine psychiatric care. *Acta Psychiatrica Scandinavica* 2013;128:457-67. doi: 10.1111/acps.12079.

25. Hopewell S, Clarke M, Moher D, et al. CONSORT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts: Explanation and Elaboration. *PLoS Med* 2008;5(1):e20. doi:10.1371/journal.pmed.0050020.

26. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *Int J of Surg* 2012;10(1):28-55. doi:10.1016/j.jclinepi.2010.03.004.

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27. Ventry IM, Weinstein BE. The Hearing Handicap Inventory for the Elderly: a new tool. *Ear Hear* 1982;3(3):128-34.

28. Demorest ME, Erdman SA. Development of the Communication profile for the hearing impaired. *J Speech Hear Disord* 1987;52(2):129-43. doi:10.1044/jshd.5202.129.

29. Zigmod AS, Snaith RP. The Hospital Anxiety Depression Scale. *Acta Psychiatr Scand* 1983;67:361-70. doi: 10.1111/j.1600-0447.1983.tb09716.

30. Cox R, Hyde M, Gatehouse S, et al. Optimal Outcome Measures, Research Priorities, and International Cooperation. *Ear Hear* 2000;21(4):106-15.

31. Öberg M, Lunner T, Andersson G. Psychometric evaluation of hearing specific self-report measures and their associations with psychosocial and demographic variables. *Audiol Med* 2007;5:188-99. doi:10.1080/16513860701560214.

32. Hallberg LRM, Eriksson-Mangold M, Carlsson SG. Psychometric evaluation of a Swedish version of the Communication Strategies Scale of the Communication Profile for the Hearing Impaired. *J Speech Hear Res* 1992;35:666-74. doi:10.1044/jshr.3503.666.

33. Sundewall ET, Andersson G, Lunner T. The use of research questionnaires with hearing impaired adults: online vs. paper-and pencil administration. *BMC Ear Nose Throat Disord* 2012;12:12. doi:10.1186/1472-6815-12-12.

34. Elberling C, Worsøe K. When the sounds are weaker - on hearing and hearing aids. Herlev: Bording A/S 2006.

35. Hickson L, Worrall L, Scarinci N. A randomized controlled trial evaluating the active communication education program for older people with hearing impairment. *Ear Hear* 2007;28:212-30. doi: 10.1097/AUD.0b013e31803126c8.

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36. Öberg M, Bohn T, Larsson U. Short- and Long-Term Effects of the Modified Swedish Version of the Active Communication Education (ACE) Program for Adults with Hearing Loss. *J Am Acad Audiol* 2014;25(9):848-58. doi: 10.3766/jaaa.25.9.7.

37. SPSS (data analysis software system) (2011) Statistical Package for the Social Sciences for Windows. Version 19.0. www.spss.com

38. Fergusson D, Aaron SD, Guyatt G, et al. Post-randomisation exclusions: the intention to treat principle and excluding patients from analysis. *BMJ* 2002;325:652-4. doi: http://dx.doi.org/10.1136/bmj.325.7365.652.

39. Gueorguieva R, Krystal JH. Move Over ANOVA. Progress in Analyzing Repeated-Measures Data and Its Reflection in Papers Published in the Archives of General Psychiatry. *Arch Gen Psychiatry* 2004;61:310-17. doi:10.1001/archpsyc.61.3.310.

40. Laplante-Lévesque A, Hickson L, Worall L. What makes adults with hearing impairment take up hearing aids or communication programs and achieve successful outcomes? *Ear Hear* 2011;32(5):1-15. doi: 10.1097/AUD.0b013e31822c26dc.

41. Linde L, Fässler M, Meissner K. Placebo interventions, placebo effects and clinical practice. *Phil Trans R Soc B* 2011;366:1905-12. doi: 10.1098/rstb.2010.0383.

42. Andersson G, Strömgren T, Ström L, et al. Randomized Controlled Trial of Internet-Based Cognitive Behavior Therapy for Distress Associated With Tinnitus. *Psychosom Med* 2002;64(5):810-16. doi: 10.1097/01.PSY.0000031577.42041.F8.

43. Preminger JE. Issues Associated With the Measurement of Psychosocial Benefits of Group Audiologic Rehabilitation Programs. *Trends in Amplification* 2007;11(2):113-23. doi: 10.1177/1084713807301084.

44. Swanepoel de W, Hall JW III. A systematic review of telehealth applications in audiology. *Telemedicine and e-health* 2010;16(2):181-200. doi:10.1089/tmj.2009.0111.

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Figure 1. Flowchart for the study procedure. Sets 1 + 2 of the recruitment process are presented in parentheses [n=set1+set2]. Set 1=20- to 59-year age group, set 2=60- to 80-year age group. *HHIE, Hearing Handicap Inventory for the Elderly; CSS, Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI); HADS, Hospital Anxiety and Depression Scale; IOI-HA, International Outcome Inventory for Hearing Aids.

Figure 2. The full internet-based program outlined for the intervention group and the element of the internet-based program outlined for the control group. The full internet-based program consisted of four elements: reading, home training, interaction with an audiologist, and interaction with peers in an internet-based discussion forum. Weeks 1-4 of the intervention concluded with a quiz. The small part of the internet-based program consisted of the reading element.

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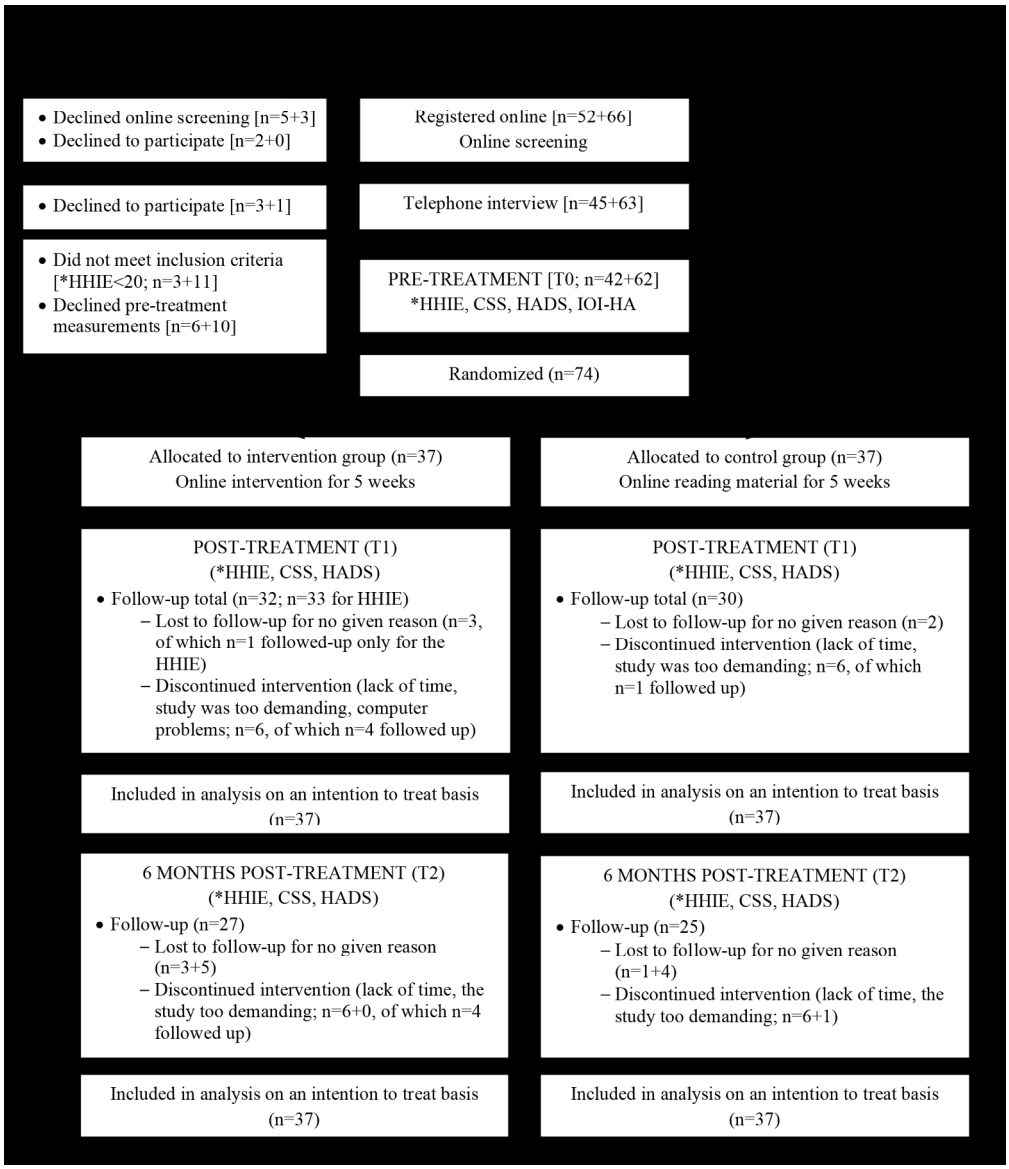

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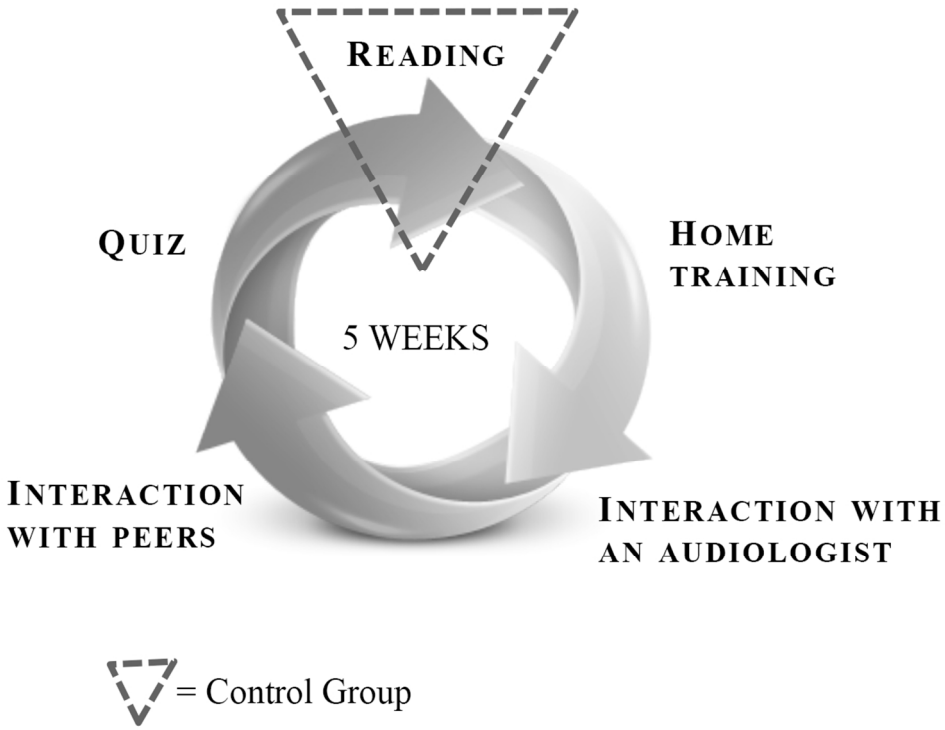

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Complementary Appendix I. (n=74) Estimated marginal means (EMM) and standard error (Std.Error) of the outcome measures HHIE, CSS and HADS for both groups at pre-treatment (T0), post-treatment (T1) and 6-months post-treatment (T2).

	EMM (Std. Error)					
	Intervention group			Control group		
Scale	T0	T1	T2	T0	T1	T2
HHIE-Total						
Total	42.0 (2.4)	35.1 (2.5)	37.8 (2.5)	36.1 (2.4)	31.7 (2.5)	35.7 (2.6)
20-59 years	44.7 (3.3)	39.3 (3.4)	42.2 (3.7)	38.0 (3.4)	33.9 (3.5)	36.5 (3.7)
60-80 years	39.7 (3.4)	31.7 (3.4)	34.5 (3.5)	34.7 (3.3)	29.9 (3.5)	35.0 (3.5)
HHIE-*Social*						
Total	20.2 (1.2)	18.0 (1.3)	18.9 (1.3)	18.5 (1.2)	15.7 (1.3)	19.1 (1.3)
20-59 years	21.2 (1.8)	19.0 (1.9)	20.2 (2.1)	19.8 (1.9)	16.5 (1.9)	20.1 (2.1)
60-80 years	19.3 (1.7)	17.1 (1.7)	17.9 (1.7)	17.5 (1.7)	15.2 (1.7)	18.3 (1.8)
HHIE-*Emotional*						
Total	21.8 (1.4)	17.2 (1.5)	18.9 (1.5)	17.6 (1.4)	15.9 (1.5)	16.6 (1.5)
20-59 years	23.5 (2.0)	20.3 (2.0)	22.0 (2.2)	18.3 (2.1)	17.4 (2.1)	16.3 (2.2)
60-80 years	20.4 (2.0)	14.6 (2.0)	16.5 (2.0)	17.1 (1.9)	14.7 (2.1)	16.8 (2.1)
CSS-Total						
Total	68.1 (2.0)	74.4 (2.0)	71.9 (2.1)	67.2 (2.0)	68.1 (2.1)	67.6 (2.2)
20-59 years	68.8 (2.6)	75.9 (2.8)	73.4 (3.1)	67.7 (2.6)	72.2 (2.8)	70.7 (3.1)
60-80 years	67.4 (2.9)	73.4 (2.9)	71.1 (3.0)	66.8 (2.8)	64.6 (3.0)	65.0 (3.0)
CSS-*Maladaptive*						
Total	17.9 (0.7)	17.7 (0.8)	18.1 (0.8)	17.2 (0.7)	16.5 (0.8)	17.2 (0.8)
20-59 years	18.1 (1.0)	17.1 (1.0)	17.7 (1.1)	16.7 (1.0)	16.7 (1.1)	16.3 (1.1)
60-80 years	17.8 (1.1)	18.0 (1.1)	18.4 (1.1)	17.7 (1.1)	16.3 (1.2)	17.9 (1.2)
CSS-*Verbal*						
Total	22.6 (1.0)	25.8 (1.0)	24.1 (1.1)	21.8 (1.0)	23.7 (1.1)	22.0 (1.1)
20-59 years	23.0 (1.6)	26.5 (1.6)	24.6 (1.8)	22.4 (1.6)	25.4 (1.7)	24.6 (1.8)
60-80 years	22.2 (1.3)	25.2 (1.3)	23.7 (1.3)	21.4 (1.2)	22.4 (1.3)	20.1 (1.4)
CSS-*Nonverbal*						
Total	27.6 (1.0)	31.0 (1.0)	29.7 (1.1)	28.1 (1.0)	27.8 (1.0)	28.3 (1.1)
20-59 years	27.7 (1.3)	32.1 (1.4)	30.9 (1.5)	28.6 (1.3)	30.1 (1.4)	29.9 (1.5)
60-80 years	27.5 (1.5)	30.3 (1.5)	28.8 (1.5)	27.8 (1.4)	25.9 (1.5)	27.0 (1.5)
HADS-Total						
Total	8.5 (1.0)	7.6 (1.0)	6.3 (1.0)	7.4 (1.0)	7.0 (1.0)	7.6 (1.0)
20-59 years	9.5 (1.2)	9.6 (1.3)	6.9 (1.4)	8.3 (1.3)	8.0 (1.3)	7.7 (1.4)
60-80 years	7.7 (1.4)	5.9 (1.4)	5.6 (1.4)	6.8 (1.4)	6.3 (1.4)	7.3 (1.4)
HADS-*Anxiety*						
Total	4.6 (0.6)	3.9 (0.6)	3.1 (0.6)	4.3 (0.6)	4.1 (0.6)	4.2 (0.6)
20-59 years	5.2 (0.8)	5.0 (0.8)	3.5 (0.8)	5.1 (0.8)	5.0 (0.8)	4.8 (0.9)
60-80 years	4.1 (0.8)	3.0 (0.8)	2.8 (0.8)	3.7 (0.8)	3.5 (0.8)	3.7 (0.8)
HADS-*Depression*						
Total	4.0 (0.5)	3.7 (0.5)	3.1 (0.5)	3.1 (0.5)	2.9 (0.5)	3.4 (0.5)
20-59 years	4.3 (0.7)	4.6 (0.7)	3.4 (0.8)	3.2 (0.7)	3.0 (0.7)	3.0 (0.8)
60-80 years	3.6 (0.7)	2.9 (0.7)	2.8 (0.7)	3.0 (0.7)	2.8 (0.7)	3.6 (0.8)

HHIE: Hearing Handicap Inventory for the Elderly, *Social* and *Emotional* subscales. CSS: Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI), *Maladaptive*, *Verbal* and *Nonverbal* subscales. HADS: Hospital Anxiety and Depression Scale, *Anxiety* and *Depression* subscales.

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Complementary Appendix II. Sensitivity analysis (n=50). Observed means (OM) and standard deviations (SD) of the outcome measures HHIE, CSS and HADS for both groups at pre-treatment (T0), post-treatment (T1) and 6-months post-treatment (T2). *P-values* illustrate the significance of the difference in estimated marginal means between the intervention and control group. F-values illustrate the interaction effect for time^{x}group (t^{x}gr).

	OM (SD)			T0-T1	T0-T2	T0-T1, (t^{x}gr)	T0-T2, (t^{x}gr)
Scale	T0	T1	T2	(*p-value*)	(*p-value*)	F-value	F-value
HHIE-Total							
I-group	40.2 (17.2)	33.5 (15.6)	36.0 (16.1)	3.3 (*0.252*)	4.5 (*0.238*)	1.3	1.5
C-group	33.8 (10.1)	30.4 (11.9)	34.2 (13.4)				
HHIE-*Social*							
I-group	19.4 (9.0)	17.6 (7.2)	18.3 (8.0)	0.4 (*0.788*)	2.2 (*0.171*)	0.1	1.8
C-group	17.3 (5.6)	15.2 (6.5)	18.5 (7.2)				
HHIE-*Emotional*							
I-group	20.8 (9.8)	15.9 (9.4)	17.7 (9.7)	3.7 (*0.043*)	2.2 (*0.099*)	4.3*	2.4
C-group	16.5 (7.0)	15.3 (7.2)	15.7 (8.5)				
CSS-Total							
I-group	67.2 (14.6)	72.5 (10.5)	70.5 (10.4)	3.9 (*0.141*)	2.3 (*0.364*)	2.2	1.0
C-group	66.8 (10.0)	68.2 (11.0)	67.8 (10.6)				
CSS-*Maladaptive*							
I-group	17.1 (3.6)	16.4 (3.5)	17.0 (3.6)	0.6 (*0.523*)	0.4 (*0.818*)	0.4	0.2
C-group	17.1 (3.6)	17.0 (3.4)	17.4 (4.4)				
CSS-*Verbal*							
I-group	23.0 (6.8)	25.6 (6.2)	24.2 (4.9)	0.7 (*0.591*)	0.9 (*0.803*)	0.3	0.2
C-group	22.0(4.9)	23.8 (5.9)	22.3 (5.3)				
CSS-*Nonverbal*							
I-group	27.1 (7.9)	30.6 (4.9)	29.4 (4.9)	3.8 (*0.012*)	1.8 (*0.036*)	6.8*	3.5*
C-group	27.6 (5.3)	27.3 (6.0)	28.1 (5.7)				
HADS-Total							
I-group	7.4 (5.8)	6.2 (5.4)	5.2 (4.5)	1.3 (*0.166*)	2.8 (*0.048*)	2.0	3.1*
C-group	6.2 (4.5)	6.3 (5.2)	6.8 (6.0)				
HADS-*Anxiety*							
I-group	3.9 (3.4)	3.2 (3.1)	2.5 (2.0)	0.6 (*0.298*)	1.5 (*0.078*)	1.1	2.6
C-group	3.7 (2.7)	3.5 (3.1)	3.8 (3.3)				
HADS-*Depression*							
I-group	3.4 (2.8)	3.0 (2.7)	2.7 (2.9)	0.7 (*0.185*)	1.4 (*0.089*)	1.8	2.5
C-group	2.5 (2.1)	2.8 (2.5)	3.0 (3.0)				

**p<0.05*; HHIE: Hearing Handicap Inventory for the Elderly, *Social* and *Emotional* subscales. CSS: Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI), *Maladaptive*, *Verbal* and *Nonverbal* subscales. HADS: Hospital Anxiety and Depression Scale, *Anxiety* and *Depression* subscales. I-group: intervention group; C-group: control group.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-5
	2b	Specific objectives or hypotheses	4-5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	na
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8,9,11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	na
Sample size	7a	How sample size was determined	12
	7b	When applicable, explanation of any interim analyses and stopping guidelines	na
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

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		assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	9-11
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11-13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11-13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Fig 1, table 1&2
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1, page13
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6,7,11
	14b	Why the trial ended or was stopped	na
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	8
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	11-13
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	14-19
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	na
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	na
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	na
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	22-23
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	23-24
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	23-24
Other information			
Registration	23	Registration number and name of trial registry	3,6
Protocol	24	Where the full trial protocol can be accessed, if available	7
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	25

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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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

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Primary Subject Heading:	Ear, nose and throat/otolaryngology
Secondary Subject Heading:	Medical education and training
Keywords:	Audiology < OTOLARYNGOLOGY, Aural Rehabilitation, Internet, Clinical practice, Hearing loss

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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

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Key words: Audiology, Aural rehabilitation, Internet, Clinical practice, Hearing loss

Abbreviations: AR=aural rehabilitation; CSS=Communication Strategy Scale; CPHI=Communication Profile for the Hearing Impaired; HA=hearing aid; HADS=Hospital Anxiety and Depression Scale; HHIE=Hearing Handicap Inventory for the Elderly; IOI-HA=International Outcome Inventory for Hearing Aids; ITT=intention to treat; PTA=pure-tone average; RCT=randomized controlled trial; SD=standard deviation.

