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Hearing aid effectiveness after aural rehabilitation: Individual versus group trial results

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Abstract—We designed this noninferiority randomized trial to determine (1) if group hearing aid fitting visits and group hearing aid follow-up visits were at least as effective as individual visits in terms of hearing-related function (measured with the Inner Effectiveness of Auditory Rehabilitation [EAR] scale) and adherence, and (2) if group visits were less costly over the 6 mo postfitting period. For 644 participants randomized to receive their hearing aid visits in an individual or group format at the Department of Veterans Affairs Puget Sound Health Care System, 6 mo outcomes showed no significant differences in Inner EAR scores between individual and group fitting ($p = 0.53$) or follow-up ($p = 0.11$), or in the number of hours per day hearing aids were worn between individual and group fitting ($p = 0.90$) or follow-up ($p = 0.24$). We found significantly higher cost for individual compared with group fitting ($p < 0.001$) and follow-up ($p < 0.001$). We conclude that outcomes for group hearing aid fitting and hearing aid follow-up visits were not inferior to individual hearing aid fitting and follow-up visits, with group fitting and follow-up visits yielding cost savings.

Clinical Trial Registration: ClinicalTrials.gov, NCT00260663, "The Hearing Aid Effectiveness After Aural Rehabilitation (HEAR) Trial"; http://clinicaltrials.gov/ct2/show/NCT00260663

Key words: education, group visits, health resources, health services research, hearing aids, hearing loss, outcome assessment, patient satisfaction, rehabilitation of hearing impaired, Veterans.

INTRODUCTION

In fiscal year 2011, the Department of Veterans Affairs (VA) reported 702,000 Veterans with a hearing loss disability. The prevalence of hearing impairment in Veterans was

Abbreviations: AdHeRe = Adherence to Hearing Rehabilitation, CI = confidence interval, CPHI = Communication Profile for the Hearing Impaired, CPRS = Computerized Patient Record System, CPT = current procedural terminology, EAR = Effectiveness of Auditory Rehabilitation, HEARING = Hearing Aid Effectiveness After Aural Rehabilitation: Individual Versus Group, HHIE = Hearing Handicap Inventory for the Elderly, HL = hearing level, IOI-HA = International Outcome Inventory for Hearing Aids, MB = maladaptive behaviors, MCID = minimum clinically important difference, MCS = mental component score, NS = nonverbal strategies, PCS = physical component score, SADL = Satisfaction with Amplification in Daily Life, SC = service and cost, SF-12 = Short Form 12-Item Survey, VA = Department of Veterans Affairs, VHA = Veterans Health Administration, VS = verbal strategies.

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second only to tinnitus, representing a 950 percent increase from fiscal year 2000 [1–2]. There was a 764 percent increase in the number of hearing aids provided to Veterans from 1996 to 2010,* mainly from increases in the aging population and numbers of hearing-impaired Veterans, as well as hearing aid eligibility changes.

In 2006, the VA published Veterans Health Administration (VHA) Directive 2006–028, committing to providing timely, quality, and clinically appropriate care. Systems Redesign strategies, formerly called Advance Clinic Access, were recommended in order to improve healthcare while matching supply and demand for services. This commitment was reiterated in the March 14, 2011, Audiology and Speech-Language Pathology Services VHA Handbook 1170.2, recommending the use of Systems Redesign to improve efficiency and productivity of clinics. One of the recommended strategies is using group visits to increase capacity. Hearing aid visits may be appropriate for a group format because the main components of these visits are patient education and training in the use of hearing aids and largely consist of standardized information and recurrent discussion topics pertinent to most patients.

Prior research reported by managed healthcare organizations for chronic disease management found that group visits produced better results with lower costs [3–5] compared with individual visits. They found that healthcare utilization was lower [3,5–7] and that patient self-efficacy [5,7], health status [4,7–10], satisfaction [3,7–8,11], compliance [12], quality of life [5], and provider satisfaction [3] were better. We anticipated that group hearing aid visits would produce similar results.

Previous research into audiology group visits has shown equivalent or better patient outcomes when group aural rehabilitation was provided in addition to an individual visit [13–26].† Two observational, nonrandomized studies that examined group hearing aid visits as a replacement for individual visits suggested that group visits resulted in similar or better hearing handicap, hearing-related function, hearing aid satisfaction, and hearing aid adherence compared with individual visits [27–28]. While the preponderance of evidence suggests that group visits yield similar or better outcomes compared with individual visits, the tenets of evidence-based medicine strongly suggest that such findings be confirmed with a randomized trial before making widespread clinical recommendations. Results from prospective randomized comparisons provide the best evidence regarding the effectiveness of an intervention [29] but previously have not been applied to group compared with individual hearing aid visits.

The purpose of this study was to fill this gap by examining the effect of group compared with individual hearing aid fitting and follow-up visits on patient outcomes and costs using a prospective noninferiority randomized clinical trial. We used a noninferiority design because the main goal was to demonstrate that the outcomes would not be worse ("inferior") with group visits; equivalent (and certainly superior) results could be justified by anticipated cost savings from reduced clinician-hours required to conduct group visits. In addition, we sought to identify other elements of a visit that might contribute to the success of group rehabilitation, such as attention from and time spent with care providers. We also examined potential differences in information retained between individual and group visits.

METHODS

A detailed description of the Hearing Aid Effectiveness After Aural Rehabilitation: Individual Versus Group (HEARING) trial design, methods, and baseline characteristics has been published elsewhere [30]. The information presented here is a summary of that report, and we refer readers to that report for more detailed information.

Design

In brief, we conducted this noninferiority factorial trial to examine (1) the effectiveness of group hearing aid fitting and group hearing aid follow-up visits compared with individual visits in terms of hearing-related function and hearing aid adherence 6 mo after the fitting visit, and (2) if group visits were less costly. We hypothesized that (1) group fitting and group follow-up visits would result in similar or better hearing-related function (primary outcome) and hearing aid adherence, and (2) group visits would be less costly because of fewer clinician-hours

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†Northern J, Beyer CM. Reducing hearing aid returns through patient education. Audiology Today. 1999;11:10–11.

required and because of lower rates of unplanned visits during the 6 mo following the fitting. Other secondary outcomes included hearing handicap, communication strategies, hearing aid outcomes, and satisfaction.

Participants

The **Figure** depicts the randomization, fitting, and follow-up process. Study participants were recruited from those patients seen for a hearing aid evaluation at the VA Puget Sound Health Care System Audiology Clinics. Participant recruitment was conducted from February 2006 through October 2007. Patients were eligible if they had no history of hearing aid use and monaural or binaural air-conduction hearing aids were ordered as part of their evaluation. We excluded patients from the study for the following reasons: (1) previously used a hearing aid, (2) not able or willing to attend a group visit, (3) not able or willing to provide informed consent, (4) not able or willing to complete a follow-up visit, or (5) not able or willing to complete and return outcomes questionnaires. After enrollment, we randomized participants to receive either a group or individual fitting and to receive either a group or individual follow-up. We invited participants' significant others to attend all individual and group visits.