Word Count: 5080

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ABSTRACT

Objective: Guided internet-based intervention beyond hearing aid (HA) fitting has been shown to be efficacious in randomized controlled trials (RCT). However, internet interventions have rarely been applied clinically as a part of regular aural rehabilitation (AR). Our aim was to evaluate the effectiveness of internet-based AR for HA users from a clinical population.

Outcome measures: The Hearing Handicap Inventory for the Elderly (HHIE) was used as the primary outcome measure, and the Communication Strategies Scale (CSS) and the Hospital Anxiety and Depression Scale (HADS) were used as secondary outcome measures. All questionnaires were administered before and directly after the intervention and at 6 months post-intervention.

Methods: We used a parallel group design (RCT). The data were collected in 2013-2014 at three different clinics. Seventy-four HA users were randomly assigned to receive either full internet-based AR (intervention group, n=37) or one element of the internet-based AR (control group, n=37).

Results: Data were analyzed following the intention-to-treat principle. Each group showed improved HHIE scores over time and did not differ significantly from each other. The intervention group showed significantly greater improvement compared with the control group for the CSS total and the *Nonverbal* subscale scores.

The intervention group and control group were also subdivided into two age groups: 20-59 years and 60-80 years. Significantly better improvement on the CSS total and *Nonverbal* subscale scores was found in the older group compared with the younger participants.

Conclusions: This study indicates that participants in an internet-based intervention applied in general clinical practice showed improved self-reported communication skills compared

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with a control group. Receiving a full intervention was not more effective in improving self-reported hearing problems than receiving just one element of the internet-based intervention.

Trial registration: This trial is registered at ClinicalTrals.gov, number NCT01837550.

Strengths and limitations of this study:

- This is one of the first randomized controlled trials in Sweden to implement internet-based rehabilitation beyond conventional hearing aid fitting in a general clinical practice.
- The recruitment process used in the clinical trial will provide indications of the types of hearing aid users who are interested in this type of intervention.
- One limitation of this study is that the control group received an active intervention.
- Another limitation of this study is that the control group received only one of the 4 elements of the program, overlooking the relative benefit of any other element alone/combination of elements might have as compared to the full intervention.

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INTRODUCTION

Hearing impairment influences communication in people's daily life. In agreement with the International Classification of Functioning, Disability, and Health[1], the objective of aural rehabilitation (AR) is to promote social participation for people with hearing impairment. Addressing this objective includes fitting the client with hearing aids (HA), educating him or her about the condition, and providing perceptual training and counseling[2]. To improve communication for people with hearing impairment, researchers recommend combining group AR with HA use[3-6]. This combination has shown to be more cost-effective than HA use alone[7]. However, despite the recommendations, the most common approach is the use of HAs alone[8]. This discrepancy could be explained by clinicians' lack of time and the difficulties of scheduling comprehensive AR in addition to HA fitting[9]. Moreover, HA users with stressful life situations may have very limited time to spend on traveling to participate in rehabilitation courses offered by the clinic. Also, many HA users experience communication difficulties despite today's HA technology. This could cause patients to stop using their HAs[10], which can lead to withdrawal from and/or avoidance of interpersonal interactions or involvement in community life. A review of the literature showed that, HA users' self-perceived hearing difficulties can affect help seeking, HA uptake, HA use, and satisfaction[11]. Although combining group AR with HA use can be beneficial, the overall availability of and adherence to communication programs are still low[12].

Several studies have suggested that AR could be provided without in-person meetings[13-20]; for example by providing educational programs using telephone/internet-based AR. A recent systematic review indicated that such resources show benefits such as increased access to care, cost-effectiveness and improved quality of care in terms of user satisfaction[20]. Further on, Internet use is increasing among people with hearing impairment, which encourages

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including the Internet for AR in future research[21-23]. There is evidence to suggest that learning and educational support delivered via the Internet could support firs time HA users in clinical practice[19]. However, the effectiveness of clinical use of the Internet for AR is sparsely examined.

Our research group designed a randomized controlled trial (RCT) of internet-based AR[18]. The results showed significantly increased activity and participation in the intervention group by using the Internet to provide AR in addition to HA fitting, while the control group did not improve. The study provided proof of concept that AR beyond HA fitting could be performed over the Internet[16,18]. However, participants were recruited through advertisements and articles in Swedish national daily newspapers and on the Internet, and the study did not indicate whether internet-based interventions could be feasible if strictly administered in a clinical setting. Nonetheless, we chose to use this same RCT design[18] as described above and supplement the trial with telephone support, and then implement the trial in a clinical setting at a later time. Our earlier research showed promising results for telephone-supported AR beyond HA fitting in general clinical practice (GCP)[17]. A study of self-help treatment for tinnitus in a clinical setting showed significant improvements pre- to post-treatment and at follow-up when internet-based treatments were used, indicating that self-help treatment can be transferred to the clinic[24]. Studies in other research fields, such as panic disorders, have shown that guided internet-based therapy is efficacious and effective when delivered as part of routine psychiatric care[25].

The first aim of this study was to evaluate whether internet-based AR for HA users will be effective in GCP. Our assumption was that the internet-based AR program would reduce residual hearing problems among HA users and improve the participants' communication strategies and psychosocial well-being, while participating in the control group would not.

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The intervention groups improvements post treatment is expected to be maintained when assessed 6-months post treatment. The second aim of the study was to analyze the effect of internet-based AR in GCP among two age-groups: 20-59 years and 60-80 years. Our hypothesis was that the 20-59-year age group may be more receptive to internet-based AR because of their presumably greater digital literacy skills[26], compared to those who are in the 60-80-year age group.

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METHODS

The Consolidated Standards of Reporting Trials (CONSORT) checklist was followed when reporting the abstract, designing the study, and analyzing and interpreting the results[27-28]. A flowchart of the study procedure is presented in figure 1. The trial is registered at ClinicalTrals.gov, number NCT01837550.

– Figure 1 –

Recruitment and selection

The eligibility criteria targeted the most common patient category at three clinics within the Hearing Organization, Södra Älvsborg, Sweden: patients who were 20-80 years old and who had conductive or sensorineural binaural hearing loss of 20-60 dB HL pure-tone average (500, 1000, and 2000 Hz). Additional eligibility criteria included patients who had completed a HA fitting 3 months before the study began (regardless of HA manufacturer or model), who had a HHIE score ≥20 points (HHIE: Hearing Handicap Inventory for the Elderly[29]; indicative of some residual hearing problems), and gave their informed consent to participate. The study was conducted in 2013-2014. There was no difference in the three clinics in terms of patients and general procedures. The recruitment process was conducted in two sets, one for participants aged 20-59 years and one for those aged 60-80 years. All potential participants who fulfilled the criteria for age, hearing loss, and HA fitting received a recruitment letter that contained information about the study's purpose and structure and stressed that the participants' privacy would be protected and that participation was voluntary. The participants were prepared to allocate 1.5-2.0 hours each week to participate in the study and were informed that they would be placed into one of two groups. The participants were asked to

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visit the website www.iterapi.se/sites/hornet to read more about the study and to initiate participation.

The first step of the participation required registering at the website and completing a screening form. Participants who completed this first step (n=108) were called by the project leader for a telephone interview to assess their eligibility; of these, 104 agreed to participate in the study. The next step was for the participants to return a signed consent form to the project leader and to complete four standardized questionnaires (see 'Outcome Measures', below). Consequently, 74 participants were included in the study as seen in Figure 1.

The study was a randomized controlled trial with a parallel group design and a simple randomization procedure through the recruitment process that was conducted in two sets. The 74 participants were randomly assigned to either an intervention group (group 1) or a control group (group 2) according to a computer-generated list of random numbers. An independent audiologist at the clinic (not involved in the recruitment) generated the random allocation sequence using a computer software program and assigned the participants to different groups. The independent audiologist reported the allocation schedule to the project leader, who then enrolled the participants. The assigned participants were told which group they were allocated to (1 or 2) but were not informed whether the group was the intervention group or the control group. Thirty-seven participants were included in the intervention group, and 37 participants were included in the control group, as shown in table 1. No significant differences were found between the groups regarding the background variables age, age group, gender and hearing loss.

The study was reviewed and approved by the regional ethical review board in Gothenburg, Sweden. The study website was programmed using Java Script, and information was available in hypertext markup language (HTML) format.

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Table 1. Demographic and clinical characteristics of the participants. The data are reported as means (standard deviations, SD) unless stated otherwise.

	Intervention group (n=37)	Control group (n=37)
20-59-year age-group, n (%)	17 (46)	16 (43)
60-80-year age-group, n (%)	20 (54)	21 (57)
Age, years (range 31-80 years)	61.8 (11.9)	62.1 (11.4)
20-59-year age-group	50.9 (7.2)	52.3 (9.1)
60-80-year age-group	71.1 (5.4)	69.6 (5.9)
Gender, n (%)		
Men	24 (64.9)	20 (54.1)
Woman	13 (35.1)	17 (45.9)
Pure-tone average (dB HL)		
Right ear	37.5 (11.3)	38.0 (8.6)
Left ear	37.8 (10.5)	36.5 (8.5)
HA, n (%)		
Binaural	28 (75.7)	31 (83.8)
Monaural	9 (24.3)	6 (16.2)
Duration of HA use		
Years (range 0.5-55 years)	7.5 (9.6)	7.4 (6.3)
Median (Q1/Q3)*	5.0 (1.5/10.5)	6.0 (2.3/11.3)
Computer experience**, n (%)	37 (100)	37 (100)
Computer access, n (%)	37 (100)	37 (100)
Able to have a telephone conversation without HA/s?, n (%)	32 (86.5)	35 (94.6)
IOI-HA 1. Daily use	4.1 (1.1)	4.4 (1.0)
2. Benefit	3.8 (0.9)	4.1 (0.9)
3. Remaining activity limitation	3.1 (0.8)	3.1 (0.8)
4. Satisfaction	4.1 (1.1)	4.4 (0.8)
5. Remaining participation restriction	3.8 (1.1)	4.1 (0.8)
6. Impact on environment	3.6 (0.9)	3.9 (0.9)
7. Quality of life	3.6 (0.8)	3.6 (1.0)

(*Q1=the first quartile, Q3=the third quartile; **familiar with: able to log in, print information, complete a questionnaire on a website and read and send email); HA: hearing aid; IOI-HA: International Outcome Inventory for Hearing Aids.

Outcome Measures

The HHIE[29] was the primary outcome measure. The HHIE includes two subscales; the *Social* subscale comprises 12 questions addressing the social effects of hearing loss, and the *Emotional* subscale comprises 13 questions addressing the emotional effects of hearing loss. Higher scores reflect a higher self-reported hearing problem.

The Communication Strategies Scale; the CSS (from the Communication Profile for the Hearing Impaired (CPHI)[30] and the Hospital Anxiety and Depression Scale (HADS)[31] were used as secondary outcome measures. The CSS includes three subscales (*Maladaptive*

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Behaviors, Verbal Strategies and Nonverbal Strategies) and is designed to analyze participants' behavior in various communication situations. The *Maladaptive Behaviors* subscale includes 9 questions that analyze strategies that hinder communication. *Verbal Strategies* and *Nonverbal Strategies* address 16 items related to strategies that can enhance communication. Scoring for the CSS reflects how frequently a specific situation or behavior occurs. The HADS comprises 14 items separated into two subscales: *Anxiety* and *Depression*. Higher scores reflect more symptoms of anxiety and depression.

The International Outcome Inventory for Hearing Aids (IOI-HA)[32] includes seven questions measuring specific dimensions of HA outcomes: daily use, benefits, remaining activity limitations, satisfaction, remaining participation restrictions, impact on the environment, and quality of life; with higher scores indicating better outcomes. The IOI-HA was not used as an outcome measure in this study; rather, it was used to describe the demographic and clinical characteristics of the participants, as shown in table 1.

The HHIE, CSS and HADS were administered according to the methods described[29-31] and were available on the study website, in Swedish. The questionnaires were administered online before and directly after the study participation and 6 months after participation to evaluate self-reported hearing problems, communication strategies, and anxiety and depression. All of the questionnaires have a good internal consistency[33-34] and have been shown to be as reliable as the original versions when used with a Swedish population of young adults and elderly[33]. Sundewall et al[35] stressed the importance of keeping the internet-based administration format of the HHIE and HADS stable across time points.

Intervention Group

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The internet-based intervention program is based on four elements: reading, home training, interaction with an audiologist, and interaction with peers in an internet-based discussion forum. The participants received information about the intervention program and access to the reading material on the study website; they also received a book about hearing and HAs[36] and the Swedish version of Active Communication Education, a compendium of communication strategies[5, 37-38]. The website information about the intervention program, along with the book and the compendium, were also mailed to all of the participants in the intervention group.

– Figure 2 –

The reading element is divided in to five modules, one module for each of the five weeks. The participants were instructed to read specific content each week based on the various chapters of the book and information from the compendium[18]. The weekly home assignments (week 1-5) were accessible to facilitate an understanding of the contents of the book and the compendium. For example, the weekly assignments could be to observe the benefits of using HAs. The weekly home assignments were handed in on the Internet by the participants (week 1-5), and direct responses were provided online by an audiologist. The weekly home assignments were also discussed with the audiologist over the phone at the end of each treatment week. The telephone consultations lasted approximately 10-15 minutes per participant and provided the participants with an opportunity to reflect on the assignment and discuss any concerns they might have. Weeks 1-4 ended with quiz questions on the content of the past weeks' readings. The participants in the intervention group were invited to attend a discussion forum on the study website. Weekly topics were presented for the participants[18] to discuss with one other, without any interaction with the audiologist. The participants were free to use the discussion forum with no restrictions from the audiologist. However, all

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activities where strictly observed, and if needed, inappropriate postings could be deleted. No inappropriate postings occurred.

Control Group

The control group received one reading element; i.e. the first four chapters of the book[36]; and the information about participation provided on the study website. The website information and book chapters were also mailed to the participants. The control group was asked to read the four chapters over a five-week period; no assignments were given in association with their participation. To minimize the impact of professional interaction, no monitoring was provided during the program to ensure that the participants actually read the chapters.

Follow-up

At the end of the treatment period, the HHIE, CSS and HADS were made available to all participants on the study website, and the participants were asked to complete them. Both groups' participation was evaluated using a post-study telephone interview. The post-study interviews for the intervention group were conducted by five different clinical audiologists than the one who conducted the pre-study interviews and the telephone consultations during the study to minimize the influence of special attention on the participants' responses to the questionnaires. The five audiologists were trained for consistency by the project leader. The post-study interviews for the control group were conducted by the same audiologist who conducted the pre-study interviews. For the telephone interview, the audiologists used a self-designed form that contained questions about the study process, including opportunities for the participants to provide their own comments. Different forms were designed for the intervention group and the control group. All of the participants were invited to keep their copy of the reading material.

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Six months after the study participation, the participants in both groups were contacted via e-mail and asked to complete the HHIE, CSS and HADS online again.

Statistical Analyses

Statistical Package for the Social Sciences[39] software for Windows (SPSS, version 19.0) was used for the analysis of all data. Three measurement time points were examined: pre-treatment (T0), post-treatment (T1) and 6 months post-treatment (T2). To ensure a between-group effect of 80% at the 5% significance level, it was estimated that 60 participants needed to be included in the study. An effect size of Cohen's d=0.80 was expected. The expected standardized mean difference on the HHIE-total scale formed the basis of the obtained power. The within-group and between-group effect sizes of Cohen's d were calculated from T0-T1 and from T0-T2 and were categorized as small ($0.2 \leq d < 0.5$), moderate ($0.5 \leq d < 0.8$) and large ($0.8 \leq d$).

No significant differences were found between the groups at T0 for all the outcome measures. All data from the participants who did not complete T1 and/or T2 measurements were treated on an *intention to treat* (ITT) basis[40], meaning that the participants were included in the analysis (as missing data) regardless of their compliance or withdrawal from the study; see figure 1.

Given the ability to handle missing data[41], mixed effects models with compound symmetry as the covariance structure were used to analyze the HHIE, CSS and HADS. Differences between the intervention group and the control group were examined by modeling the interaction effects of group and time. A subgroup analysis was performed including two groups categorized as age-group: 20-59 years and age-group: 60-80 years.

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A sensitivity analysis was performed using mixed effects models for the HHIE, CSS and HADS, this time excluding subjects who did not complete all measurement time points (T1 and/or T2). Sensitivity analysis was performed to increase the understanding of the relationships between internet-based AR and the outcome measures, HHIE, CSS, and HADS.

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RESULTS

Attrition and adherence

Eight participants in the intervention group and five in the control group completed the study program but did not provide all T1 and/or T2 measurements, without giving a specific reason. Six participants in the intervention group and seven in the control group withdrew from participation in the study, as shown in figure 1. Five of those who withdrew from the study provided T1 measurements; four provided T2 measurements. One participant who was lost to follow-up at T1 provided T2 measurements. Consequently, 12 participants (16%) did not provide T1 measurements (of which n=1 followed up only with the HHIE), and 22 participants did not provide T2 measurements (30%). No significant differences were found when comparing the baseline values between those who discontinued the study program from T0-T1 and those who did not. Those who discontinued from T0-T2 had lower scores on baseline values for HHIE-total ($t(72)=-2.31$, $p=0.024$) and the *Emotional* subscale ($t(72)=-2.05$, $p=0.044$), and lower points on HADS-total ($t(72)=-2.73$, $p=0.008$) and the *Anxiety* ($t(72)=-2.03$, $p=0.046$) and *Depression* ($t(72)=-2.38$, $p=0.020$) subscales compared with those who continued with the study.

13% of the participants in the intervention group who completed the study program answered less than three (of four) of the weekly quizzes; and 26% provided less than four (of five) online weekly responses to the audiologist. However, all of these were active participants in conversations during the weekly telephone follow-up, and some stated a wish for the discussion forum to be more active because they considered that part of the intervention very interesting. On average, the participants posted 0.4 contributions to the discussion forum.

Primary outcome measure

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Both groups showed decreased HHIE-total scores T0-T1 (p<0.000) and T0-T2 (p<0.000). The interaction effect for HHIE-total T0-T1/T0-T2 was not significant. The results are presented in table 2, and the estimated marginal means (EMM) and standard errors of the outcome measures HHIE, CSS and HADS for both groups are presented as supplementary material in Complementary Appendix I. Both groups showed decreased scores for both of the HHIE subscales from T0-T1 (p<0.001) and T0-T2 (p<0.001). The interaction effect was not significant for T0-T1 for the *Social* subscale or for T0-T2 for the *Social* and *Emotional* subscale. A borderline significant interaction effect emerged for the *Emotional* subscale T0-T1 ($F_{(1,64.3)}$=3.8, p=0.054). Small to large between-group effect sizes were found for the HHIE, as shown in table 2.

Table 2. (n=74) Observed means (OM) and standard deviations (SD) of the outcome measures HHIE, CSS and HADS for both groups at pre-treatment (T0), post-treatment (T1) and 6-months post-treatment (T2). Cohen's pooled within-group and between-group small/moderate/large effect sizes (ES) and 95% confidence intervals (CI) for the intervention (I-group) and control group (C-group) are presented. *P-values* illustrate the significance of the difference in estimated marginal means between the intervention and control group. F-values illustrate the interaction effect for time x group (t x gr).

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			OM (SD)			ES (95% CI) Within-group		ES (95% CI) Between-group		Interaction effect (*p-value*) (F-value)	
			T0	T1	T2	T0-T1	T0-T2	T0-T1	T0-T2	T0-T1	T0-T2
HHIE											
Total		I-group	42.0 (16.9)	35.8 (15.2)	36.0 (15.8)	S (-0.08 to 0.84)	S (-0.10 to 0.82)	S (-0.16 to 0.76)		2.5 (*0.297*)	3.8 (*0.306*)
		C-group	36.1 (11.8)	31.3 (14.3)	34.0 (13.2)	S (-0.10 to 0.82)					
Social		I-group	20.2 (8.8)	18.3 (7.1)	18.2 (7.8)	S (-0.22 to 0.69)	S (-0.22 to 0.69)	S (-0.08 to 0.84)		0.4 (*0.732*)	1.8 (*0.224*)
		C-group	18.5 (6.6)	15.5 (7.3)	18.2 (7.1)	S (-0.03 to 0.89)					
Emotional		I-group	21.8 (9.5)	17.5 (9.4)	17.8 (9.5)	M (-0.01 to 0.91)	S (-0.04 to 0.88)		S (-0.22 o 0.69)	3.0 (*0.054*) (txgr=3.8)	1.9 (*0.132*)
		C-group	17.6 (7.3)	15.8 (8.2)	15.7 (8.3)	S (-0.23 to 0.69)	S (-0.22 to 0.70)				
CSS											
Total		I-group	68.1 (13.6)	74.7 (11.1)	70.9 (10.5)	M (-0.99 to -0.06)	S (-0.69 to 0.23)	M (0.06 to 0.98)	S (-0.08 to 0.84)	5.2 (*0.021*) (txgr=5.6)*	3.5 (*0.064*) (txgr=2.8)
		C-group	67.2 (11.3)	68.5 (12.4)	66.7 (11.6)						
Maladaptive		I-group	17.9 (4.5)	17.8 (5.7)	17.4 (4.3)			S (-0.23 to 0.69)		0.3 (*0.739*)	0.2 (*0.893*)
		C-group	17.2 (3.5)	16.7 (3.5)	17.3 (4.4)						
Verbal		I-group	22.6 (6.7)	25.8 (6.1)	24.1 (4.8)	M (-0.96 to -0.03)	S (-0.71 to 0.20)	S (-0.14 to 0.78)	S (-0.04 to 0.88)	1.2 (*0.299*)	1.4 (*0.455*)
		C-group	21.8 (5.6)	23.8 (6.4)	21.9 (5.5)	S (-0.79 to 0.13)					
Nonverbal		I-group	27.6 (6.9)	31.2 (4.8)	29.3 (4.8)	M (-1.07 to -0.13)	S (-0.74 to 0.17)	M (0.09 to 1.02)	S (-0.14 to 0.78)	3.7 (*0.004*) (txgr=9.2)**	1.9 (*0.011*) (txgr=4.7)*
		C-group	28.1 (6.2)	28.0 (6.5)	27.5 (6.2)						
HADS											
Total		I-group	8.5 (6.6)	7.5 (6.3)	4.8 (4.5)		M (0.18 to 1.12)		S (-0.84 to 0.08)	0.7 (*0.463*)	2.4 (*0.070*)
		C-group	7.4 (4.8)	6.5 (5.2)	6.8 (5.9)						
Anxiety		I-group	4.6 (3.8)	3.8 (3.4)	2.4 (2.0)	S (-0.24 to 0.68)	M (0.25 to 1.19)		M (-0.94 to -0.02)	0.6 (*0.198*)	1.4 (*0.071*)
		C-group	4.3 (3.2)	3.7 (3.1)	3.7 (3.2)						
Depression		I-group	3.9 (3.3)	3.7 (3.5)	2.6 (2.8)		S (-0.04 to 0.88)	S (-0.16 to 0.75)		0.0 (*0.984*)	1.1 (*0.171*)
		C-group	3.1 (2.5)	2.8 (2.4)	3.1 (2.9)						
HHIE Age groups											
Total	I-group	20-59 years	44.7 (13.6)	40.8 (13.3)	43.4 (14.6)	S (-0.17 to 0.74)		M (0.01 to 0.93)	L (0.39 to 1.35)	1.3 *(0.681)*	1.0 *(0.919)*
	C-group	20-59 years	38.0 (12.7)	34.0 (15.3)	31.6 (13.5)	S (-0.18 to 0.74)	M (0.02 to 0.95)				
	I-group	60-80 years	39.7 (19.3)	31.7 (15.8)	31.6 (15.2)	M (-0.01 to 0.91)	M (0.00 to 0.92)		S (-0.73 to 0.19)	3.5 *(0.344)*	5.5 *(0.282)*
	C-group	60-80 years	34.7 (11.1)	29.0 (13.3)	35.5 (13.3)	M (0.00 to 0.92)					
Social	I-group	20-59 years	21.2 (7.9)	19.6 (6.6)	21.0 (7,6)	S (-0.24 to 0.68)		S (-0.03 to 0.89)	S (-0.08 to 0.86)	1.1 *(0.570)*	1.3 *(0.604)*
	C-group	20-59 years	19.8 (7.0)	16.4 (8.0)	17.8 (8.9)	M (-0.01 to 0.91)	S (-0.21 to 0.71)				
	I-group	60-80 years	19.3 (9.6)	17.2 (7.4)	16.6 (7.7)	S (-0.21 to 0.70)	S (-0.15 to 0.77)	S (-0.12 to 0.79)	S (-0.73 to 0.19)	0.1 *(0.954)*	2.1 *(0.381)*
	C-group	60-80 years	17.5 (6.2)	14.8 (6.8)	18.5 (6.0)	S (-0.04 to 0.87)					
Emotional	I-group	20-59 years	23.5 (7.8)	21.2 (8.2)	22.4 (10.0)	S (-0.02 to 0.74)		S (-0.04 to 0.88)	L (0.48 to 1.44)	2.4 *(0.190)*	0.4 *(0.340)*
	C-group	20-59 years	18.3 (7.6)	17.6 (8.7)	13.8 (7.5)		M (0.12 to 1.06)				
	I-group	60-80 years	20.4 (10.7)	14.4 (9.3)	15.1 (8.3)	M (0.13 to 1.06)	M (0.08 to 1.01)		S (-0.66 to 0.25)	3.4*(0.158)*	3.5 *(0.212)*
	C-group	60-80 years	17.1 (7.3)	14.3 (7.7)	16.9 (8.9)	S (-0.09 to 0.83)					
CSS Age groups											
Total	I-group	20-59 years	68.8 (12.0)	76.4 (8.3)	73.5 (8.6)	M (-1.20 to -0.26)	M (-0.91 to 0.02)	S (-0.08 to 0.84)	M (0.06 to 0.99)	2.5 *(0.504)*	1.5 *(0.806)*
	C-group	20-59 years	67.7 (11.3)	72.3 (12.4)	69.2 (7.5)	S (-0.84 to 0.08)					

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	I-group	60-80 years	67.4 (15.1)	73.4 (10.6)	69.4 (11.4)	M (-0.92 to 0.01)					
	C-group	60-80 years	66.8 (11.5)	65.1 (11.6)	65.0 (13.8)			L (0.27 to 1.21)	S (-0.12 to 0.80)	7.8 (*0.004*) (txgr=9.3)**	5.5 (*0.017*) (txgr=4.3)*
Maladaptive	I-group	20-59 years	18.2 (4.1)	17.9 (5.8)	17.6 (2.5)						
	C-group	20-59 years	16.7 (3.5)	16.9 (3.2)	16.1 (3.5)			S (-0.25 to 0.67)	M (0.03 to 0.95)	1.0 (*0.426*)	0.1 (*0.631*)
	I-group	60-80 years	17.8 (5.0)	17.7 (5.8)	17.3 (5.1)						
	C-group	60-80 years	17.7 (4.3)	16.6 (3.9)	18.1 (4.8)	S (-0.19 to 0.72)		S (-0.24 to 0.68)		1.3 (*0.337*)	0.4 (*0.543*)
Verbal	I-group	20-59 years	23.0 (8.0)	26.4 (6.8)	25.3 (4.8)	M (0.91 to 0.01)	S (-0.80 to 0.11)				
	C-group	20-59 years	22.4 (5.5)	25.4 (6.6)	24.4 (3.2)	M (-0.95 to -0.03)	S (-0.90 to 0.02)		S (-0.24 to 0.68)	0.6 (*0.756*)	0.6 (*0.875*)
	I-group	60-80 years	22.2 (5.5)	25.3 (5.5)	23.5 (4.8)	M (-1.02 to -0.09)	S (-0.71 to 0.21)				
	C-group	60-80 years	21.4 (5.6)	22.4 (6.0)	20.2 (6.1)		S (-0.25 to 0.66)	M (0.04 to 0.96)	M (0.13 to 1.06)	1.8 (*0.231*)	2.8 (*0.190*)
Nonverbal	I-group	20-59 years	27.7 (5.6)	32.1 (4.1)	30.6 (4.9)	L (-1.36 to -0.41)	M (-1.01 to -0.08)				
	C-group	20-59 years	28.6 (5.5)	30.0 (6.5)	28.7 (4.2)	S (-0.69 to 0.23)		S (-0.01 to 0.84)	S (0.05 to 0.87)	2.8 (*0.106*)	1.9 (*0.318*)
	I-group	60-80 years	27.5 (8.0)	30.4 (5.2)	28.6 (4.8)	S (-0.89 to 0.03)					
	C-group	60-80 years	27.8 (7.3)	26.2 (6.1)	26.7 (7.3)	S (-0.22 to 0.69)		M (0.26 to 1.20)	S (-0.15 to 0.76)	4.7 (*0.010*) (txgr=7.4)*	2.2 (*0.019*) (txgr=4.2)*
HADS Age groups											
Total	I-group	20-59 years	9.5 (5.8)	9.4 (4.9)	6.5 (4.5)		M (0.11 to 1.03)				
	C-group	20-59 years	8.3 (4.3)	7.7 (4.5)	6.7 (7.4)		S (-0.20 to 0.72)	S (-0.10 to 0.82)		0.3 (*0.804*)	2.1 (*0.300*)
	I-group	60-80 years	7.7 (7.3)	5.9 (7.0)	4.1 (4.4)	S (-0.21 to 0.71)	M (0.13 to 1.06)				
	C-group	60-80 years	6.8 (5.2)	5.4 (5.7)	6.9 (4.9)	S (-0.20 to 0.71)			M (-1.06 to -0.13)	1.4 (*0.257*)	2.7 (*0.178*)
Anxiety	I-group	20-59 years	5.2 (3.6)	4.8 (3.2)	3.1 (2.0)		M (0.24 to 1.18)				
	C-group	20-59 years	5.1 (2.6)	4.7 (2.9)	4.2 (4.1)		S (-0.20 to 0.72)		S (-0.80 to 0.12)	0.1 (*0.858*)	1.5 (*0.198*)
	I-group	60-80 years	4.1 (4.0)	2.9 (3.5)	2.0 (1.9)	S (-0.14 to 0.77)	M (0.20 to 1.13)				
	C-group	60-80 years	3.7 (3.6)	2.8 (3.2)	3.4 (2.6)	S (-0.20 to 0.72)			M (-1.07 to -0.14)	1.0 (*0.117*)	1.3 (*0.254*)
Depression	I-group	20-59 years	4.3 (2.9)	4.6 (3.0)	3.4 (2.8)		S (-0.15 to 0.77)				
	C-group	20-59 years	3.2 (2.2)	3.0 (2.0)	2.6 (3.6)		S (-0.26 to 0.66)	M (0.15 to 1.09)	S (-0.21 to 0.70)	0.5 (*0.556*)	0.7 (*0.501*)
	I-group	60-80 years	3.6 (3.6)	3.0 (3.9)	2.1 (2.8)		M (-0.00 to 0.92)				
	C-group	60-80 years	3.1 (2.7)	2.6 (2.8)	3.5 (2.4)				S (-0.72 to 0.19)	0.4 (*0.678*)	1.3 (*0.278*)

Effect size below 0.2 is not reported in the table, S=small effect size ($0.2 \leq d < 0.5$), M=moderate effect size ($0.5 \leq d < 0.8$), L=large effect size ($0.8 \leq d$); HHIE: Hearing Handicap Inventory for the Elderly; *Social* and *Emotional* subscales. CSS: Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI); *Maladaptive*, *Verbal* and *Nonverbal* subscales. HADS: Hospital Anxiety and Depression Scale; *Anxiety* and *Depression* subscales.

*$p<0.05$, **$p<0.01$.

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Secondary outcome measures

Significantly greater improvement was found for the intervention group compared with the control group T0-T1 for the CSS-total ($F_{(1, 62.9)}$=5.6, p<0.05) and for the *Nonverbal* subscale ($F_{(1, 63.8)}$=9.2, p<0.01). This interaction effect persisted from T0-T2 for the *Nonverbal* subscale ($F_{(2, 115.8)}$=4.7, p<0.05), and was on the borderline for CSS-total ($F_{(2,114.4)}$=2.8, p=0.064). Moderate within-group effect sizes from T0-T1 were observed for the intervention group for the CSS-total and for the *Verbal* and *Nonverbal* subscales. Moderate between-group effect sizes were shown for the CSS-total and for the *Nonverbal* subscale T0-T1, as shown in table 2.

The analyses for HADS showed that both the intervention group and the control group improved their total scores over the time, and the analyses identified no significant differences when modeling the interaction effects from T0-T1 or T0-T2, as shown in table 2. Moderate within-group effect sizes were found for the HADS-total T0-T2, as shown in table 2.

Subgroup analysis

A subgroup analysis for different age groups was performed for the HHIE, CSS and HADS scores from T0-T1 and T0-T2. No significant interaction effect was found for the outcome measures HHIE and HADS from T0-T1 or T0-T2 for the age groups 20-59-years and 60-80-years, as shown in table 2. Nevertheless, a large between-group effect was found from T0-T2 for the HHIE-total score and for the *Emotional* subscale among the participants in the 20-59-year age group, as shown in table 2. The participants in the 60-80-year age group showed medium between-group effect sizes for the HADS-total scale and *Anxiety* subscale.

The CSS-total showed an interaction effect from T0-T1 ($F_{(1, 33.2)}$=9.3, p<0.01), indicating that the 60-80-years old in the intervention group showed significantly more improvement than the 60-80-year-olds in the control group. This effect persisted from T0-T2 ($F_{(2, 63.7)}$=4.3,

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$p<0.05$). There was also an interaction effect from T0-T1 for the *Nonverbal* subscale, with the 60-80-year-olds in the intervention group showing significantly greater improvement ($F_{(1, 33.7)}=7.4$, $p<0.05$) compared with the 60-80-year-olds in the control group. This effect persisted from T0-T2 ($F_{(2,64.1)}=4.2$, $p<0.05$). It may be noted that the participants of the age 60-80 years in the control group declined over time as measured by CSS-total and *Nonverbal* subscale, and that improvements in the intervention group were of effect size small or moderate. However, the younger subgroup (20-59 years of age), was improving over time in both the control (small effect sizes) and the intervention group (moderate or large effect sizes).

Sensitivity analysis

A sensitivity analysis was performed for the HHIE, CSS and HADS by excluding all data from the participants who did not complete all three measurement time points (T0, T1 and T2; n=50). However, 50 participants are not sufficient to ensure a between-group effect of 80%. Nonetheless, the sensitivity analysis revealed an interaction effect for the HHIE-*Emotional* subscale from T0-T1 ($F_{(1, 48.0)}=4.3$, $p<0.05$) with the intervention group showing an advantage, as shown in the Complementary Appendix II. This interaction effect did not remain 6 months post-treatment.

The interaction effect for the CSS-total that was achieved when participants were treated on an ITT basis (n=74) was not apparent in the sensitivity analysis (n=50). The results for the CSS showed an interaction effect for the *Nonverbal* subscale from T0-T1 ($F_{(1, 48.0)}=6.8$, $p<0.05$) and from T0-T2 ($F_{(2, 96.0)}=3.5$, $p<0.05$), with the intervention group showing significantly greater improvement compared with the control group, similar to the results for the whole group (n=74).

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Furthermore, the sensitivity analysis showed significant results for the HADS-total scale from T0-T2 ($F_{(2, 96.0)}$=3.1, p<0.05), indicating that the intervention group's scores had improved more than those of the control group. The sensitivity analysis for the remaining scales and subscales showed no changes in significance compared with the previous analysis (n=74), as shown in Complementary Appendix II.

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DISCUSSION

The aim of this study was to evaluate whether internet-based AR for HA users would be effective in GCP and whether the assumed positive effect of participating in the internet-based AR program would be maintained 6 months after the program was completed. Our aim was also to analyze the effect of the program in two age-groups.

Both the intervention group and the control group improved their HHIE scores from T0-T1 and from T0-T2; however, the improvements were not significantly different between groups, unlike the findings of our research group's previous study[18] (for demographics, see Table 1). Differences in the results could be related to differences in the recruitment process. In our previous study[18], the participants were recruited through advertisements and articles in Swedish national daily newspapers and on the Internet; the recruited participants were well educated and had a higher education level than the general population. This indicated that the intervention program is well suited for educated patients, although education was not a significant predictor of intervention outcomes[42]. This recruitment strategy recruited participants who actively sought involvement in research. Additionally, the participants were somewhat older and were more experienced HA users than the participants in the current study. Thus, the internet-based intervention program may be more suited for older adults and experienced HA users, than for younger adults and less experienced. Also, the participants in the current study received similar clinical treatments prior to participating in the study, which may impact the effectiveness of the current study, in particular if the participants experience positive clinical treatment outcomes. Another underlying explanation for the differences in improvement could be that the control group was more active in the present study compared with our previous study[18], in which the participants read a book about the history of HAs, though not online. Participants being enrolled in a research study might generally be more positive afterward their participation[43], which could be considered research bias assuming that

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the full internet-based AR is more effective than one element of the program. A borderline significant interaction effect emerged for the HHIE *Emotional* subscale from T0-T1, indicating that the full internet-based AR could have had a positive impact on the emotional effects of the participants' hearing loss. This could be due to the *reading* and *home training* element that by educating raises participants' abilities, which can lead to increased self-esteem. This increased self-esteem might be additionally acknowledged by the audiologist during the weekly telephone consultations.

The sensitivity analysis that was performed (n=50) revealed an interaction effect for the HHIE-*Emotional* subscale from T0-T1, for the CSS-*Nonverbal Strategies* subscale from T0-T1 and from T0-T2; and for the HADS-total scale from T0-T2; all interaction effects indicated an advantage for the intervention group. It appears that participants who were especially persistent and who participated in all aspects of the full internet-based AR or were just conscientious may show changes in the HHIE score and in their communications skills, and changes in symptoms of anxiety and depression. Thus, the sensitivity analysis makes the study underpowered, and these interaction effects should be treated with caution.

The participants who did not provide T0-T2 measurements for present study had lower baseline scores on the HHIE and HADS compared with those who continued in the present study, indicating that insubstantial self-reported social and emotional effects of hearing loss as well as anxiety and depression symptoms can influence the decision to drop out. Laplante-Lévesque et al[42] showed that greater self-reported hearing disability is one of the predictors for intervention uptake and positive outcomes. Another potential influencing factor might be that it is easier to drop out when the intervention is internet-based, as discussed by Andersson et al[44].

In our earlier research, the HHIE was an appropriate measure for the outcomes of telephone-supported AR beyond HA fitting in GCP[17]; in that study, the program for the intervention

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group did not include parts of the ACE program, which targets the communication difficulties experienced by older people with hearing impairment in everyday life[37-38]. In the clinical population of the present study, we found effects for the CSS-total and the *Nonverbal* subscale; thus, it seems that participating in the full internet-based AR program containing the ACE program has a larger effect on communication skills compared with partial participation. Determining the element responsible for the interaction improvement in the present study is challenging. The *reading* and *home training* elements of the full internet-based AR program might have contributed to improved communication skills, but so, too, might the telephone follow-up by the audiologist. Having personal phone contact with an audiologist may have encouraged the participants to try out the program's suggested strategies. The effect on the CSS, however, raises doubts about the applicability of the HHIE as a main outcome measure for the present study (e.g. power calculation and sample size).

The intervention and control groups were also analyzed using subgroups. The 60-80-year-olds in the intervention group obtained significantly greater improvement compared with the 60-80-year-olds in the control group in terms of the CSS-total and the *Nonverbal* subscale, contradicting our hypothesis that the 20-59-year-age group would be more receptive to internet-based AR. As mentioned, the ACE program targets the everyday life of older people, which may have been reflected in the results of the CSS subgroup analysis. However, it might be that the decline in scores as measured by CSS-total and the *Nonverbal* subscale for the 60-80-year-olds in the control group contributes to that the small effect in the intervention group becomes more pronounced in this subgroup than the differences in the improvements seen in both control and intervention group in the younger subgroup (20-59 years). Additionally, it might be that the older adults use more non-verbal strategies when communicating because of their presumably grater cognitive demands when trying to understand speech[45]. However, the subgroup analysis includes small groups and these results should be treated with caution.

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Thorén et al[18] found significant improvements in the intervention group when measuring participants' psychosocial well-being using the HADS. Our results showed that both the intervention group and the control group showed improved HADS scores, although the difference between the groups was not significant. Preminger[46] reviewed the importance of taking psychosocial outcomes into account when implementing group adult aural rehabilitation and highlighted the importance of outcome studies. The HADS is believed to be sensitive enough to detect the effects of online education[16, 18].

Limitations

One limitation is that the participants in this study have been HA users for an average of 7.5 years. In our previous study in a GCP setting, that number was 6.5 years[17]; for Thorén et al, the average was 9.9 years[18]. Despite inclusion criteria that acknowledged the heterogeneity of a clinical population, the participants in the present study were experienced HA users. Though, new HA users are more likely to benefit from educational programs, compared to experienced HA users[13]. Thus, although different aspects of AR may not suit every individual client, the current study increases the confidence that the clinical use of group AR will likely have positive outcomes[47]. Additionally, included participants were asked to sign-up via the Internet and are thus competent Internet users, which would likely impact the effectiveness of the current study. Another limitations are that the control group received an active intervention, and only one of the 4 elements of the program. We are unaware of the relative benefit of any other element alone/combination of elements might have as compared to the full intervention. A more clear result may generate from a control group that receives no intervention.