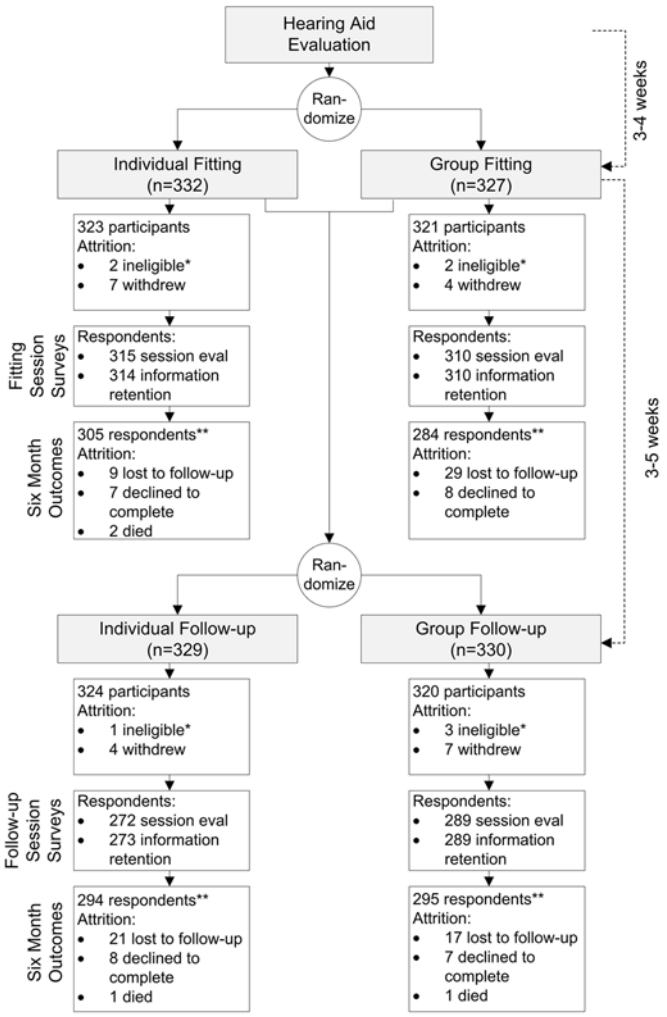

Figure.
Randomization and follow-up. *Determined to be ineligible after randomization because air-conduction hearing aid not ordered or participant did not pick up hearing aids. **Returned at least one completed questionnaire of packet. Eval = evaluation.

Baseline Assessment

After enrollment, participants completed baseline assessment. We measured the following hearing-related outcomes:

- Hearing-related function measured with the first module of the Effectiveness of Auditory Rehabilitation (EAR) [31], called the Inner EAR. This 10-item module measures hearing difficulty and is scored from 0 to 100, with higher scores representing better function.
- Hearing-related handicap using the Hearing Handicap Inventory for the Elderly (HHIE) [32]. The HHIE yields a total score that ranges from 0 to 100, as well as social and emotional hearing-handicap domain scores. Higher scores indicate greater handicap.
- Communication strategies using the maladaptive behaviors (MB), verbal strategies (VS), and nonverbal strategies (NS) subscales of the Communication Profile for the Hearing Impaired (CPHI) [33]. These scales each have 25 questions that are scored on a 5-point scale. Higher scores indicate better use of the strategy.

We also measured the following baseline characteristics:

- Health status using the Short Form 12-Item Survey (SF-12) [34], which yields a physical component score (PCS) and mental component score (MCS). Higher scores indicate better health.
- Age and sex obtained from the VA Computerized Patient Record System (CPRS).
- Audiometric thresholds obtained from CPRS.

Interventions

Hearing Aid Fitting Visits

The first randomized intervention was the orientation component of the hearing aid fitting visit, which occurred between 3 and 4 wk following the hearing aid evaluation.

There were two sessions in the hearing aid fitting visits. The first was a 45 min individual session with an audiologist, at which time participants' hearing aids were programmed and adjusted according to individual needs. In the second session, participants received either a group or individual orientation, both of which used standardized teaching topics; incorporated hands-on practice aimed at teaching effective hearing aid use, care, and maintenance; and were guided by PowerPoint slides or handouts, copies of which were provided to participants after the fitting. Group orientations accommodated up to six participants, whose hearing aids were programmed in two sequential groups. The first group of three participants was seen by three different audiologists. Participants then waited while audiologists saw the second group of three participants. All six participants, along with their significant others, then met together for the 60 min orientation. The session was conducted by an audiologist or hearing aid technician and used a total of 5.5 clinician hours (4.5 h of audiologist time and 1 h of audiologist or technician time). The individual orientation was conducted during the 30 min following the programming by the audiologist who programmed the aids. This format required 7.5 h for audiologists to meet with six participants.

Hearing Aid Follow-up Visits

The follow-up visit was the second randomized intervention and followed the fitting by approximately 3 to 5 wk. All follow-up visits were conducted by an audiologist, used standardized topics, and were guided by PowerPoint slides or handouts, copies of which were provided after the follow-up. The group follow-up required 75 min for as many as five participants. The first 45 min of the visit consisted of a review of orientation topics as well as additional information designed to promote effective long-term hearing aid use. If needed, hearing aid adjustments were made individually during the 30 min following the group meeting. The individual follow-up visit was a 30 min session to discuss any difficulties that arose since the fitting and to adjust the hearing aids as necessary. This format required 2.5 h for up to five participants.