Another concern that needs to be mentioned is that the observed standardized mean difference on the HHIE between the intervention and control group was much lower than what was

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expected when comparing with previous research and anticipated in the sample size calculation; also, the standard deviation was larger than expected. Thus, increasing the sample size initially could maybe result in statistically significant difference between the groups; nevertheless, it is not certain that the standardized mean difference between the groups in a larger sample would lead to clinically meaningful difference for the participants.

Conclusion

The internet-based approach expands the availability of AR in GCP, offering accessibility to many people, including hard-to-reach populations[48]. The present study shows that using the Internet for interactions between the audiologist and the HA user had a positive effect on communication skills for the intervention group compared with the control group. Furthermore, the full internet-based AR program was not more effective than one element of the internet-based AR program. Although, the advantages of an internet-based approach, both for the patient and the clinician[47], may inspire clinicians and operation managers in their future utilization of comprehensive AR in addition to HA fitting.

More research is needed to examine the efficacy and applicability of this type of intervention. This study is one of the first RCTs in Sweden to implement internet-based rehabilitation beyond conventional HA fitting in a GCP; and is explicitly at the beginning of exploring the possible clinical applicability of this type of intervention. Further analysis is needed to examine the individual elements of the full internet-based AR program to evaluate which part of the internet-supported educational intervention had the greatest effect: the reading material, the weekly assignments, the discussion forum, or the contact with the audiologist. In addition, guided internet-based intervention should be compared with face-to-face AR to analyze whether the two approaches are equally effective. Also, this type of internet-based intervention delivered exclusively to new HA users should be compared to a matched group

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who only receive HA in order to know the relative efficacy of the internet-based AR program. Additionally, the individual needs of the HA user should be taken into account when designing group AR, as should including significant others in the intervention.

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Contributors

GA, TL and MM contributed to the conception and design of the study, and to the acquisition of data for the study. MM contributed to data collection and analyzed the data. GA, TL, MM and KK contributed to the analysis of data and participated in interpretation of data for the study; in drafting the study and revising it critically for important intellectual content and in giving final approval of the version to be published. GA, TL and KK provided continuous supervision during the entire study.

Competing interest

The authors declare no competing interests.

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Data sharing statement

No additional data available.

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REFERENCES

1. World Health Organization. International Classification of Functioning, Disability and Health (ICF). Geneva: World Health Organization 2001.
2. Boothroyd A. Adult aural rehabilitation: what is it and does it work? *Trends in Amplif* 2007;11(2):63-71. doi: 10.1177/1084713807301073.
3. Hickson L, Worall L. Beyond hearing aid fitting: improving communication for older adults. *Int J Audiol* 2003;42(2):S84-91. doi:10.3109/14992020309074649.
4. Hawkins D. Effectiveness of Counselling-Based Adult Group Aural Rehabilitation Programs: A Systematic Review of Evidence. *J Am Acad Audiol* 2005;16:485-93. doi: http://dx.doi.org/10.3766/jaaa.16.7.8.
5. Hickson L, Worall L, Scarinci N. Measuring outcomes of a communication program for older people with hearing impairment using the International Outcome Inventory. *Int J Audiol* 2006;45:238-46. doi:10.1080/14992020500429625.
6. Chisolm T, Arnold M. Evidence about the effectiveness of aural rehabilitation programs for adults. In: Wong L, Hickson L, eds. Evidence-based practice in audiology: Evaluating interventions for children and adults with hearing impairment. San Diego, CA: Plural 2012:237-66.
7. Abrams H, Hnath-Chisolm T, McArdle R. A cost-utility of adult group audiologic rehabilitation: Are the benefits worth the cost? *J Rehabil Res Dev* 2002;39(5):549-58.
8. Kochkin S. Marke Trak VIII: 25-years in trends in the hearing health market. *Hearing review* 2009;16(11):12-31.
9. Grenness C, Hickson L, Laplante-Lévesque A, et al. Patient-centred care: A review for rehabilitative audiologists. *Int J Audiol* 2014;53(Suppl 1):P60-7. doi:10.3109/14992027.2013.847286.

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10. McCormack A, Fortnum H. Why do people fitted with hearing aids do no wear them? *Int J Audiol* 2013;52:360-8. doi:10.3109/14992027.2013.769066.

11. Knudsen LV, Öber M, Nielsen C, et al. Factors Influencing Help Seeking, Hearing Aid Uptake, Hearing Aid Use and Satisfaction With Hearing Aids: A Review of the Litterature. *Trends in Amplification* 2010;14(3):127-54. doi: 10.1177/1084713810385712.

12. Laplante-Lévesque A, Hickson L, Worall L. Rehabilitation of older adults with hearing impairment: a critical review. *J Aging Health* 2010;22(2):143-53. doi:10.1177/0898264309352731.

13. Kramer SE, Allesie GHM, Dondorp AW, et al. A home education program for older adults with hearing impairment and their significant others: A randomized trial evaluating short- and long-term effects. *Int J Audiol* 2005;44:255-64. doi: 10.1080/14992020500060453.

14. Laplante-Lévesque A, Pichora-Fuller MK, Gagne JP. Providing an internet-based audiological counselling programme to new hearing aid users: a qualitative study. *Int J Audiol* 2006;45:697-706. doi:10.1080/14992020600944408.

15. Sweetow RW, Henderson SJ. Technologic advices in aural rehabilitation: applications and innovative methods of service delivery. *Trends in Amplification* 2007;11:101-11. doi: 10.1177/1084713807301321.

16. Thorén E, Svensson M, Törnqvist A, et al. Rehabilitative online education versus internet, discussion group for hearing aid users: a randomized controlled trial. *J Am Acad Audiol* 2011;22:274-85. doi: 10.3766/jaaa.22.5.4.

17. Lundberg M, Andersson G, Lunner T. A randomized, controlled trial of the short-term effects of complementing an educational program for hearing aid users with telephone consultations. *J Am Acad Audiol* 2011;22(10):654-62. doi: 10.3766/jaaa.22.10.4.

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18. Thorén ES, Öberg M, Wänström G, et al. A randomized controlled trial evaluating the effects of online rehabilitative intervention of adult hearing-aid users. *Int J Audiol* 2014;53:452-61. doi:10.3109/14992027.2014.892643.

19. Ferguson M, Brandreth M, Brassington W, et al. A Randomized Controlled Trial to Evaluate the Benefits of a Multimedia Educational Program for First-Time Hearing Aid Users. *Ear Hear* 2016;37(2):123-36. doi: 10.1097/AUD.0000000000000237.

20. Molini-Avejonas DR, Rondon-Melo S, De la Higuera Amato CA, et al. A systematic review of the use of telehealth in speech, language and hearing sciences. *J Telemed Telecare* 2015;21:367-76. doi: 10.1177/1357633X15583215.

21. Barak A, Sadovsky Y. Internet use and personal empowerment of hearing-impaired adolescents. *Comput Human Behav* 2008;24:1802-15. doi:10.1016/j.chb.2008.02.007.

22. Henshaw H, Clark Daniel PA, Kang S, et al. Computer Skills and Internet Use in Adults Aged 50-74 Years: Influence of Hearing Difficulties. *J Med Internet Res* 2012;14(4):e113. doi:10.2196/jmir.2036.

23. Sundewall ET, Öberg M, Wänström G, et al. Internet Access and Use in Adults With Hearing Loss. *J Med Internet Res* 2013;15(5):e91. doi: 10.2196/jmir.2221.

24. Kaldo-Sandström V, Larsen HC, Andersson G. Internet-Based Cognitive-Behavioral Self-Help Treatment of Tinnitus: Clinical Effectiveness and Predictors of Outcome. *Am J Audiol* 2004;13:185-92. doi:10.1044/1059-0889(2004/023).

25. Hedman E, Ljótsson B, Rück C, et al. Effectiveness of Internet-based cognitive behaviour therapy for panic disorder in routine psychiatric care. *Acta Psychiatrica Scandinavica* 2013;128:457-67. doi: 10.1111/acps.12079.

26. Moore AN, Rothpletz AM, Preminger JE. The effect of chronological age on the acceptance of Internet-based hearing health care. *Am Journal Audiol* 2015; 24:280-3. doi: 10.1044/2015_AJA-14-0082.

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27. Hopewell S, Clarke M, Moher D, et al. CONSORT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts: Explanation and Elaboration. *PLoS Med* 2008;5(1):e20. doi:10.1371/journal.pmed.0050020.

28. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *Int J of Surg* 2012;10(1):28-55. doi:10.1016/j.jclinepi.2010.03.004.

29. Ventry IM, Weinstein BE. The Hearing Handicap Inventory for the Elderly: a new tool. *Ear Hear* 1982;3(3):128-34.

30. Demorest ME, Erdman SA. Development of the Communication profile for the hearing impaired. *J Speech Hear Disord* 1987;52(2):129-43. doi:10.1044/jshd.5202.129.

31. Zigmod AS, Snaith RP. The Hospital Anxiety Depression Scale. *Acta Psychiatr Scand* 1983;67:361-70. doi: 10.1111/j.1600-0447.1983.tb09716.

32. Cox R, Hyde M, Gatehouse S, et al. Optimal Outcome Measures, Research Priorities, and International Cooperation. *Ear Hear* 2000;21(Suppl 4):P106-15.

33. Öberg M, Lunner T, Andersson G. Psychometric evaluation of hearing specific self-report measures and their associations with psychosocial and demographic variables. *Audiol Med* 2007;5:188-99. doi:10.1080/16513860701560214.

34. Hallberg LRM, Eriksson-Mangold M, Carlsson SG. Psychometric evaluation of a Swedish version of the Communication Strategies Scale of the Communication Profile for the Hearing Impaired. *J Speech Hear Res* 1992;35:666-74. doi:10.1044/jshr.3503.666.

35. Sundewall ET, Andersson G, Lunner T. The use of research questionnaires with hearing impaired adults: online vs. paper-and pencil administration. *BMC Ear Nose Throat Disord* 2012;12:12. doi:10.1186/1472-6815-12-12.

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36. Elberling C, Worsøe K. When the sounds are weaker - on hearing and hearing aids. Herlev: Bording A/S 2006.

37. Hickson L, Worrall L, Scarinci N. A randomized controlled trial evaluating the active communication education program for older people with hearing impairment. *Ear Hear* 2007;28:212-30. doi: 10.1097/AUD.0b013e31803126c8.

38. Öberg M, Bohn T, Larsson U. Short- and Long-Term Effects of the Modified Swedish Version of the Active Communication Education (ACE) Program for Adults with Hearing Loss. *J Am Acad Audiol* 2014;25(9):848-58. doi: 10.3766/jaaa.25.9.7.

39. SPSS (data analysis software system). Statistical Package for the Social Sciences for Windows. Version 19.0. www.spss.com 2011.

40. Fergusson D, Aaron SD, Guyatt G, et al. Post-randomisation exclusions: the intention to treat principle and excluding patients from analysis. *BMJ* 2002;325:652-4. doi: http://dx.doi.org/10.1136/bmj.325.7365.652.

41. Gueorguieva R, Krystal JH. Move Over ANOVA. Progress in Analyzing Repeated-Measures Data and Its Reflection in Papers Published in the Archives of General Psychiatry. *Arch Gen Psychiatry* 2004;61:310-17. doi:10.1001/archpsyc.61.3.310.

42. Laplante-Lévesque A, Hickson L, Worall L. What makes adults with hearing impairment take up hearing aids or communication programs and achieve successful outcomes? *Ear Hear* 2011;32(5):1-15. doi: 10.1097/AUD.0b013e31822c26dc.

43. Linde L, Fässler M, Meissner K. Placebo interventions, placebo effects and clinical practice. *Phil Trans R Soc B* 2011;366:1905-12. doi: 10.1098/rstb.2010.0383.

44. Andersson G, Strömgren T, Ström L, et al. Randomized Controlled Trial of Internet-Based Cognitive Behavior Therapy for Distress Associated With Tinnitus. *Psychosom Med* 2002;64(5):810-6. doi: 10.1097/01.PSY.0000031577.42041.F8.

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For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

45. Pichora-Fuller MK. Processing speed and timing in aging adults: psychoacoustics, speech perception, and comprehension. *Int J Audiol* 2003;42(Suppl 1):P59-67. doi: 10.3109/14992020309074625.

46. Preminger JE. Issues Associated With the Measurement of Psychosocial Benefits of Group Audiologic Rehabilitation Programs. *Trends in Amplification* 2007;11(2):113-23. doi: 10.1177/1084713807301084.

47. Malmberg M, Lunner T, Kähäri K, et al. Implementing internet-based aural rehabilitation in a general clinical practice. *Am J Audiol* 2015;24, 325-8.

48. Swanepoel de W, Hall JW III. A systematic review of telehealth applications in audiology. *Telemedicine and e-health* 2010;16(2):181-200. doi:10.1089/tmj.2009.0111.

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Figure 1. Flowchart for the study procedure. Sets 1 + 2 of the recruitment process are presented in parentheses [n=set1+set2]. Set 1=20-59-year age group, set 2=60-80-year age group. *HHIE, Hearing Handicap Inventory for the Elderly; CSS, Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI); HADS, Hospital Anxiety and Depression Scale; IOI-HA, International Outcome Inventory for Hearing Aids.

Figure 2. The full internet-based program outlined for the intervention group and the element of the internet-based program outlined for the control group. The full internet-based program consisted of four elements: reading, home training, interaction with an audiologist, and interaction with peers in an internet-based discussion forum. Weeks 1-4 of the intervention concluded with a quiz. The small part of the internet-based program consisted of the reading element.

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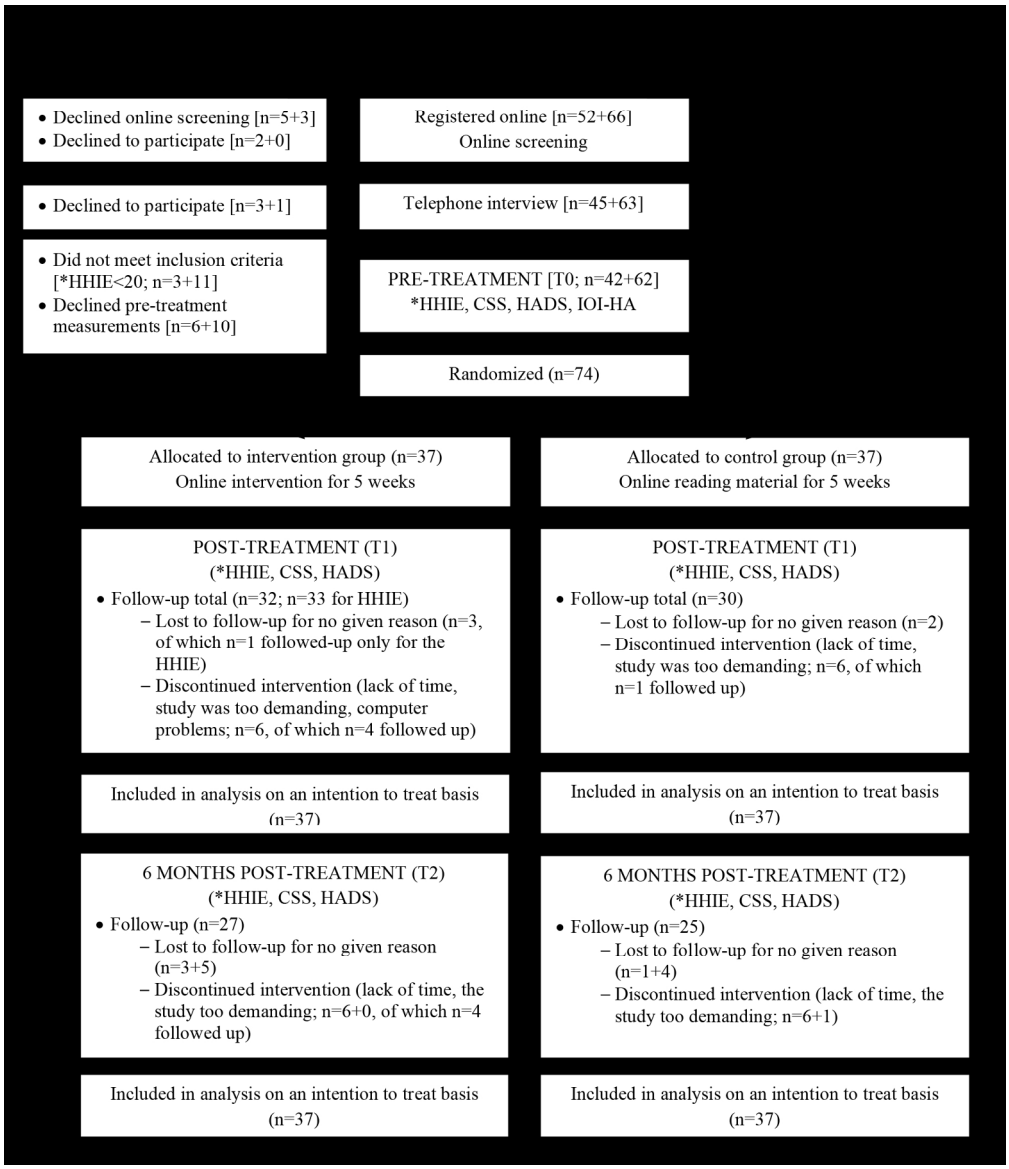

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168x195mm (300 x 300 DPI)

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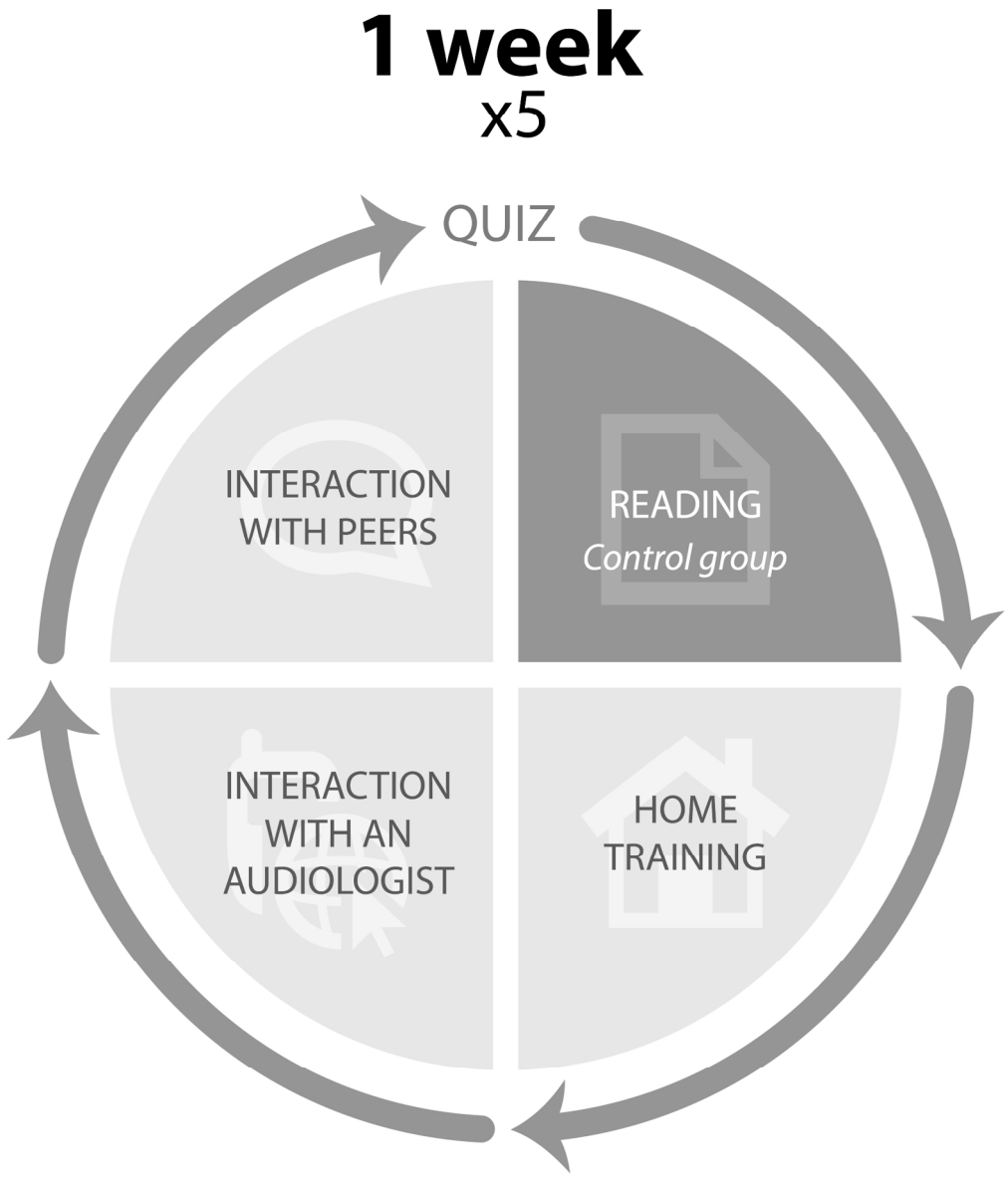

Figure 2. The full internet-based program outlined for the intervention group and the element of the internet-based program outlined for the control group. The full internet-based program consisted of four elements: reading, home training, interaction with an audiologist, and interaction with peers in an internet-based discussion forum. Weeks 1-4 of the intervention concluded with a quiz. The small part of the internet-based program consisted of the reading element.

156x182mm (300 x 300 DPI)

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Complementary Appendix I. (n=74) Estimated marginal means (EMM) and standard error (Std.Error) of the outcome measures HHIE, CSS and HADS for both groups at pre-treatment (T0), post-treatment (T1) and 6-months post-treatment (T2).

	EMM (Std. Error)					
	Intervention group			Control group		
Scale	T0	T1	T2	T0	T1	T2
HHIE-Total						
Total	42.0 (2.4)	35.1 (2.5)	37.8 (2.5)	36.1 (2.4)	31.7 (2.5)	35.7 (2.6)
20-59 years	44.7 (3.3)	39.3 (3.4)	42.2 (3.7)	38.0 (3.4)	33.9 (3.5)	36.5 (3.7)
60-80 years	39.7 (3.4)	31.7 (3.4)	34.5 (3.5)	34.7 (3.3)	29.9 (3.5)	35.0 (3.5)
HHIE-*Social*						
Total	20.2 (1.2)	18.0 (1.3)	18.9 (1.3)	18.5 (1.2)	15.7 (1.3)	19.1 (1.3)
20-59 years	21.2 (1.8)	19.0 (1.9)	20.2 (2.1)	19.8 (1.9)	16.5 (1.9)	20.1 (2.1)
60-80 years	19.3 (1.7)	17.1 (1.7)	17.9 (1.7)	17.5 (1.7)	15.2 (1.7)	18.3 (1.8)
HHIE-*Emotional*						
Total	21.8 (1.4)	17.2 (1.5)	18.9 (1.5)	17.6 (1.4)	15.9 (1.5)	16.6 (1.5)
20-59 years	23.5 (2.0)	20.3 (2.0)	22.0 (2.2)	18.3 (2.1)	17.4 (2.1)	16.3 (2.2)
60-80 years	20.4 (2.0)	14.6 (2.0)	16.5 (2.0)	17.1 (1.9)	14.7 (2.1)	16.8 (2.1)
CSS-Total						
Total	68.1 (2.0)	74.4 (2.0)	71.9 (2.1)	67.2 (2.0)	68.1 (2.1)	67.6 (2.2)
20-59 years	68.8 (2.6)	75.9 (2.8)	73.4 (3.1)	67.7 (2.6)	72.2 (2.8)	70.7 (3.1)
60-80 years	67.4 (2.9)	73.4 (2.9)	71.1 (3.0)	66.8 (2.8)	64.6 (3.0)	65.0 (3.0)
CSS-*Maladaptive*						
Total	17.9 (0.7)	17.7 (0.8)	18.1 (0.8)	17.2 (0.7)	16.5 (0.8)	17.2 (0.8)
20-59 years	18.1 (1.0)	17.1 (1.0)	17.7 (1.1)	16.7 (1.0)	16.7 (1.1)	16.3 (1.1)
60-80 years	17.8 (1.1)	18.0 (1.1)	18.4 (1.1)	17.7 (1.1)	16.3 (1.2)	17.9 (1.2)
CSS-*Verbal*						
Total	22.6 (1.0)	25.8 (1.0)	24.1 (1.1)	21.8 (1.0)	23.7 (1.1)	22.0 (1.1)
20-59 years	23.0 (1.6)	26.5 (1.6)	24.6 (1.8)	22.4 (1.6)	25.4 (1.7)	24.6 (1.8)
60-80 years	22.2 (1.3)	25.2 (1.3)	23.7 (1.3)	21.4 (1.2)	22.4 (1.3)	20.1 (1.4)
CSS-*Nonverbal*						
Total	27.6 (1.0)	31.0 (1.0)	29.7 (1.1)	28.1 (1.0)	27.8 (1.0)	28.3 (1.1)
20-59 years	27.7 (1.3)	32.1 (1.4)	30.9 (1.5)	28.6 (1.3)	30.1 (1.4)	29.9 (1.5)
60-80 years	27.5 (1.5)	30.3 (1.5)	28.8 (1.5)	27.8 (1.4)	25.9 (1.5)	27.0 (1.5)
HADS-Total						
Total	8.5 (1.0)	7.6 (1.0)	6.3 (1.0)	7.4 (1.0)	7.0 (1.0)	7.6 (1.0)
20-59 years	9.5 (1.2)	9.6 (1.3)	6.9 (1.4)	8.3 (1.3)	8.0 (1.3)	7.7 (1.4)
60-80 years	7.7 (1.4)	5.9 (1.4)	5.6 (1.4)	6.8 (1.4)	6.3 (1.4)	7.3 (1.4)
HADS-*Anxiety*						
Total	4.6 (0.6)	3.9 (0.6)	3.1 (0.6)	4.3 (0.6)	4.1 (0.6)	4.2 (0.6)
20-59 years	5.2 (0.8)	5.0 (0.8)	3.5 (0.8)	5.1 (0.8)	5.0 (0.8)	4.8 (0.9)
60-80 years	4.1 (0.8)	3.0 (0.8)	2.8 (0.8)	3.7 (0.8)	3.5 (0.8)	3.7 (0.8)
HADS-*Depression*						
Total	4.0 (0.5)	3.7 (0.5)	3.1 (0.5)	3.1 (0.5)	2.9 (0.5)	3.4 (0.5)
20-59 years	4.3 (0.7)	4.6 (0.7)	3.4 (0.8)	3.2 (0.7)	3.0 (0.7)	3.0 (0.8)
60-80 years	3.6 (0.7)	2.9 (0.7)	2.8 (0.7)	3.0 (0.7)	2.8 (0.7)	3.6 (0.8)

HHIE: Hearing Handicap Inventory for the Elderly, *Social* and *Emotional* subscales. CSS: Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI), *Maladaptive*, *Verbal* and *Nonverbal* subscales. HADS: Hospital Anxiety and Depression Scale, *Anxiety* and *Depression* subscales.

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Complementary Appendix II. Sensitivity analysis (n=50). Observed means (OM) and standard deviations (SD) of the outcome measures HHIE, CSS and HADS for both groups at pre-treatment (T0), post-treatment (T1) and 6-months post-treatment (T2). *P-values* illustrate the significance of the difference in estimated marginal means between the intervention and control group. F-values illustrate the interaction effect for time x group (txgr).

	OM (SD)			T0-T1	T0-T2	T0-T1, (txgr)	T0-T2, (txgr)
Scale	T0	T1	T2	(*p-value*)	(*p-value*)	F-value	F-value
HHIE-Total							
I-group	40.2 (17.2)	33.5 (15.6)	36.0 (16.1)	3.3 (*0.252*)	4.5 (*0.238*)	1.3	1.5
C-group	33.8 (10.1)	30.4 (11.9)	34.2 (13.4)				
HHIE-*Social*							
I-group	19.4 (9.0)	17.6 (7.2)	18.3 (8.0)	0.4 (*0.788*)	2.2 (*0.171*)	0.1	1.8
C-group	17.3 (5.6)	15.2 (6.5)	18.5 (7.2)				
HHIE-*Emotional*							
I-group	20.8 (9.8)	15.9 (9.4)	17.7 (9.7)	3.7 (*0.043*)	2.2 (*0.099*)	4.3*	2.4
C-group	16.5 (7.0)	15.3 (7.2)	15.7 (8.5)				
CSS-Total							
I-group	67.2 (14.6)	72.5 (10.5)	70.5 (10.4)	3.9 (*0.141*)	2.3 (*0.364*)	2.2	1.0
C-group	66.8 (10.0)	68.2 (11.0)	67.8 (10.6)				
CSS-*Maladaptive*							
I-group	17.1 (3.6)	16.4 (3.5)	17.0 (3.6)	0.6 (*0.523*)	0.4 (*0.818*)	0.4	0.2
C-group	17.1 (3.6)	17.0 (3.4)	17.4 (4.4)				
CSS-*Verbal*							
I-group	23.0 (6.8)	25.6 (6.2)	24.2 (4.9)	0.7 (*0.591*)	0.9 (*0.803*)	0.3	0.2
C-group	22.0(4.9)	23.8 (5.9)	22.3 (5.3)				
CSS-*Nonverbal*							
I-group	27.1 (7.9)	30.6 (4.9)	29.4 (4.9)	3.8 (*0.012*)	1.8 (*0.036*)	6.8*	3.5*
C-group	27.6 (5.3)	27.3 (6.0)	28.1 (5.7)				
HADS-Total							
I-group	7.4 (5.8)	6.2 (5.4)	5.2 (4.5)	1.3 (*0.166*)	2.8 (*0.048*)	2.0	3.1*
C-group	6.2 (4.5)	6.3 (5.2)	6.8 (6.0)				
HADS-*Anxiety*							
I-group	3.9 (3.4)	3.2 (3.1)	2.5 (2.0)	0.6 (*0.298*)	1.5 (*0.078*)	1.1	2.6
C-group	3.7 (2.7)	3.5 (3.1)	3.8 (3.3)				
HADS-*Depression*							
I-group	3.4 (2.8)	3.0 (2.7)	2.7 (2.9)	0.7 (*0.185*)	1.4 (*0.089*)	1.8	2.5
C-group	2.5 (2.1)	2.8 (2.5)	3.0 (3.0)				

**p<0.05*; HHIE: Hearing Handicap Inventory for the Elderly, *Social* and *Emotional* subscales. CSS: Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI), *Maladaptive*, *Verbal* and *Nonverbal* subscales. HADS: Hospital Anxiety and Depression Scale, *Anxiety* and *Depression* subscales. I-group: intervention group; C-group: control group.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-6
	2b	Specific objectives or hypotheses	5-6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	na
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	10-13
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7-13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	na
Sample size	7a	How sample size was determined	7-8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	na
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7-8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

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		assessing outcomes) and how	8
	11b	If relevant, description of the similarity of interventions	10-13
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	13-14
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	13-14
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Fig 1, table 1&2
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1, page15
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7-8,12-13
	14b	Why the trial ended or was stopped	na
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	9
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1, 13-14
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	15-21
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	na
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	na
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	na
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	25-26
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	25-27
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	22-27
Other information			
Registration	23	Registration number and name of trial registry	3,7
Protocol	24	Where the full trial protocol can be accessed, if available	8
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	27-28

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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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

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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

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Key words: Audiology, Aural rehabilitation, Internet, Clinical practice, Hearing loss

Abbreviations: AR=aural rehabilitation; CSS=Communication Strategy Scale; CPHI=Communication Profile for the Hearing Impaired; HA=hearing aid; HADS=Hospital Anxiety and Depression Scale; HHIE=Hearing Handicap Inventory for the Elderly; IOI-HA=International Outcome Inventory for Hearing Aids; ITT=intention to treat; PTA=pure-tone average; RCT=randomized controlled trial; SD=standard deviation.

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ABSTRACT

Objective: Guided internet-based intervention beyond hearing aid (HA) fitting has been shown to be efficacious in randomized controlled trials (RCT). However, internet interventions have rarely been applied clinically as a part of regular aural rehabilitation (AR). Our aim was to evaluate the effectiveness of internet-based AR for HA users from a clinical population.

Outcome measures: The Hearing Handicap Inventory for the Elderly (HHIE) was used as the primary outcome measure, and the Communication Strategies Scale (CSS) and the Hospital Anxiety and Depression Scale (HADS) were used as secondary outcome measures. All questionnaires were administered before and directly after the intervention and at 6 months post-intervention.

Methods: We used a parallel group design (RCT). The data were collected in 2013-2014 at three different clinics. Seventy-four HA users were randomly assigned to receive either full internet-based AR (intervention group, n=37) or one element of the internet-based AR (control group, n=37).

Results: Data were analyzed following the intention-to-treat principle. Each group showed improved HHIE scores over time and did not differ significantly from each other. The intervention group showed significantly greater improvement compared with the control group for the CSS total and the *Nonverbal* subscale scores.

The intervention group and control group were also subdivided into two age groups: 20-59 years and 60-80 years. Significantly better improvement on the CSS total and *Nonverbal* subscale scores was found in the older group compared with the younger participants.

Conclusions: This study indicates that participants in an internet-based intervention applied in general clinical practice showed improved self-reported communication skills compared

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with a control group. Receiving a full intervention was not more effective in improving self-reported hearing problems than receiving just one element of the internet-based intervention.

Trial registration: This trial is registered at ClinicalTrals.gov, number NCT01837550.

Strengths and limitations of this study:

- This is one of the first randomized controlled trials in Sweden to implement internet-based rehabilitation beyond conventional hearing aid fitting in a general clinical practice.
- The recruitment process used in the clinical trial will provide indications of the types of hearing aid users who are interested in this type of intervention.
- One limitation of this study is that the control group received an active intervention.
- Another limitation of this study is that the control group received only one of the 4 elements of the program, overlooking the relative benefit of any other element alone/combination of elements might have as compared to the full intervention.

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INTRODUCTION

Hearing impairment influences communication in people's daily life. In agreement with the International Classification of Functioning, Disability, and Health[1], the objective of aural rehabilitation (AR) is to promote social participation for people with hearing impairment. Addressing this objective includes fitting the client with hearing aids (HA), educating him or her about the condition, and providing perceptual training and counseling[2]. To improve communication for people with hearing impairment, researchers recommend combining group AR with HA use[3-6]. This combination has been shown to be more cost-effective than HA use alone[7]. However, despite the recommendations, the most common approach is the use of HAs alone[8]. This discrepancy could be explained by clinicians' lack of time and the difficulties of scheduling comprehensive AR in addition to HA fitting[9]. Moreover, HA users with stressful life situations may have very limited time to spend on traveling to participate in rehabilitation courses offered by the clinic. Also, many HA users experience communication difficulties despite today's HA technology. This could cause patients to stop using their HAs[10], which can lead to withdrawal from and/or avoidance of interpersonal interactions or involvement in community life. A review of the literature showed that, HA users' self-perceived hearing difficulties can affect help seeking, HA uptake, HA use, and satisfaction[11]. Although combining group AR with HA use can be beneficial, the overall availability of and adherence to communication programs are still low[12].

Several studies have suggested that AR could be provided without in-person meetings[13-20]; for example by providing educational programs using telephone/internet-based AR. A recent systematic review indicated that such resources show benefits such as increased access to care, cost-effectiveness and improved quality of care in terms of user satisfaction[20]. Further on, Internet use is increasing among people with hearing impairment, which encourages

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including the Internet for AR in future research[21-23]. There is evidence to suggest that learning and educational support delivered via the Internet could support firs time HA users in clinical practice[19]. However, the effectiveness of clinical use of the Internet for AR is sparsely examined.

Our research group designed a randomized controlled trial (RCT) of internet-based AR[18]. The results showed significantly increased activity and participation in the intervention group by using the Internet to provide AR in addition to HA fitting, while the control group did not improve. The study provided proof of concept that AR beyond HA fitting could be performed over the Internet[16,18]. However, participants were recruited through advertisements and articles in Swedish national daily newspapers and on the Internet, and the study did not indicate whether internet-based interventions could be feasible if strictly administered in a clinical setting. Nonetheless, we chose to use this same RCT design[18] as described above and supplement the trial with telephone support, and then implement the trial in a clinical setting at a later time. Our earlier research showed promising results for telephone-supported AR for HA users in general clinical practice (GCP)[17]. A study of self-help treatment for tinnitus in a clinical setting showed significant improvements pre- to post-treatment and at follow-up when internet-based treatments were used, indicating that self-help treatment can be transferred to the clinic[24]. Studies in other research fields, such as panic disorders, have shown that guided internet-based therapy is efficacious and effective when delivered as part of routine psychiatric care[25].

The first aim of this study was to evaluate whether internet-based AR for HA users will be effective in GCP. Our assumption was that the internet-based AR program would reduce residual hearing problems among HA users and improve the participants' communication strategies and psychosocial well-being, while participating in the control group would not.

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The intervention groups improvements post treatment is expected to be maintained when assessed 6-months post treatment. The second aim of the study was to analyze the effect of internet-based AR in GCP among two age-groups: 20-59 years and 60-80 years. Our hypothesis was that the 20-59-year age group may be more receptive to internet-based AR because of their presumably greater digital literacy skills[26], compared to those who are in the 60-80-year age group.

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METHODS

The Consolidated Standards of Reporting Trials (CONSORT) checklist was followed when reporting the abstract, designing the study, and analyzing and interpreting the results[27-28]. A flowchart of the study procedure is presented in figure 1. The trial is registered at ClinicalTrals.gov, number NCT01837550.

– Figure 1 –

Recruitment and selection

The eligibility criteria targeted the most common patient category at three clinics within the Hearing Organization, Södra Älvsborg, Sweden: patients who were 20-80 years old and who had conductive or sensorineural binaural hearing loss of 20-60 dB HL pure-tone average (500, 1000, and 2000 Hz). Additional eligibility criteria included patients who had completed a HA fitting 3 months before the study began (regardless of HA manufacturer or model), who had a HHIE score ≥20 points (HHIE: Hearing Handicap Inventory for the Elderly[29]; indicative of some residual hearing problems), and gave their informed consent to participate. The study was conducted in 2013-2014. There was no difference in the three clinics in terms of patients and general procedures. The recruitment process was conducted in two sets, one for participants aged 20-59 years and one for those aged 60-80 years. All potential participants who fulfilled the criteria for age, hearing loss, and HA fitting received a recruitment letter that contained information about the study's purpose and structure and stressed that the participants' privacy would be protected and that participation was voluntary. The participants were prepared to allocate 1.5-2.0 hours each week to participate in the study and were informed that they would be placed into one of two groups. The participants were asked to

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visit the website www.iterapi.se/sites/hornet to read more about the study and to initiate participation.

The first step of the participation required registering at the website and completing a screening form. Participants who completed this first step (n=108) were called by the project leader for a telephone interview to assess their eligibility; of these, 104 agreed to participate in the study. The next step was for the participants to return a signed consent form to the project leader and to complete four standardized questionnaires (see 'Outcome Measures', below). Consequently, 74 participants were included in the study as seen in Figure 1.

The study was a randomized controlled trial with a parallel group design and a simple randomization procedure through the recruitment process that was conducted in two sets. The 74 participants were randomly assigned to either an intervention group (group 1) or a control group (group 2) according to a computer-generated list of random numbers. An independent audiologist at the clinic (not involved in the recruitment) generated the random allocation sequence using a computer software program and assigned the participants to different groups. The independent audiologist reported the allocation schedule to the project leader, who then enrolled the participants. The assigned participants were told which group they were allocated to (1 or 2) but were not informed whether the group was the intervention group or the control group. Thirty-seven participants were included in the intervention group, and 37 participants were included in the control group, as shown in table 1. No significant differences were found between the groups regarding the background variables age, age group, gender and hearing loss.

The study was reviewed and approved by the regional ethical review board in Gothenburg, Sweden. The study website was programmed using Java Script, and information was available in hypertext markup language (HTML) format.

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Table 1. Demographic and clinical characteristics of the participants. The data are reported as means (standard deviations, SD) unless stated otherwise.

	Intervention group (n=37)	Control group (n=37)
20-59-year age-group, n (%)	17 (46)	16 (43)
60-80-year age-group, n (%)	20 (54)	21 (57)
Age, years (range 31-80 years)	61.8 (11.9)	62.1 (11.4)
20-59-year age-group	50.9 (7.2)	52.3 (9.1)
60-80-year age-group	71.1 (5.4)	69.6 (5.9)
Gender, n (%)		
Men	24 (64.9)	20 (54.1)
Woman	13 (35.1)	17 (45.9)
Pure-tone average (dB HL)		
Right ear	37.5 (11.3)	38.0 (8.6)
Left ear	37.8 (10.5)	36.5 (8.5)
HA, n (%)		
Binaural	28 (75.7)	31 (83.8)
Monaural	9 (24.3)	6 (16.2)
Duration of HA use		
Years (range 0.5-55 years)	7.5 (9.6)	7.4 (6.3)
Median (Q1/Q3)*	5.0 (1.5/10.5)	6.0 (2.3/11.3)
Computer experience**, n (%)	37 (100)	37 (100)
Computer access, n (%)	37 (100)	37 (100)
Able to have a telephone conversation without HA/s?, n (%)	32 (86.5)	35 (94.6)
IOI-HA 1. Daily use	4.1 (1.1)	4.4 (1.0)
2. Benefit	3.8 (0.9)	4.1 (0.9)
3. Remaining activity limitation	3.1 (0.8)	3.1 (0.8)
4. Satisfaction	4.1 (1.1)	4.4 (0.8)
5. Remaining participation restriction	3.8 (1.1)	4.1 (0.8)
6. Impact on environment	3.6 (0.9)	3.9 (0.9)
7. Quality of life	3.6 (0.8)	3.6 (1.0)

(*Q1=the first quartile, Q3=the third quartile; **familiar with: able to log in, print information, complete a questionnaire on a website and read and send email); HA: hearing aid; IOI-HA: International Outcome Inventory for Hearing Aids.