Outcomes

Post-Hearing Aid Fitting and Post–Follow-Up

We mailed outcomes surveys 10 d following the fitting visit and 2 wk after the follow-up visit. Participants returned the surveys via postage-paid mail. In addition to the EAR, HHIE, and CPHI surveys, we also measured the following:

- Hearing aid adherence with the Adherence to Hearing Rehabilitation (AdHeRe) questionnaire [35], using dichotomous response ("Do you use your hearing aids?") and continuous response ("How many hours a day do you use your hearing aid?") questions.
- Hearing aid-related outcomes with the second module of the EAR, called the Outer EAR. This 10-item scale [31] is scored from 0 to 100, with higher scores indicating better function.
- Hearing aid satisfaction with the Satisfaction with Amplification in Daily Life (SADL) [36]. This 15-item scale provides an overall satisfaction score along with four subscale scores examining positive effects, service and cost (SC), negative features, and personal image. We eliminated item 14 regarding cost because Veterans do not purchase their aids. Scores can range from 1 to 7, with higher scores representing more satisfaction.
- Hearing aid outcomes were also measured with the International Outcome Inventory for Hearing Aids (IOI-HA) [37]. This is an 8-item survey scored on a 5-point Likert scale. Higher scores indicate better outcomes.

Treatment Session Evaluation

At the end of each intervention visit, we asked participants to complete questionnaires to evaluate the session and test how much information was retained. We gathered these data to inform potential differences in outcomes between study groups. The session evaluation contained 11 questions regarding potential mediators of rehabilitation efforts, including attendance of significant others, how much time and attention was given by the provider, session pacing, amount of repetition, time available for questions, and uneasiness with social settings. For participants who received a group follow-up, we asked four more questions about group interactions and use of PowerPoint. These 15 questions were rated on a 10-point scale with 1 indicating "strongly disagree" and 10 indicating "strongly agree." Information retention was assessed with 12 multiple-choice questions about basic hearing aid information that participants were instructed on and should know in order to effectively use their aids, such as what to do if the aid squeals while talking on the telephone. Hearing aid features, such as style, which ear(s) was fit, volume control, multimemory, etc., were abstracted from CPRS 6 mo after the fitting.

Six-Month Follow-Up

Participants were asked to complete and return questionnaires with postage-paid mail 6 mo after the hearing aid fitting visit. The questionnaires included the SF-12, EAR (Inner and Outer), HHIE, CPHI, AdHeRe, SADL, and IOI-HA.

Statistical Analyses

This noninferiority factorial study was designed to concurrently test if group hearing aid fitting and group hearing aid follow-up visits were at least as effective as individual fitting and follow-up visits. This analysis was selected in order to gain insight about the effectiveness of a group format for both types of visits using one randomized clinical trial. The primary outcome was hearing-related function measured 6 mo after the fitting visit. Hearing-related function was measured with the Inner EAR. We also collected data about hearing aid adherence, defined as self-report hours of use per day. Other secondary outcomes included the HHIE, CPHI, SADL, Outer EAR, SADL, and IOI-HA. We estimated our sample size based on the following conditions: (1) a change in the Inner EAR minimum clinically important difference (MCID) score of 6.0 points and standard deviation of 23.5 [30], (2) a conservative 20 percent loss to follow-up, and (3) anticipated weak (<0.10) within-group correlation. As a result, we estimated that a total enrollment of 660 participants (330 per group) would produce 90 percent power to reject the null hypothesis with an alpha error of 5 percent. When planning the trial, we did not anticipate interaction between the fitting and follow-up visits for the Inner EAR, and analyses of results showed no evidence of interaction for any of our outcomes; therefore, we pursued more straightforward analyses of overall effectiveness of group compared with individual hearing aid fitting and group compared with individual follow-up visits.

We conducted adjusted analyses using random effects models accounting for the clustering of patients within a provider in the group arm of the trial, adjusting for a treatment indicator for the fitting and an indicator for the follow-up, and for factors determined a priori to be potentially related to hearing function (baseline function, age, sex, degree of hearing loss, binaural vs monaural fit), as well as mental and physical health status, site, and provider. Since the trial was a noninferiority study, for the main outcome we tested the one-sided hypothesis that the effect of group visits on Inner EAR scores does not lead to a detrimental effect beyond the MCID of 6.0 points. We reported a two-sided 95 percent confidence interval (CI) for the main outcome since the upper bound is equivalent to the upper bound of a one-sided 97.5 percent CI used to determine noninferiority. Unadjusted means and adjusted analyses with two-sided CIs are reported for all remaining secondary outcomes.