Outcome Measures

The HHIE[29] was the primary outcome measure. The HHIE includes two subscales; the *Social* subscale comprises 12 questions addressing the social effects of hearing loss, and the *Emotional* subscale comprises 13 questions addressing the emotional effects of hearing loss. Higher scores reflect a higher self-reported hearing problem.

The Communication Strategies Scale; the CSS (from the Communication Profile for the Hearing Impaired (CPHI)[30] and the Hospital Anxiety and Depression Scale (HADS)[31] were used as secondary outcome measures. The CSS includes three subscales (*Maladaptive*

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Behaviors, Verbal Strategies and Nonverbal Strategies) and is designed to analyze participants' behavior in various communication situations. The *Maladaptive Behaviors* subscale includes 9 questions that analyze strategies that hinder communication. *Verbal Strategies* and *Nonverbal Strategies* address 16 items related to strategies that can enhance communication. Scoring for the CSS reflects how frequently a specific situation or behavior occurs. The HADS comprises 14 items separated into two subscales: *Anxiety* and *Depression*. Higher scores reflect more symptoms of anxiety and depression.

The International Outcome Inventory for Hearing Aids (IOI-HA)[32] includes seven questions measuring specific dimensions of HA outcomes: daily use, benefits, remaining activity limitations, satisfaction, remaining participation restrictions, impact on the environment, and quality of life; with higher scores indicating better outcomes. The IOI-HA was not used as an outcome measure in this study; rather, it was used to describe the demographic and clinical characteristics of the participants, as shown in table 1.

The HHIE, CSS and HADS were administered according to the methods described[29-31] and were available on the study website, in Swedish. The questionnaires were administered online before and directly after the study participation and 6 months after participation to evaluate self-reported hearing problems, communication strategies, and anxiety and depression. All of the questionnaires have a good internal consistency[33-34] and have been shown to be as reliable as the original versions when used with a Swedish population of young adults and elderly[33]. Sundewall et al[35] stressed the importance of keeping the internet-based administration format of the HHIE and HADS stable across time points.

Intervention Group

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The internet-based intervention program is based on four elements: reading, home training, interaction with an audiologist, and interaction with peers in an internet-based discussion forum. The participants received information about the intervention program and access to the reading material on the study website; they also received a book about hearing and HAs[36] and the Swedish version of Active Communication Education, a compendium of communication strategies[5, 37-38]. The website information about the intervention program, along with the book and the compendium, were also mailed to all of the participants in the intervention group.

– Figure 2 –

The reading element is divided in to five modules, one module for each of the five weeks. The participants were instructed to read specific content each week based on the various chapters of the book and information from the compendium[18]. The weekly home assignments (week 1-5) were accessible to facilitate an understanding of the contents of the book and the compendium. For example, the weekly assignments could be to observe the benefits of using HAs. The weekly home assignments were handed in on the Internet by the participants (week 1-5), and direct responses were provided online by an audiologist. The weekly home assignments were also discussed with the audiologist over the phone at the end of each treatment week. The telephone consultations lasted approximately 10-15 minutes per participant and provided the participants with an opportunity to reflect on the assignment and discuss any concerns they might have. Weeks 1-4 ended with quiz questions on the content of the past weeks' readings. The participants in the intervention group were invited to attend a discussion forum on the study website. Weekly topics were presented for the participants[18] to discuss with one other, without any interaction with the audiologist. The participants were free to use the discussion forum with no restrictions from the audiologist. However, all

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activities where strictly observed, and if needed, inappropriate postings could be deleted. No inappropriate postings occurred.

Control Group

The control group received one reading element; i.e. the first four chapters of the book[36]; and the information about participation provided on the study website. The website information and book chapters were also mailed to the participants. The control group was asked to read the four chapters over a five-week period; no assignments were given in association with their participation. To minimize the impact of professional interaction, no monitoring was provided during the program to ensure that the participants actually read the chapters.

Follow-up

At the end of the treatment period, the HHIE, CSS and HADS were made available to all participants on the study website, and the participants were asked to complete them. Both groups' participation was evaluated using a post-study telephone interview. The post-study interviews for the intervention group were conducted by five different clinical audiologists than the one who conducted the pre-study interviews and the telephone consultations during the study to minimize the influence of special attention on the participants' responses to the questionnaires. The five audiologists were trained for consistency by the project leader. The post-study interviews for the control group were conducted by the same audiologist who conducted the pre-study interviews. For the telephone interview, the audiologists used a self-designed form that contained questions about the study process, including opportunities for the participants to provide their own comments. Different forms were designed for the intervention group and the control group. All of the participants were invited to keep their copy of the reading material.

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Six months after the study participation, the participants in both groups were contacted via e-mail and asked to complete the HHIE, CSS and HADS online again.

Statistical Analyses

Statistical Package for the Social Sciences[39] software for Windows (SPSS, version 19.0) was used for the analysis of all data. Three measurement time points were examined: pre-treatment (T0), post-treatment (T1) and 6 months post-treatment (T2). To ensure a between-group effect of 80% at the 5% significance level, it was estimated that 60 participants needed to be included in the study. An effect size of Cohen's d=0.80 was expected. The expected standardized mean difference on the HHIE-total scale formed the basis of the obtained power. The within-group and between-group effect sizes of Cohen's d were calculated from T0-T1 and from T0-T2 and were categorized as small ($0.2 \leq d < 0.5$), moderate ($0.5 \leq d < 0.8$) and large ($0.8 \leq d$).

No significant differences were found between the groups at T0 for all the outcome measures. All data from the participants who did not complete T1 and/or T2 measurements were treated on an *intention to treat* (ITT) basis[40], meaning that the participants were included in the analysis (as missing data) regardless of their compliance or withdrawal from the study; see figure 1.

Given the ability to handle missing data[41], mixed effects models with compound symmetry as the covariance structure were used to analyze the HHIE, CSS and HADS. Differences between the intervention group and the control group were examined by modeling the interaction effects of group and time. A subgroup analysis was performed including two groups categorized as age-group: 20-59 years and age-group: 60-80 years.

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A sensitivity analysis was performed using mixed effects models for the HHIE, CSS and HADS, this time excluding subjects who did not complete all measurement time points (T1 and/or T2). Sensitivity analysis was performed to increase the understanding of the relationships between internet-based AR and the outcome measures, HHIE, CSS, and HADS.

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RESULTS

Attrition and adherence

Eight participants in the intervention group and five in the control group completed the study program but did not provide all T1 and/or T2 measurements, without giving a specific reason. Six participants in the intervention group and seven in the control group withdrew from participation in the study, as shown in figure 1. Five of those who withdrew from the study provided T1 measurements; four provided T2 measurements. One participant who was lost to follow-up at T1 provided T2 measurements. Consequently, 12 participants (16%) did not provide T1 measurements (of which n=1 followed up only with the HHIE), and 22 participants did not provide T2 measurements (30%). No significant differences were found when comparing the baseline values between those who discontinued the study program from T0-T1 and those who did not. Those who discontinued from T0-T2 had lower scores on baseline values for HHIE-total ($t(72)=-2.31$, $p=0.024$) and the *Emotional* subscale ($t(72)=-2.05$, $p=0.044$), and lower points on HADS-total ($t(72)=-2.73$, $p=0.008$) and the *Anxiety* ($t(72)=-2.03$, $p=0.046$) and *Depression* ($t(72)=-2.38$, $p=0.020$) subscales compared with those who continued with the study.

13% of the participants in the intervention group who completed the study program answered less than three (of four) of the weekly quizzes; and 26% provided less than four (of five) online weekly responses to the audiologist. However, all of these were active participants in conversations during the weekly telephone follow-up, and some stated a wish for the discussion forum to be more active because they considered that part of the intervention very interesting. On average, the participants posted 0.4 contributions to the discussion forum.

Primary outcome measure

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Both groups showed decreased HHIE-total scores T0-T1 (p<0.000) and T0-T2 (p<0.000). The interaction effect for HHIE-total T0-T1/T0-T2 was not significant. The results are presented in table 2, and the estimated marginal means (EMM) and standard errors of the outcome measures HHIE, CSS and HADS for both groups are presented as supplementary material in Complementary Appendix I. Both groups showed decreased scores for both of the HHIE subscales from T0-T1 (p<0.001) and T0-T2 (p<0.001). The interaction effect was not significant for T0-T1 for the *Social* subscale or for T0-T2 for the *Social* and *Emotional* subscale. A borderline significant interaction effect emerged for the *Emotional* subscale T0-T1 ($F_{(1,64.3)}$=3.8, p=0.054). Small to large between-group effect sizes were found for the HHIE, as shown in table 2.

Table 2. (n=74) Observed means (OM) and standard deviations (SD) of the outcome measures HHIE, CSS and HADS for both groups at pre-treatment (T0), post-treatment (T1) and 6-months post-treatment (T2). Cohen's pooled within-group and between-group small/moderate/large effect sizes (ES) and 95% confidence intervals (CI) for the intervention (I-group) and control group (C-group) are presented. *P-values* illustrate the significance of the difference in estimated marginal means between the intervention and control group. F-values illustrate the interaction effect for time x group (t x gr).

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			OM (SD)			ES (95% CI) Within-group		ES (95% CI) Between-group		Interaction effect (*p-value*) (F-value)	
			T0	T1	T2	T0-T1	T0-T2	T0-T1	T0-T2	T0-T1	T0-T2
HHIE											
Total		I-group	42.0 (16.9)	35.8 (15.2)	36.0 (15.8)	S (-0.08 to 0.84)	S (-0.10 to 0.82)	S (-0.16 to 0.76)		2.5 (*0.297*)	3.8 (*0.306*)
		C-group	36.1 (11.8)	31.3 (14.3)	34.0 (13.2)	S (-0.10 to 0.82)					
Social		I-group	20.2 (8.8)	18.3 (7.1)	18.2 (7.8)	S (-0.22 to 0.69)	S (-0.22 to 0.69)	S (-0.08 to 0.84)		0.4 (*0.732*)	1.8 (*0.224*)
		C-group	18.5 (6.6)	15.5 (7.3)	18.2 (7.1)	S (-0.03 to 0.89)					
Emotional		I-group	21.8 (9.5)	17.5 (9.4)	17.8 (9.5)	M (-0.01 to 0.91)	S (-0.04 to 0.88)		S (-0.22 o 0.69)	3.0 (*0.054*) (txgr=3.8)	1.9 (*0.132*)
		C-group	17.6 (7.3)	15.8 (8.2)	15.7 (8.3)	S (-0.23 to 0.69)	S (-0.22 to 0.70)				
CSS											
Total		I-group	68.1 (13.6)	74.7 (11.1)	70.9 (10.5)	M (-0.99 to -0.06)	S (-0.69 to 0.23)	M (0.06 to 0.98)	S (-0.08 to 0.84)	5.2 (*0.021*) (txgr=5.6)*	3.5 (*0.064*) (txgr=2.8)
		C-group	67.2 (11.3)	68.5 (12.4)	66.7 (11.6)						
Maladaptive		I-group	17.9 (4.5)	17.8 (5.7)	17.4 (4.3)			S (-0.23 to 0.69)		0.3 (*0.739*)	0.2 (*0.893*)
		C-group	17.2 (3.5)	16.7 (3.5)	17.3 (4.4)						
Verbal		I-group	22.6 (6.7)	25.8 (6.1)	24.1 (4.8)	M (-0.96 to -0.03)	S (-0.71 to 0.20)	S (-0.14 to 0.78)	S (-0.04 to 0.88)	1.2 (*0.299*)	1.4 (*0.455*)
		C-group	21.8 (5.6)	23.8 (6.4)	21.9 (5.5)	S (-0.79 to 0.13)					
Nonverbal		I-group	27.6 (6.9)	31.2 (4.8)	29.3 (4.8)	M (-1.07 to -0.13)	S (-0.74 to 0.17)	M (0.09 to 1.02)	S (-0.14 to 0.78)	3.7 (*0.004*) (txgr=9.2)**	1.9 (*0.011*) (txgr=4.7)*
		C-group	28.1 (6.2)	28.0 (6.5)	27.5 (6.2)						
HADS											
Total		I-group	8.5 (6.6)	7.5 (6.3)	4.8 (4.5)		M (0.18 to 1.12)		S (-0.84 to 0.08)	0.7 (*0.463*)	2.4 (*0.070*)
		C-group	7.4 (4.8)	6.5 (5.2)	6.8 (5.9)						
Anxiety		I-group	4.6 (3.8)	3.8 (3.4)	2.4 (2.0)	S (-0.24 to 0.68)	M (0.25 to 1.19)		M (-0.94 to -0.02)	0.6 (*0.198*)	1.4 (*0.071*)
		C-group	4.3 (3.2)	3.7 (3.1)	3.7 (3.2)						
Depression		I-group	3.9 (3.3)	3.7 (3.5)	2.6 (2.8)		S (-0.04 to 0.88)	S (-0.16 to 0.75)		0.0 (*0.984*)	1.1 (*0.171*)
		C-group	3.1 (2.5)	2.8 (2.4)	3.1 (2.9)						
HHIE Age groups											
Total	I-group	20-59 years	44.7 (13.6)	40.8 (13.3)	43.4 (14.6)	S (-0.17 to 0.74)		M (0.01 to 0.93)	L (0.39 to 1.35)	1.3 *(0.681)*	1.0 *(0.919)*
	C-group	20-59 years	38.0 (12.7)	34.0 (15.3)	31.6 (13.5)	S (-0.18 to 0.74)	M (0.02 to 0.95)				
	I-group	60-80 years	39.7 (19.3)	31.7 (15.8)	31.6 (15.2)	M (-0.01 to 0.91)	M (0.00 to 0.92)		S (-0.73 to 0.19)	3.5 *(0.344)*	5.5 *(0.282)*
	C-group	60-80 years	34.7 (11.1)	29.0 (13.3)	35.5 (13.3)	M (0.00 to 0.92)					
Social	I-group	20-59 years	21.2 (7.9)	19.6 (6.6)	21.0 (7,6)	S (-0.24 to 0.68)		S (-0.03 to 0.89)	S (-0.08 to 0.86)	1.1 *(0.570)*	1.3 *(0.604)*
	C-group	20-59 years	19.8 (7.0)	16.4 (8.0)	17.8 (8.9)	M (-0.01 to 0.91)	S (-0.21 to 0.71)				
	I-group	60-80 years	19.3 (9.6)	17.2 (7.4)	16.6 (7.7)	S (-0.21 to 0.70)	S (-0.15 to 0.77)	S (-0.12 to 0.79)	S (-0.73 to 0.19)	0.1 *(0.954)*	2.1 *(0.381)*
	C-group	60-80 years	17.5 (6.2)	14.8 (6.8)	18.5 (6.0)	S (-0.04 to 0.87)					
Emotional	I-group	20-59 years	23.5 (7.8)	21.2 (8.2)	22.4 (10.0)	S (-0.02 to 0.74)		S (-0.04 to 0.88)	L (0.48 to 1.44)	2.4 *(0.190)*	0.4 *(0.340)*
	C-group	20-59 years	18.3 (7.6)	17.6 (8.7)	13.8 (7.5)		M (0.12 to 1.06)				
	I-group	60-80 years	20.4 (10.7)	14.4 (9.3)	15.1 (8.3)	M (0.13 to 1.06)	M (0.08 to 1.01)		S (-0.66 to 0.25)	3.4*(0.158)*	3.5 *(0.212)*
	C-group	60-80 years	17.1 (7.3)	14.3 (7.7)	16.9 (8.9)	S (-0.09 to 0.83)					
CSS Age groups											
Total	I-group	20-59 years	68.8 (12.0)	76.4 (8.3)	73.5 (8.6)	M (-1.20 to -0.26)	M (-0.91 to 0.02)	S (-0.08 to 0.84)	M (0.06 to 0.99)	2.5 *(0.504)*	1.5 *(0.806)*
	C-group	20-59 years	67.7 (11.3)	72.3 (12.4)	69.2 (7.5)	S (-0.84 to 0.08)					

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	I-group	60-80 years	67.4 (15.1)	73.4 (10.6)	69.4 (11.4)	M (-0.92 to 0.01)					
	C-group	60-80 years	66.8 (11.5)	65.1 (11.6)	65.0 (13.8)			L (0.27 to 1.21)	S (-0.12 to 0.80)	7.8 (*0.004*) (txgr=9.3)**	5.5 (*0.017*) (txgr=4.3)*
Maladaptive	I-group	20-59 years	18.2 (4.1)	17.9 (5.8)	17.6 (2.5)						
	C-group	20-59 years	16.7 (3.5)	16.9 (3.2)	16.1 (3.5)			S (-0.25 to 0.67)	M (0.03 to 0.95)	1.0 (*0.426*)	0.1 (*0.631*)
	I-group	60-80 years	17.8 (5.0)	17.7 (5.8)	17.3 (5.1)						
	C-group	60-80 years	17.7 (4.3)	16.6 (3.9)	18.1 (4.8)	S (-0.19 to 0.72)		S (-0.24 to 0.68)		1.3 (*0.337*)	0.4 (*0.543*)
Verbal	I-group	20-59 years	23.0 (8.0)	26.4 (6.8)	25.3 (4.8)	M (0.91 to 0.01)	S (-0.80 to 0.11)				
	C-group	20-59 years	22.4 (5.5)	25.4 (6.6)	24.4 (3.2)	M (-0.95 to -0.03)	S (-0.90 to 0.02)		S (-0.24 to 0.68)	0.6 (*0.756*)	0.6 (*0.875*)
	I-group	60-80 years	22.2 (5.5)	25.3 (5.5)	23.5 (4.8)	M (-1.02 to -0.09)	S (-0.71 to 0.21)				
	C-group	60-80 years	21.4 (5.6)	22.4 (6.0)	20.2 (6.1)		S (-0.25 to 0.66)	M (0.04 to 0.96)	M (0.13 to 1.06)	1.8 (*0.231*)	2.8 (*0.190*)
Nonverbal	I-group	20-59 years	27.7 (5.6)	32.1 (4.1)	30.6 (4.9)	L (-1.36 to -0.41)	M (-1.01 to -0.08)				
	C-group	20-59 years	28.6 (5.5)	30.0 (6.5)	28.7 (4.2)	S (-0.69 to 0.23)		S (-0.01 to 0.84)	S (0.05 to 0.87)	2.8 (*0.106*)	1.9 (*0.318*)
	I-group	60-80 years	27.5 (8.0)	30.4 (5.2)	28.6 (4.8)	S (-0.89 to 0.03)					
	C-group	60-80 years	27.8 (7.3)	26.2 (6.1)	26.7 (7.3)	S (-0.22 to 0.69)		M (0.26 to 1.20)	S (-0.15 to 0.76)	4.7 (*0.010*) (txgr=7.4)*	2.2 (*0.019*) (txgr=4.2)*
HADS Age groups											
Total	I-group	20-59 years	9.5 (5.8)	9.4 (4.9)	6.5 (4.5)		M (0.11 to 1.03)				
	C-group	20-59 years	8.3 (4.3)	7.7 (4.5)	6.7 (7.4)		S (-0.20 to 0.72)	S (-0.10 to 0.82)		0.3 (*0.804*)	2.1 (*0.300*)
	I-group	60-80 years	7.7 (7.3)	5.9 (7.0)	4.1 (4.4)	S (-0.21 to 0.71)	M (0.13 to 1.06)				
	C-group	60-80 years	6.8 (5.2)	5.4 (5.7)	6.9 (4.9)	S (-0.20 to 0.71)			M (-1.06 to -0.13)	1.4 (*0.257*)	2.7 (*0.178*)
Anxiety	I-group	20-59 years	5.2 (3.6)	4.8 (3.2)	3.1 (2.0)		M (0.24 to 1.18)				
	C-group	20-59 years	5.1 (2.6)	4.7 (2.9)	4.2 (4.1)		S (-0.20 to 0.72)		S (-0.80 to 0.12)	0.1 (*0.858*)	1.5 (*0.198*)
	I-group	60-80 years	4.1 (4.0)	2.9 (3.5)	2.0 (1.9)	S (-0.14 to 0.77)	M (0.20 to 1.13)				
	C-group	60-80 years	3.7 (3.6)	2.8 (3.2)	3.4 (2.6)	S (-0.20 to 0.72)			M (-1.07 to -0.14)	1.0 (*0.117*)	1.3 (*0.254*)
Depression	I-group	20-59 years	4.3 (2.9)	4.6 (3.0)	3.4 (2.8)		S (-0.15 to 0.77)				
	C-group	20-59 years	3.2 (2.2)	3.0 (2.0)	2.6 (3.6)		S (-0.26 to 0.66)	M (0.15 to 1.09)	S (-0.21 to 0.70)	0.5 (*0.556*)	0.7 (*0.501*)
	I-group	60-80 years	3.6 (3.6)	3.0 (3.9)	2.1 (2.8)		M (-0.00 to 0.92)				
	C-group	60-80 years	3.1 (2.7)	2.6 (2.8)	3.5 (2.4)				S (-0.72 to 0.19)	0.4 (*0.678*)	1.3 (*0.278*)

Effect size below 0.2 is not reported in the table, S=small effect size ($0.2 \leq d < 0.5$), M=moderate effect size ($0.5 \leq d < 0.8$), L=large effect size ($0.8 \leq d$); HHIE: Hearing Handicap Inventory for the Elderly; *Social* and *Emotional* subscales. CSS: Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI); *Maladaptive*, *Verbal* and *Nonverbal* subscales. HADS: Hospital Anxiety and Depression Scale; *Anxiety* and *Depression* subscales.

*$p<0.05$, **$p<0.01$.

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Secondary outcome measures

Significantly greater improvement was found for the intervention group compared with the control group T0-T1 for the CSS-total ($F_{(1, 62.9)}$=5.6, p<0.05) and for the *Nonverbal* subscale ($F_{(1, 63.8)}$=9.2, p<0.01). This interaction effect persisted from T0-T2 for the *Nonverbal* subscale ($F_{(2, 115.8)}$=4.7, p<0.05), and was on the borderline for CSS-total ($F_{(2,114.4)}$=2.8, p=0.064). Moderate within-group effect sizes from T0-T1 were observed for the intervention group for the CSS-total and for the *Verbal* and *Nonverbal* subscales. Moderate between-group effect sizes were shown for the CSS-total and for the *Nonverbal* subscale T0-T1, as shown in table 2.

The analyses for HADS showed that both the intervention group and the control group improved their total scores over the time, and the analyses identified no significant differences when modeling the interaction effects from T0-T1 or T0-T2, as shown in table 2. Moderate within-group effect sizes were found for the HADS-total T0-T2, as shown in table 2.

Subgroup analysis

A subgroup analysis for different age groups was performed for the HHIE, CSS and HADS scores from T0-T1 and T0-T2. No significant interaction effect was found for the outcome measures HHIE and HADS from T0-T1 or T0-T2 for the age groups 20-59-years and 60-80-years, as shown in table 2. Nevertheless, a large between-group effect was found from T0-T2 for the HHIE-total score and for the *Emotional* subscale among the participants in the 20-59-year age group, as shown in table 2. The participants in the 60-80-year age group showed medium between-group effect sizes for the HADS-total scale and *Anxiety* subscale.

The CSS-total showed an interaction effect from T0-T1 ($F_{(1, 33.2)}$=9.3, p<0.01), indicating that the 60-80-years old in the intervention group showed significantly more improvement than the 60-80-year-olds in the control group. This effect persisted from T0-T2 ($F_{(2, 63.7)}$=4.3,

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$p<0.05$). There was also an interaction effect from T0-T1 for the *Nonverbal* subscale, with the 60-80-year-olds in the intervention group showing significantly greater improvement ($F_{(1, 33.7)}=7.4$, $p<0.05$) compared with the 60-80-year-olds in the control group. This effect persisted from T0-T2 ($F_{(2,64.1)}=4.2$, $p<0.05$). It may be noted that the participants of the age 60-80 years in the control group declined over time as measured by CSS-total and *Nonverbal* subscale, and that improvements in the intervention group were of small or moderate effect size. However, the younger subgroup (20-59 years of age), was improving over time in both the control (small effect sizes) and the intervention group (moderate or large effect sizes).

Sensitivity analysis

A sensitivity analysis was performed for the HHIE, CSS and HADS by excluding all data from the participants who did not complete all three measurement time points (T0, T1 and T2; n=50). However, 50 participants are not sufficient to ensure a between-group effect of 80%. Nonetheless, the sensitivity analysis revealed an interaction effect for the HHIE-*Emotional* subscale from T0-T1 ($F_{(1, 48.0)}=4.3$, $p<0.05$) with the intervention group showing an advantage, as shown in the Complementary Appendix II. This interaction effect did not remain 6 months post-treatment.

The interaction effect for the CSS-total that was achieved when participants were treated on an ITT basis (n=74) was not apparent in the sensitivity analysis (n=50). The results for the CSS showed an interaction effect for the *Nonverbal* subscale from T0-T1 ($F_{(1, 48.0)}=6.8$, $p<0.05$) and from T0-T2 ($F_{(2, 96.0)}=3.5$, $p<0.05$), with the intervention group showing significantly greater improvement compared with the control group, similar to the results for the whole group (n=74).

Furthermore, the sensitivity analysis showed significant results for the HADS-total scale from T0-T2 ($F_{(2, 96.0)}=3.1$, $p<0.05$), indicating that the intervention group's scores had improved

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more than those of the control group. The sensitivity analysis for the remaining scales and subscales showed no changes in significance compared with the previous analysis (n=74), as shown in Complementary Appendix II.

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DISCUSSION

The aim of this study was to evaluate whether internet-based AR for HA users would be effective in GCP and whether the assumed positive effect of participating in the internet-based AR program would be maintained 6 months after the program was completed. Our aim was also to analyze the effect of the program in two age-groups.

Both the intervention group and the control group improved their HHIE scores from T0-T1 and from T0-T2; however, the improvements were not significantly different between groups, unlike the findings of our research group's previous study[18] (for demographics, see Table 1). Differences in the results could be related to differences in the recruitment process. In our previous study[18], the participants were recruited through advertisements and articles in Swedish national daily newspapers and on the Internet; the recruited participants were well educated and had a higher education level than the general population. This indicated that the intervention program is well suited for educated patients, although education was not a significant predictor of intervention outcomes[42]. This recruitment strategy recruited participants who actively sought involvement in research. Additionally, the participants were somewhat older and were more experienced HA users than the participants in the current study. Thus, the internet-based intervention program may be more suited for older adults and experienced HA users, than for younger adults and less experienced. Also, the participants in the current study received similar clinical treatments prior to participating in the study, which may impact the effectiveness of the current study, in particular if the participants' experience positive clinical treatment outcomes. Another underlying explanation for the differences in improvement could be that the control group was more active in the present study compared with our previous study[18], in which the participants read a book about the history of HAs, though not online. Participants being enrolled in a research study might generally be more positive afterward their participation[43], which could be considered research bias assuming that

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the full internet-based AR is more effective than one element of the program. A borderline significant interaction effect emerged for the HHIE *Emotional* subscale from T0-T1, indicating that the full internet-based AR could have had a positive impact on the emotional effects of the participants' hearing loss. This could be due to the *reading* and *home training* element that by educating raises participants' abilities, which can lead to increased self-esteem. This increased self-esteem might be additionally acknowledged by the audiologist during the weekly telephone consultations.

The sensitivity analysis that was performed (n=50) revealed an interaction effect for the HHIE-*Emotional* subscale from T0-T1, for the CSS-*Nonverbal Strategies* subscale from T0-T1 and from T0-T2; and for the HADS-total scale from T0-T2; all interaction effects indicated an advantage for the intervention group. It appears that participants who were especially persistent and who participated in all aspects of the full internet-based AR or were just conscientious may show changes in the HHIE score and in their communications skills, and changes in symptoms of anxiety and depression. Thus, the sensitivity analysis makes the study underpowered, and these interaction effects should be treated with caution.

The participants who did not provide T0-T2 measurements for present study had lower baseline scores on the HHIE and HADS compared with those who continued in the present study, indicating that insubstantial self-reported social and emotional effects of hearing loss as well as anxiety and depression symptoms can influence the decision to drop out. Laplante-Lévesque et al[42] showed that greater self-reported hearing disability is one of the predictors for intervention uptake and positive outcomes. Another potential influencing factor might be that it is easier to drop out when the intervention is internet-based, as discussed by Andersson et al[44].

In our earlier research, the HHIE was an appropriate measure for the outcomes of telephone-supported AR beyond HA fitting in GCP[17]; in that study, the program for the intervention

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group did not include parts of the ACE program, which targets the communication difficulties experienced by older people with hearing impairment in everyday life[37-38]. In the clinical population of the present study, we found effects for the CSS-total and the *Nonverbal* subscale; thus, it seems that participating in the full internet-based AR program containing the ACE program has a larger effect on communication skills compared with partial participation. Determining the element responsible for the interaction improvement in the present study is challenging. The *reading* and *home training* elements of the full internet-based AR program might have contributed to improved communication skills, but so, too, might the telephone follow-up by the audiologist. Having personal phone contact with an audiologist may have encouraged the participants to try out the program's suggested strategies. The effect on the CSS, however, raises doubts about the applicability of the HHIE as a main outcome measure for the present study (e.g. power calculation and sample size).

The intervention and control groups were also analyzed using subgroups. The 60-80-year-olds in the intervention group obtained significantly greater improvement compared with the 60-80-year-olds in the control group in terms of the CSS-total and the *Nonverbal* subscale, contradicting our hypothesis that the 20-59-year-age group would be more receptive to internet-based AR. As mentioned, the ACE program targets the everyday life of older people, which may have been reflected in the results of the CSS subgroup analysis. However, it might be that the decline in scores as measured by CSS-total and the *Nonverbal* subscale for the 60-80-year-olds in the control group contributes to that the small effect in the intervention group becomes more pronounced in this subgroup than the differences in the improvements seen in both control and intervention group in the younger subgroup (20-59 years). Additionally, it might be that the older adults use more non-verbal strategies when communicating because of their presumably grater cognitive demands when trying to understand speech[45]. However, the subgroup analysis includes small groups and these results should be treated with caution.

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Thorén et al[18] found significant improvements in the intervention group when measuring participants' psychosocial well-being using the HADS. Our results showed that both the intervention group and the control group showed improved HADS scores, although the difference between the groups was not significant. Preminger[46] reviewed the importance of taking psychosocial outcomes into account when implementing group adult aural rehabilitation and highlighted the importance of outcome studies. The HADS is believed to be sensitive enough to detect the effects of online education[16, 18].

Limitations

One limitation is that the participants in this study have been HA users for an average of 7.5 years. In our previous study in a GCP setting, that number was 6.5 years[17]; for Thorén et al, the average was 9.9 years[18]. Despite inclusion criteria that acknowledged the heterogeneity of a clinical population, the participants in the present study were experienced HA users. However, new HA users are more likely to benefit from educational programs, compared to experienced HA users[13]. Thus, although different aspects of AR may not suit every individual client, the current study increases the confidence that the clinical use of group AR will likely have positive outcomes[47]. Additionally, included participants were asked to sign-up via the Internet and are thus competent Internet users, which would likely impact the effectiveness of the current study. Another limitations are that the control group received an active intervention, and only one of the 4 elements of the program. We are unaware of the relative benefit of any other element alone/combination of elements might have as compared to the full intervention. A more clear result may generate from a control group that receives no intervention.

Another concern that needs to be mentioned is that the observed standardized mean difference on the HHIE between the intervention and control group was much lower than what was

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expected when comparing with previous research and anticipated in the sample size calculation; also, the standard deviation was larger than expected. Thus, increasing the sample size initially could maybe result in statistically significant difference between the groups; nevertheless, it is not certain that the standardized mean difference between the groups in a larger sample would lead to clinically meaningful difference for the participants.

Conclusion

The internet-based approach expands the availability of AR in GCP, offering accessibility to many people, including hard-to-reach populations[48]. The present study shows that using the Internet for interactions between the audiologist and the HA user had a positive effect on communication skills for the intervention group compared with the control group. Furthermore, the full internet-based AR program was not more effective than one element of the internet-based AR program. However, the advantages of an internet-based approach, both for the patient and the clinician[47], may inspire clinicians and operation managers in their future utilization of comprehensive AR in addition to HA fitting.

More research is needed to examine the efficacy and applicability of this type of intervention. This study is one of the first RCTs in Sweden to implement internet-based rehabilitation beyond conventional HA fitting in a GCP; and is explicitly at the beginning of exploring the possible clinical applicability of this type of intervention. Further analysis is needed to examine the individual elements of the full internet-based AR program to evaluate which part of the internet-supported educational intervention had the greatest effect: the reading material, the weekly assignments, the discussion forum, or the contact with the audiologist. In addition, guided internet-based intervention should be compared with face-to-face AR to analyze whether the two approaches are equally effective. Also, this type of internet-based intervention delivered exclusively to new HA users should be compared to a matched group

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who only receive HA in order to know the relative efficacy of the internet-based AR program. Additionally, the individual needs of the HA user should be taken into account when designing group AR, as should including significant others in the intervention.

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A report of the trial was presented at the First International Meeting on the Internet and Audiology 3-4 October 2014, Linköping, Sweden.

Contributors

GA, TL and MM contributed to the conception and design of the study, and to the acquisition of data for the study. MM contributed to data collection and analyzed the data. GA, TL, MM and KK contributed to the analysis of data and participated in interpretation of data for the study; in drafting the study and revising it critically for important intellectual content and in giving final approval of the version to be published. GA, TL and KK provided continuous supervision during the entire study.

Competing interest

The authors declare no competing interests.

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Data sharing statement

No additional data available.

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REFERENCES

1. World Health Organization. International Classification of Functioning, Disability and Health (ICF). Geneva: World Health Organization 2001.
2. Boothroyd A. Adult aural rehabilitation: what is it and does it work? *Trends in Amplif* 2007;11(2):63-71. doi: 10.1177/1084713807301073.
3. Hickson L, Worall L. Beyond hearing aid fitting: improving communication for older adults. *Int J Audiol* 2003;42(2):S84-91. doi:10.3109/14992020309074649.
4. Hawkins D. Effectiveness of Counselling-Based Adult Group Aural Rehabilitation Programs: A Systematic Review of Evidence. *J Am Acad Audiol* 2005;16:485-93. doi: http://dx.doi.org/10.3766/jaaa.16.7.8.
5. Hickson L, Worall L, Scarinci N. Measuring outcomes of a communication program for older people with hearing impairment using the International Outcome Inventory. *Int J Audiol* 2006;45:238-46. doi:10.1080/14992020500429625.
6. Chisolm T, Arnold M. Evidence about the effectiveness of aural rehabilitation programs for adults. In: Wong L, Hickson L, eds. Evidence-based practice in audiology: Evaluating interventions for children and adults with hearing impairment. San Diego, CA: Plural 2012:237-66.
7. Abrams H, Hnath-Chisolm T, McArdle R. A cost-utility of adult group audiologic rehabilitation: Are the benefits worth the cost? *J Rehabil Res Dev* 2002;39(5):549-58.
8. Kochkin S. Marke Trak VIII: 25-years in trends in the hearing health market. *Hearing review* 2009;16(11):12-31.
9. Grenness C, Hickson L, Laplante-Lévesque A, et al. Patient-centred care: A review for rehabilitative audiologists. *Int J Audiol* 2014;53(Suppl 1):P60-7. doi:10.3109/14992027.2013.847286.

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10. McCormack A, Fortnum H. Why do people fitted with hearing aids do no wear them? *Int J Audiol* 2013;52:360-8. doi:10.3109/14992027.2013.769066.

11. Knudsen LV, Öber M, Nielsen C, et al. Factors Influencing Help Seeking, Hearing Aid Uptake, Hearing Aid Use and Satisfaction With Hearing Aids: A Review of the Litterature. *Trends in Amplif* 2010;14(3):127-54. doi: 10.1177/1084713810385712.

12. Laplante-Lévesque A, Hickson L, Worall L. Rehabilitation of older adults with hearing impairment: a critical review. *J Aging Health* 2010;22(2):143-53. doi:10.1177/0898264309352731.

13. Kramer SE, Allesie GHM, Dondorp AW, et al. A home education program for older adults with hearing impairment and their significant others: A randomized trial evaluating short- and long-term effects. *Int J Audiol* 2005;44:255-64. doi: 10.1080/14992020500060453.

14. Laplante-Lévesque A, Pichora-Fuller MK, Gagne JP. Providing an internet-based audiological counselling programme to new hearing aid users: a qualitative study. *Int J Audiol* 2006;45:697-706. doi:10.1080/14992020600944408.

15. Sweetow RW, Henderson SJ. Technologic advices in aural rehabilitation: applications and innovative methods of service delivery. *Trends in Amplif* 2007;11:101-11. doi: 10.1177/1084713807301321.

16. Thorén E, Svensson M, Törnqvist A, et al. Rehabilitative online education versus internet, discussion group for hearing aid users: a randomized controlled trial. *J Am Acad Audiol* 2011;22:274-85. doi: 10.3766/jaaa.22.5.4.

17. Lundberg M, Andersson G, Lunner T. A randomized, controlled trial of the short-term effects of complementing an educational program for hearing aid users with telephone consultations. *J Am Acad Audiol* 2011;22(10):654-62. doi: 10.3766/jaaa.22.10.4.

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18. Thorén ES, Öberg M, Wänström G, et al. A randomized controlled trial evaluating the effects of online rehabilitative intervention of adult hearing-aid users. *Int J Audiol* 2014;53:452-61. doi:10.3109/14992027.2014.892643.

19. Ferguson M, Brandreth M, Brassington W, et al. A Randomized Controlled Trial to Evaluate the Benefits of a Multimedia Educational Program for First-Time Hearing Aid Users. *Ear Hear* 2016;37(2):123-36. doi: 10.1097/AUD.0000000000000237.

20. Molini-Avejonas DR, Rondon-Melo S, De la Higuera Amato CA, et al. A systematic review of the use of telehealth in speech, language and hearing sciences. *J Telemed Telecare* 2015;21:367-76. doi: 10.1177/1357633X15583215.

21. Barak A, Sadovsky Y. Internet use and personal empowerment of hearing-impaired adolescents. *Comput Human Behav* 2008;24:1802-15. doi:10.1016/j.chb.2008.02.007.

22. Henshaw H, Clark Daniel PA, Kang S, et al. Computer Skills and Internet Use in Adults Aged 50-74 Years: Influence of Hearing Difficulties. *J Med Internet Res* 2012;14(4):e113. doi:10.2196/jmir.2036.

23. Sundewall ET, Öberg M, Wänström G, et al. Internet Access and Use in Adults With Hearing Loss. *J Med Internet Res* 2013;15(5):e91. doi: 10.2196/jmir.2221.

24. Kaldo-Sandström V, Larsen HC, Andersson G. Internet-Based Cognitive-Behavioral Self-Help Treatment of Tinnitus: Clinical Effectiveness and Predictors of Outcome. *Am J Audiol* 2004;13:185-92. doi:10.1044/1059-0889(2004/023).

25. Hedman E, Ljótsson B, Rück C, et al. Effectiveness of Internet-based cognitive behaviour therapy for panic disorder in routine psychiatric care. *Acta Psychiat Scand* 2013;128:457-67. doi: 10.1111/acps.12079.

26. Moore AN, Rothpletz AM, Preminger JE. The effect of chronological age on the acceptance of Internet-based hearing health care. *Am J Audiol* 2015; 24:280-3. doi: 10.1044/2015_AJA-14-0082.

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27. Hopewell S, Clarke M, Moher D, et al. CONSORT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts: Explanation and Elaboration. *PLoS Med* 2008;5(1):e20. doi:10.1371/journal.pmed.0050020.

28. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *Int J Surg* 2012;10(1):28-55. doi:10.1016/j.jclinepi.2010.03.004.

29. Ventry IM, Weinstein BE. The Hearing Handicap Inventory for the Elderly: a new tool. *Ear Hear* 1982;3(3):128-34.

30. Demorest ME, Erdman SA. Development of the Communication profile for the hearing impaired. *J Speech Hear Disord* 1987;52(2):129-43. doi:10.1044/jshd.5202.129.

31. Zigmod AS, Snaith RP. The Hospital Anxiety Depression Scale. *Acta Psychiatr Scand* 1983;67:361-70. doi: 10.1111/j.1600-0447.1983.tb09716.

32. Cox R, Hyde M, Gatehouse S, et al. Optimal Outcome Measures, Research Priorities, and International Cooperation. *Ear Hear* 2000;21(Suppl 4):P106-15.

33. Öberg M, Lunner T, Andersson G. Psychometric evaluation of hearing specific self-report measures and their associations with psychosocial and demographic variables. *Audiol Med* 2007;5:188-99. doi:10.1080/16513860701560214.

34. Hallberg LRM, Eriksson-Mangold M, Carlsson SG. Psychometric evaluation of a Swedish version of the Communication Strategies Scale of the Communication Profile for the Hearing Impaired. *J Speech Hear Res* 1992;35:666-74. doi:10.1044/jshr.3503.666.

35. Sundewall ET, Andersson G, Lunner T. The use of research questionnaires with hearing impaired adults: online vs. paper-and pencil administration. *BMC Ear Nose Throat Disord* 2012;12:12. doi:10.1186/1472-6815-12-12.

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36. Elberling C, Worsøe K. When the sounds are weaker - on hearing and hearing aids. Herlev: Bording A/S 2006.