Costs

We assessed the effect of group visits on two measures from VA's perspective: (1) the number of unplanned visits during the 6 mo follow-up period after the hearing aid fitting, and (2) the total cost of planned (fitting and follow-up) and unplanned audiology visits. The cost of an individual fitting or follow-up was calculated by summing the cost of each current procedural terminology (CPT) code recorded in the visit. The cost of each CPT code was obtained from the VA cost accounting system. The personnel cost of a group fitting or follow-up visit was estimated based on the provider time and their salaries. Fringe benefits were included in the personnel costs. Indirect and overhead costs were included in all cost measures. We calculated the total audiology care cost for each participant, including the costs of fitting, follow-up, and unplanned visits. We estimated all costs in 2008 dollars adjusting for inflation using the Consumer Price Index. We conducted the same statistical approach described previously. We used a count model with the Poisson distribution to assess the effect on the number of unplanned visits and a log normal model to assess the effect on costs with the log of total cost as the dependent variable.

RESULTS

We enrolled and randomized 659 participants, with 644 ultimately participating in the trial because 11 requested to be removed, 1 died prior to his hearing aid fitting, and 3 were later found to be ineligible. Of the 644 participants, 323 were randomized to individual fitting and 321 to group fitting, and we randomized 324 to an individual follow-up and 320 to a group follow-up. The **Figure** shows the flow of participants through the trial, including randomization assignments, withdrawals, and numbers of surveys returned.

As expected, tests of interaction between the fit and follow-up visits for the Inner EAR, adherence, and all other secondary outcomes showed no evidence of interaction; therefore, we conducted analyses of overall effectiveness of group versus individual hearing aid fitting and group versus individual hearing aid follow-up visits.

Table 1.
Baseline demographic, health status, hearing and hearing aid characteristics, and outcome measures.

Variable	Fitting			Follow-Up		
	I (*n*)	G (*n*)	*p*-Value*	I (*n*)	G (*n*)	*p*-Value*
Characteristic						
Sex,% Male	98.2 (323)	98.8 (321)	0.53	99.1 (324)	97.8 (320)	0.20
Age, mean years ± SD	65.7 ± 10.5 (323)	65.4 ± 11.5 (321)	0.70	65.3 ± 11.0 (324)	65.8 ± 11.1 (320)	0.56
Binaural HF PTA, dB HL ± SD	50.8 ± 12.6 (323)	50.4 ± 12.7 (320)	0.67	50.9 ± 12.9 (323)	50.3 ± 12.4 (320)	0.57
Binaural Fitting,%	86.1 (323)	86.3 (321)	0.61	85.2 (324)	87.2 (320)	0.67
SF-12 PCS, mean ± SD	38.4 ± 11.4 (314)	39.1 ± 11.4 (304)	0.46	38.5 ± 11.3 (313)	39.0 ± 11.4 (305)	0.62
SF-12 MCS, mean ± SD	48.9 ± 12.5 (314)	48.4 ± 11.6 (304)	0.58	48.8 ± 11.4 (313)	48.5 ± 12.7 (305)	0.78
Outcome Measures, mean ± SD						
Inner EAR	26.9 ± 13.8 (318)	27.7 ± 14.2 (312)	0.48	26.8 ± 14.0 (315)	27.9 ± 14.0 (315)	0.33
HHIE						
Social	23.8 ± 11.2 (316)	23.9 ± 11.2 (306)	0.91	24.0 ± 11.0 (312)	23.6 ± 11.4 (310)	0.68
Emotional	24.0 ± 13.4 (317)	24.6 ± 13.4 (305)	0.57	24.6 ± 12.9 (312)	24.0 ± 13.8 (310)	0.60
Total	47.8 ± 23.7 (315)	48.5 ± 23.3 (300)	0.69	48.5 ± 23.0 (308)	47.8 ± 24.0 (307)	0.68
CPHI						
MB	4.1 ± 0.7 (319)	4.0 ± 0.7 (311)	0.43	4.0 ± 0.7 (316)	4.1 ± 0.8 (314)	0.46
VS	2.7 ± 0.8 (319)	2.8 ± 0.9 (311)	0.02	2.7 ± 0.9 (316)	2.7 ± 0.9 (314)	0.74
NS	3.3 ± 0.9 (319)	3.4 ± 0.9 (311)	0.08	3.4 ± 0.9 (316)	3.4 ± 0.9 (314)	0.78

*Comparisons were made with two-sample *t*-tests for continuous outcomes, and with the chi-square test for sex and binaural fitting.
CPHI = Communication Profile for the Hearing Impaired, EAR = Effectiveness of Aural Rehabilitation, G = group, HF PTA = high-frequency pure-tone average (average of thresholds at 1,000, 2,000, 3,000, and 4,000 Hz) for right and left ears, HHIE = Hearing Handicap Inventory for the Elderly, HL = hearing level, I = individual, MB = maladaptive behaviors, MCS = mental component scale, NS = nonverbal strategies, PCS = physical component score, SD = standard deviation, SF-12 = Short Form 12-Item Survey, VS = verbal strategies.

Baseline characteristics were described in detail previously [30], and those pertinent to this report are shown in **Table 1**. Characteristics were evenly distributed between the individual and group formats for the hearing aid fitting and the hearing aid follow-up visits. Ninety-eight percent of participants were men. The average age was 65.5 yr, ranging in age from 23.3 to 93.1 yr. The average hearing loss was mild sloping to moderately severe, with a 1,000, 2,000, 3,000, and 4,000 Hz average of 49.0 dB hearing level (HL) for the right and 52.2 dB HL for the left. Monosyllabic word recognition was good for both ears (88.6% and 87.0% correct for the right and left, respectively). Most participants had bilateral (98.0%) sensorineural (94.9% and 96.0% in the right and left, respectively) hearing loss. SF-12 physical and mental health status measures showed average PCS and MCS scores in the bottom 50th percentile of normative scores for men in the general U.S. population aged 65 to 74 yr [34]. Outcome measure baseline scores are also shown in **Table 1**. Measures were balanced between individual and group formats with the exception of the CPHI VS fitting score. Since this measure was one of three subscores measuring communication strategies, any statistical adjustment for multiple comparisons would render this difference nonsignificant. Average scores were 27.3 for the Inner EAR; 48.2 for the HHIE (total); and 4.0, 2.7, and 3.4 for the CPHI MB, VS, and NS scores, respectively, and are consistent with those for other older hearing-impaired Veteran cohorts [32–33,38]. All participants were fit with digital hearing aids programmed to match NAL-NL1 (National Acoustics Labs, Non-Linear, version 1) real-ear targets [39]. Most participants were fit binaurally (86%), with other hearing aid features such as style, directional microphone, telephone program, multiple memory, volume control, and remote control well balanced across treatment groups.

Six-month follow-up response rate was high, with 94.4 and 88.5 percent of participants returning at least one of the questionnaires for the individual and group fitting, respectively, and 90.7 and 92.2 percent of participants returning at least one of the questionnaires for the individual and group follow-up, respectively. Because of the larger loss-to-follow-up rate for the group fitting compared with the individual fitting, we compared baseline scores for the 46 participants who completed baseline surveys but were lost to follow-up and found no systematic differences between the groups.

For all three postfitting time points after hearing aid use (postfit, post–follow-up, and 6 mo follow-up) unadjusted analyses of outcomes showed significant overall improvement from unaided baseline scores, but no statistically or clinically significant differences were found for

Table 2.
Outcomes 6 mo after fitting.