37. Hickson L, Worrall L, Scarinci N. A randomized controlled trial evaluating the active communication education program for older people with hearing impairment. *Ear Hear* 2007;28:212-30. doi: 10.1097/AUD.0b013e31803126c8.

38. Öberg M, Bohn T, Larsson U. Short- and Long-Term Effects of the Modified Swedish Version of the Active Communication Education (ACE) Program for Adults with Hearing Loss. *J Am Acad Audiol* 2014;25(9):848-58. doi: 10.3766/jaaa.25.9.7.

39. SPSS (data analysis software system). Statistical Package for the Social Sciences for Windows. Version 19.0. www.spss.com 2011.

40. Fergusson D, Aaron SD, Guyatt G, et al. Post-randomisation exclusions: the intention to treat principle and excluding patients from analysis. *BMJ* 2002;325:652-4. doi: http://dx.doi.org/10.1136/bmj.325.7365.652.

41. Gueorguieva R, Krystal JH. Move Over ANOVA. Progress in Analyzing Repeated-Measures Data and Its Reflection in Papers Published in the Archives of General Psychiatry. *Arch Gen Psychiatry* 2004;61:310-17. doi:10.1001/archpsyc.61.3.310.

42. Laplante-Lévesque A, Hickson L, Worall L. What makes adults with hearing impairment take up hearing aids or communication programs and achieve successful outcomes? *Ear Hear* 2011;32(5):1-15. doi: 10.1097/AUD.0b013e31822c26dc.

43. Linde L, Fässler M, Meissner K. Placebo interventions, placebo effects and clinical practice. *Phil Trans R Soc B* 2011;366:1905-12. doi: 10.1098/rstb.2010.0383.

44. Andersson G, Strömgren T, Ström L, et al. Randomized Controlled Trial of Internet-Based Cognitive Behavior Therapy for Distress Associated With Tinnitus. *Psychosom Med* 2002;64(5):810-6. doi: 10.1097/01.PSY.0000031577.42041.F8.

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45. Pichora-Fuller MK. Processing speed and timing in aging adults: psychoacoustics, speech perception, and comprehension. *Int J Audiol* 2003;42(Suppl 1):P59-67. doi: 10.3109/14992020309074625.

46. Preminger JE. Issues Associated With the Measurement of Psychosocial Benefits of Group Audiologic Rehabilitation Programs. *Trends in Amplif* 2007;11(2):113-23. doi: 10.1177/1084713807301084.

47. Malmberg M, Lunner T, Kähäri K, et al. Implementing internet-based aural rehabilitation in a general clinical practice. *Am J Audiol* 2015;24, 325-8.

48. Swanepoel de W, Hall JW III. A systematic review of telehealth applications in audiology. *Telemed J E Health* 2010;16(2):181-200. doi:10.1089/tmj.2009.0111.

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Figure 1. Flowchart for the study procedure. Sets 1 + 2 of the recruitment process are presented in parentheses [n=set1+set2]. Set 1=20-59-year age group, set 2=60-80-year age group. *HHIE, Hearing Handicap Inventory for the Elderly; CSS, Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI); HADS, Hospital Anxiety and Depression Scale; IOI-HA, International Outcome Inventory for Hearing Aids.

Figure 2. The full internet-based program outlined for the intervention group and the element of the internet-based program outlined for the control group. The full internet-based program consisted of four elements: reading, home training, interaction with an audiologist, and interaction with peers in an internet-based discussion forum. Weeks 1-4 of the intervention concluded with a quiz. The small part of the internet-based program consisted of the reading element.

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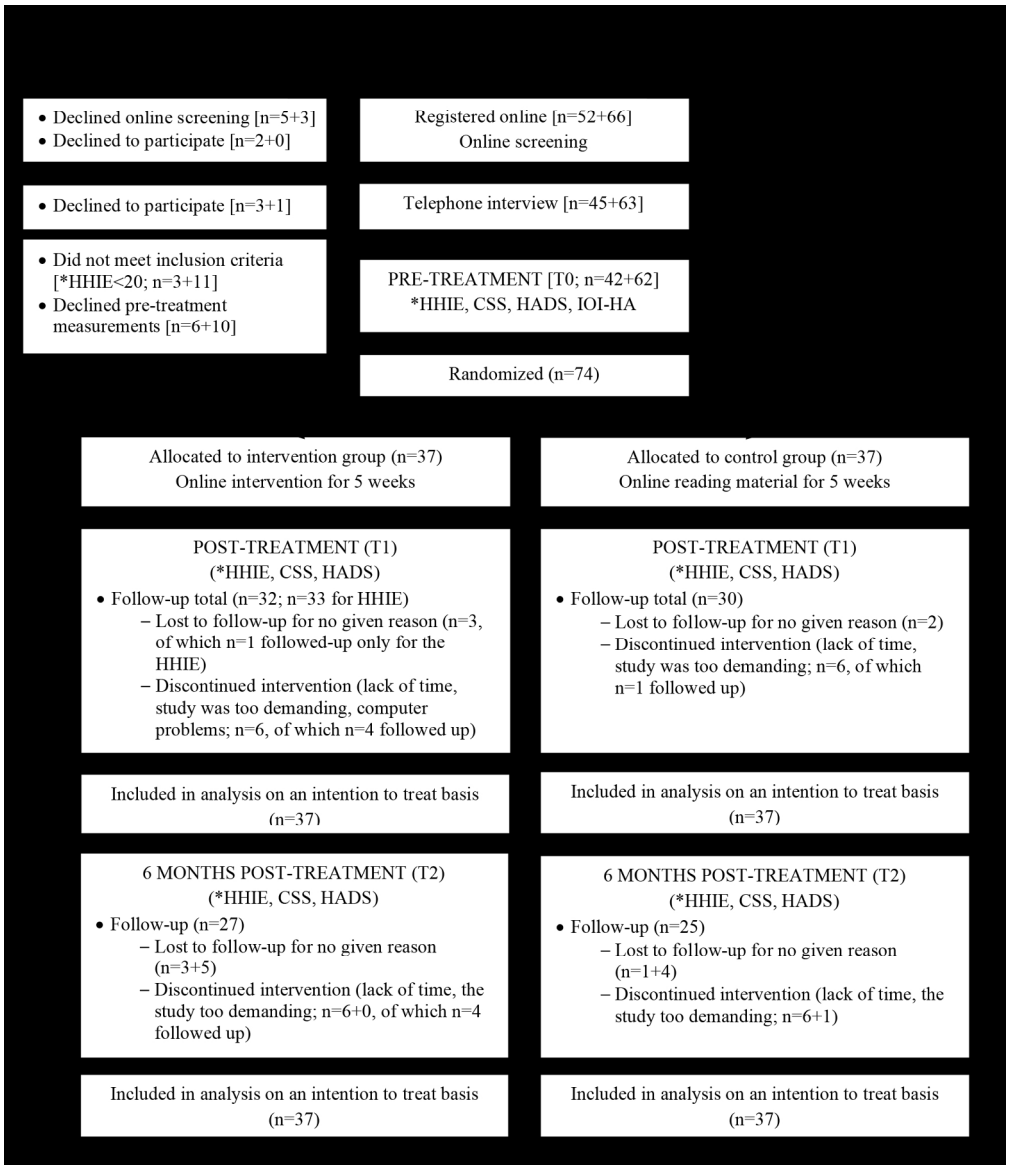

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168x195mm (300 x 300 DPI)

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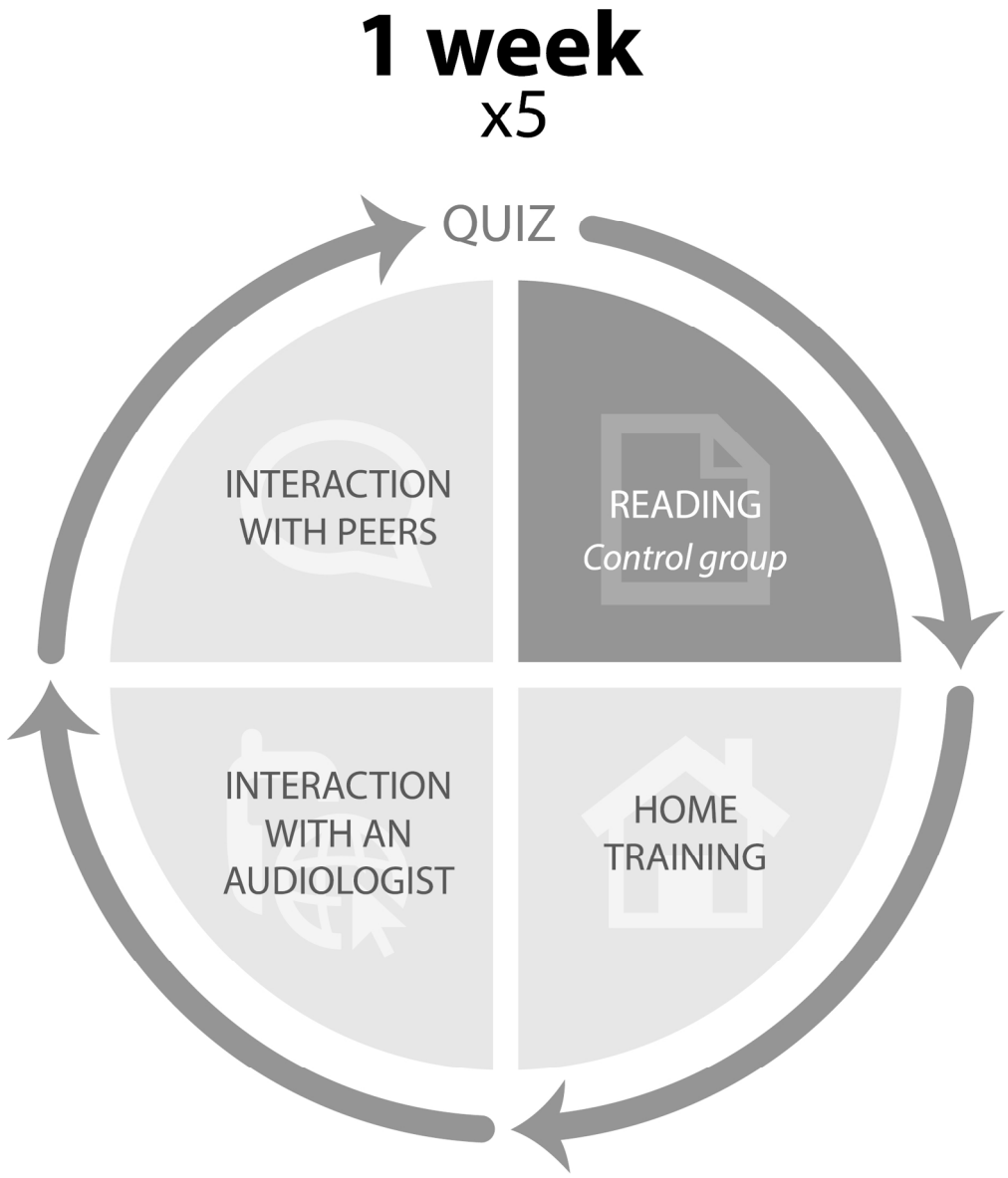

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Complementary Appendix I. (n=74) Estimated marginal means (EMM) and standard error (Std.Error) of the outcome measures HHIE, CSS and HADS for both groups at pre-treatment (T0), post-treatment (T1) and 6-months post-treatment (T2).

	EMM (Std. Error)					
	Intervention group			Control group		
Scale	T0	T1	T2	T0	T1	T2
HHIE-Total						
Total	42.0 (2.4)	35.1 (2.5)	37.8 (2.5)	36.1 (2.4)	31.7 (2.5)	35.7 (2.6)
20-59 years	44.7 (3.3)	39.3 (3.4)	42.2 (3.7)	38.0 (3.4)	33.9 (3.5)	36.5 (3.7)
60-80 years	39.7 (3.4)	31.7 (3.4)	34.5 (3.5)	34.7 (3.3)	29.9 (3.5)	35.0 (3.5)
HHIE-*Social*						
Total	20.2 (1.2)	18.0 (1.3)	18.9 (1.3)	18.5 (1.2)	15.7 (1.3)	19.1 (1.3)
20-59 years	21.2 (1.8)	19.0 (1.9)	20.2 (2.1)	19.8 (1.9)	16.5 (1.9)	20.1 (2.1)
60-80 years	19.3 (1.7)	17.1 (1.7)	17.9 (1.7)	17.5 (1.7)	15.2 (1.7)	18.3 (1.8)
HHIE-*Emotional*						
Total	21.8 (1.4)	17.2 (1.5)	18.9 (1.5)	17.6 (1.4)	15.9 (1.5)	16.6 (1.5)
20-59 years	23.5 (2.0)	20.3 (2.0)	22.0 (2.2)	18.3 (2.1)	17.4 (2.1)	16.3 (2.2)
60-80 years	20.4 (2.0)	14.6 (2.0)	16.5 (2.0)	17.1 (1.9)	14.7 (2.1)	16.8 (2.1)
CSS-Total						
Total	68.1 (2.0)	74.4 (2.0)	71.9 (2.1)	67.2 (2.0)	68.1 (2.1)	67.6 (2.2)
20-59 years	68.8 (2.6)	75.9 (2.8)	73.4 (3.1)	67.7 (2.6)	72.2 (2.8)	70.7 (3.1)
60-80 years	67.4 (2.9)	73.4 (2.9)	71.1 (3.0)	66.8 (2.8)	64.6 (3.0)	65.0 (3.0)
CSS-*Maladaptive*						
Total	17.9 (0.7)	17.7 (0.8)	18.1 (0.8)	17.2 (0.7)	16.5 (0.8)	17.2 (0.8)
20-59 years	18.1 (1.0)	17.1 (1.0)	17.7 (1.1)	16.7 (1.0)	16.7 (1.1)	16.3 (1.1)
60-80 years	17.8 (1.1)	18.0 (1.1)	18.4 (1.1)	17.7 (1.1)	16.3 (1.2)	17.9 (1.2)
CSS-*Verbal*						
Total	22.6 (1.0)	25.8 (1.0)	24.1 (1.1)	21.8 (1.0)	23.7 (1.1)	22.0 (1.1)
20-59 years	23.0 (1.6)	26.5 (1.6)	24.6 (1.8)	22.4 (1.6)	25.4 (1.7)	24.6 (1.8)
60-80 years	22.2 (1.3)	25.2 (1.3)	23.7 (1.3)	21.4 (1.2)	22.4 (1.3)	20.1 (1.4)
CSS-*Nonverbal*						
Total	27.6 (1.0)	31.0 (1.0)	29.7 (1.1)	28.1 (1.0)	27.8 (1.0)	28.3 (1.1)
20-59 years	27.7 (1.3)	32.1 (1.4)	30.9 (1.5)	28.6 (1.3)	30.1 (1.4)	29.9 (1.5)
60-80 years	27.5 (1.5)	30.3 (1.5)	28.8 (1.5)	27.8 (1.4)	25.9 (1.5)	27.0 (1.5)
HADS-Total						
Total	8.5 (1.0)	7.6 (1.0)	6.3 (1.0)	7.4 (1.0)	7.0 (1.0)	7.6 (1.0)
20-59 years	9.5 (1.2)	9.6 (1.3)	6.9 (1.4)	8.3 (1.3)	8.0 (1.3)	7.7 (1.4)
60-80 years	7.7 (1.4)	5.9 (1.4)	5.6 (1.4)	6.8 (1.4)	6.3 (1.4)	7.3 (1.4)
HADS-*Anxiety*						
Total	4.6 (0.6)	3.9 (0.6)	3.1 (0.6)	4.3 (0.6)	4.1 (0.6)	4.2 (0.6)
20-59 years	5.2 (0.8)	5.0 (0.8)	3.5 (0.8)	5.1 (0.8)	5.0 (0.8)	4.8 (0.9)
60-80 years	4.1 (0.8)	3.0 (0.8)	2.8 (0.8)	3.7 (0.8)	3.5 (0.8)	3.7 (0.8)
HADS-*Depression*						
Total	4.0 (0.5)	3.7 (0.5)	3.1 (0.5)	3.1 (0.5)	2.9 (0.5)	3.4 (0.5)
20-59 years	4.3 (0.7)	4.6 (0.7)	3.4 (0.8)	3.2 (0.7)	3.0 (0.7)	3.0 (0.8)
60-80 years	3.6 (0.7)	2.9 (0.7)	2.8 (0.7)	3.0 (0.7)	2.8 (0.7)	3.6 (0.8)

HHIE: Hearing Handicap Inventory for the Elderly, *Social* and *Emotional* subscales. CSS: Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI), *Maladaptive*, *Verbal* and *Nonverbal* subscales. HADS: Hospital Anxiety and Depression Scale, *Anxiety* and *Depression* subscales.

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Complementary Appendix II. Sensitivity analysis (n=50). Observed means (OM) and standard deviations (SD) of the outcome measures HHIE, CSS and HADS for both groups at pre-treatment (T0), post-treatment (T1) and 6-months post-treatment (T2). *P-values* illustrate the significance of the difference in estimated marginal means between the intervention and control group. F-values illustrate the interaction effect for time x group (txgr).

	OM (SD)			T0-T1	T0-T2	T0-T1, (txgr)	T0-T2, (txgr)
Scale	T0	T1	T2	(*p-value*)	(*p-value*)	F-value	F-value
HHIE-Total							
I-group	40.2 (17.2)	33.5 (15.6)	36.0 (16.1)	3.3 (*0.252*)	4.5 (*0.238*)	1.3	1.5
C-group	33.8 (10.1)	30.4 (11.9)	34.2 (13.4)				
HHIE-*Social*							
I-group	19.4 (9.0)	17.6 (7.2)	18.3 (8.0)	0.4 (*0.788*)	2.2 (*0.171*)	0.1	1.8
C-group	17.3 (5.6)	15.2 (6.5)	18.5 (7.2)				
HHIE-*Emotional*							
I-group	20.8 (9.8)	15.9 (9.4)	17.7 (9.7)	3.7 (*0.043*)	2.2 (*0.099*)	4.3*	2.4
C-group	16.5 (7.0)	15.3 (7.2)	15.7 (8.5)				
CSS-Total							
I-group	67.2 (14.6)	72.5 (10.5)	70.5 (10.4)	3.9 (*0.141*)	2.3 (*0.364*)	2.2	1.0
C-group	66.8 (10.0)	68.2 (11.0)	67.8 (10.6)				
CSS-*Maladaptive*							
I-group	17.1 (3.6)	16.4 (3.5)	17.0 (3.6)	0.6 (*0.523*)	0.4 (*0.818*)	0.4	0.2
C-group	17.1 (3.6)	17.0 (3.4)	17.4 (4.4)				
CSS-*Verbal*							
I-group	23.0 (6.8)	25.6 (6.2)	24.2 (4.9)	0.7 (*0.591*)	0.9 (*0.803*)	0.3	0.2
C-group	22.0(4.9)	23.8 (5.9)	22.3 (5.3)				
CSS-*Nonverbal*							
I-group	27.1 (7.9)	30.6 (4.9)	29.4 (4.9)	3.8 (*0.012*)	1.8 (*0.036*)	6.8*	3.5*
C-group	27.6 (5.3)	27.3 (6.0)	28.1 (5.7)				
HADS-Total							
I-group	7.4 (5.8)	6.2 (5.4)	5.2 (4.5)	1.3 (*0.166*)	2.8 (*0.048*)	2.0	3.1*
C-group	6.2 (4.5)	6.3 (5.2)	6.8 (6.0)				
HADS-*Anxiety*							
I-group	3.9 (3.4)	3.2 (3.1)	2.5 (2.0)	0.6 (*0.298*)	1.5 (*0.078*)	1.1	2.6
C-group	3.7 (2.7)	3.5 (3.1)	3.8 (3.3)				
HADS-*Depression*							
I-group	3.4 (2.8)	3.0 (2.7)	2.7 (2.9)	0.7 (*0.185*)	1.4 (*0.089*)	1.8	2.5
C-group	2.5 (2.1)	2.8 (2.5)	3.0 (3.0)				

**p<0.05*; HHIE: Hearing Handicap Inventory for the Elderly, *Social* and *Emotional* subscales. CSS: Communication Strategies Scale of the Communication Profile for the Hearing Impaired (CPHI), *Maladaptive*, *Verbal* and *Nonverbal* subscales. HADS: Hospital Anxiety and Depression Scale, *Anxiety* and *Depression* subscales. I-group: intervention group; C-group: control group.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-6
	2b	Specific objectives or hypotheses	5-6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	na
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	10-13
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7-13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	na
Sample size	7a	How sample size was determined	7-8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	na
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7-8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

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		assessing outcomes) and how	8
	11b	If relevant, description of the similarity of interventions	10-13
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	13-14
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	13-14
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Fig 1, table 1&2
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1, page15
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7-8,12-13
	14b	Why the trial ended or was stopped	na
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	9
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1, 13-14
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	15-21
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	na
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	na
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	na
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	25-26
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	25-27
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	22-27
Other information			
Registration	23	Registration number and name of trial registry	3,7
Protocol	24	Where the full trial protocol can be accessed, if available	8
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	27-28

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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