Outcome	Unadjusted Mean (*n*)		Adjusted LSM*				
	I	G	I	G	Difference	(95% CI)†	*p*-Value
Fitting							
Inner EAR	62.1 (305)	62.1 (284)	61.5	63.2	−1.7	(−7.1,3.7)	0.53
Hours/Day	10.9 (298)	10.8 (282)	10.2	10.3	−0.1	(−1.3,1.2)	0.90
HHIE							
Social	9.9 (300)	10.3 (277)	8.2	7.4	0.8	(−1.7,3.3)	0.53
Emotional	9.1 (303)	9.6 (282)	6.3	5.8	0.5	(−2.3,3.3)	0.74
Total	18.8 (299)	19.8 (277)	14.8	13.3	1.5	(−3.6,6.6)	0.56
CPHI							
MB	4.5 (303)	4.5 (284)	4.5	4.6	−0.1	(−0.2,0.1)	0.33
VS	2.4 (304)	2.3 (284)	2.4	2.3	0.1	(−0.1,0.4)	0.32
NS	3.1 (304)	3.1 (284)	2.8	2.7	0.1	(−0.2,0.3)	0.70
Outer EAR	70.1 (300)	69.1 (282)	66.9	68.5	−1.6	(−6.5,3.2)	0.51
SADL							
Global	5.3 (301)	5.3 (283)	5.3	5.4	−0.1	(−0.3,0.2)	0.70
PE	5.0 (301)	5.0 (283)	4.9	4.9	0.0	(−0.4,0.3)	0.85
SC	6.0 (300)	5.9 (283)	6.4	6.0	0.4	(0.0–0.6)	0.04
NF	5.2 (301)	5.2 (282)	5.3	5.4	−0.1	(−0.4,0.3)	0.77
PI	5.8 (301)	5.7 (283)	5.7	5.8	−0.1	(−0.5,0.1)	0.28
IOI-HA	29.5 (300)	29.1 (279)	28.9	28.5	0.4	(−0.9,1.6)	0.56
Follow-Up							
Inner EAR	61.5 (294)	62.7 (295)	61.1	63.7	−2.6	(−6.0,0.9)	0.11
Hours/Day	10.6 (289)	11.1 (291)	10.0	10.5	−0.5	(−1.3,0.3)	0.24
HHIE							
Social	10.6 (291)	9.6 (286)	7.9	7.8	0.1	(−1.5,1.7)	0.86
Emotional	10.1 (293)	8.5 (292)	6.6	5.6	1.0	(−0.8,2.8)	0.26
Total	20.6 (290)	18.0 (286)	14.6	13.4	1.2	(−2.1,4.4)	0.48
CPHI							
MB	4.4 (294)	4.5 (293)	4.6	4.5	0.1	(−0.1,0.1)	0.54
VS	2.3 (294)	2.4 (294)	2.3	2.4	−0.1	(−0.3,0.0)	0.06
NS	3.0 (294)	3.1 (294)	2.7	2.8	−0.1	(−0.4,0.0)	0.06
Outer EAR	69.3 (289)	69.9 (293)	67.5	67.9	−0.4	(−3.5,2.6)	0.77
SADL							
Global	5.3 (291)	5.4 (293)	5.3	5.4	−0.1	(−0.3,0.1)	0.26
PE	4.9 (291)	5.1 (293)	4.9	5.0	−0.1	(−0.4,0.1)	0.20
SC	5.9 (291)	6.0 (292)	6.2	6.2	0.0	(−0.2,0.2)	0.77
NF	5.2 (291)	5.2 (292)	5.4	5.3	0.1	(−0.2,0.3)	0.57
PI	5.7 (291)	5.8 (293)	5.7	5.8	−0.1	(−0.4,0.1)	0.17
IOI-HA	29.1 (287)	29.5 (292)	28.5	29.0	−0.5	(−1.3,0.2)	0.18

*Adjusted comparisons conducted using random effects models accounting for clustering of patients within provider in group arm, adjusting for treatment indicator for fitting and indicator for follow-up and for factors determined a priori to be potentially related to hearing function, as well as mental and physical health status, site, and provider.

†Difference between adjusted LMS with 95% CI and *p*-value.

CI = confidence interval, CPHI = Communication Profile for the Hearing Impaired, EAR = Effectiveness of Aural Rehabilitation, G = group visit, HHIE = Hearing Handicap Inventory for the Elderly, I = individual visit, IOI-HA = International Outcome Inventory for Hearing Aids, LSM = least-squares-mean, MB = maladaptive behaviors, NF = negative features, NS = nonverbal strategies, PE = positive effects, PI = positive image, SADL = Satisfaction With Amplification in Daily Life, SC = service and cost, VS = verbal strategies.

hearing-related function or hearing aid adherence between individual and group formats for the fitting or follow-up visits (data not shown for postfit and post–follow-up). Therefore, we report analyses for the 6 mo outcomes only. **Table 2** shows outcome scores for individual versus group follow-up. For each visit format, we show unadjusted values and the adjusted least-squares-mean (LSM) estimate, 95 percent CI, and *p*-value. For the primary outcome, Inner EAR LMS estimates were 61.5 and 63.2 (95% CI: −7.1, 3.7; $p = 0.53$) for individual and group fitting,

respectively, and 61.1 and 63.7 (95% CI: –6.0, 0.9; $p = 0.11$), for individual and group follow-up, respectively, confirming noninferiority since upper bounds of the 95 percent CIs were below the MCID of 6.0 points. LMS estimates of the number of hours per day participants wore their hearing aids were 10.2 and 10.3 h (95% CI: –1.3, 1.2; $p = 0.90$) for the individual and group fitting, respectively, and 10.0 and 10.5 h (95% CI: –1.3, 0.3; $p = 0.24$) for the individual and group follow-up, respectively. For the dichotomous yes/no adherence measure, we were unable to conduct adjusted analyses because of limited variation in the outcome and other covariates. However, the unadjusted percentage of participants reporting that they wore their hearing aids was high at 95 and 97 percent for the individual and group fitting, respectively, and 96 percent for both the individual and group follow-up. Similarly, we found no significant differences between individual and group formats for hearing handicap, communication strategies, hearing aid outcomes, and satisfaction, with the exception of better scores for the individual fitting on the SADL SC subscale. Since the SADL SC was one of three subscores measuring hearing aid satisfaction, any statistical adjustment for multiple comparisons would make this difference nonsignificant.

We found no significant differences in the number or cost of unplanned visits between individual and group treatments (**Table 3**). The adjusted analysis showed that the ratio of unplanned visits for the individual fitting to the group fitting was 0.74 (95% CI: 0.48, 1.14; $p = 0.18$), while the ratio of unplanned visits for the individual follow-up to the group follow-up was 0.78 (95% CI: 0.50 1.21; $p = 0.27$). Both were statistically nonsignificant. However, we found that the total costs for the individual visits were significantly higher than the group visits for both fitting and follow-up. For the fitting visit, the adjusted total cost per patient was $202.70 for the individual format and $112.60 for the group format. For the follow-up visit, the adjusted total cost per patient was $159.90 for the individual visit and $142.80 for the group visit. The adjusted analysis showed that total cost per patient for individual fitting was 80 percent higher than for the group fitting (95% CI: 1.64, 1.97; $p < 0.001$), while the total cost per patient for individual follow-up was 12 percent higher than for the group follow-up (95% CI: 1.02, 1.23; $p < 0.001$). Both were statistically significant. The cost differences were mainly because of higher costs of the individual treatment than the group treatment. The average cost of an individual fitting visit was $105.80, compared with $32.50 for a group visit. The average cost for an individual follow-up visit was $41.50, compared with $31.80 for a group visit. This yielded a combined cost saving of over 50 percent for group fitting and follow-up visits ($64.30) compared with individual fitting and follow-up visits ($147.30).

We also gathered information about potential mediators of the effectiveness of group sessions. While we found no differences in any of the measured outcomes between individual and group visits, the session evaluation questions (**Table 4**) suggested some factors that may affect participants' experience with their visit. Some trends favoring individual visits emerged around the amount and quality of time spent with the audiologist (questions 1, 2, and 5) and the amount of hands-on practice with the aids (question 8). When asked if they preferred the individual or group format (questions 10 and 11), participants tended to choose the format they actually received. Questions 12 through 15 show average responses to questions specific to the

Table 3.
Unplanned visits and costs in 6 mo after fitting.

Outcome	Fitting							Follow-Up						
	Unadjusted Means		Adjusted LSM		Ratio (I:G)	(95% CI)	*p*-Value	Unadjusted Means		Adjusted LSM		Ratio (I:G)	(95% CI)	*p*-Value
	I (n = 323)	G (n = 321)	I	G				I (n = 324)	G (n = 320)	I	G			
Unplanned Visits*	0.27	0.36	0.25	0.34	0.74†	(0.48–1.14)	0.18	0.29	0.34	0.26	0.33	0.78‡	(0.50–1.21)	0.2
Total Costs ($)	225.90	142.10	202.70	112.60	1.80‡	(1.64–1.97)	<0.001	193.80	174.40	159.90	142.80	1.12‡	(1.02–1.23)	<0.001

*Adjusted models accounted for clustering of patients within provider in group arm, adjusting for treatment indicator for fitting and indicator for follow-up and for factors determined a priori to be potentially related to hearing function, as well as mental and physical health status, site, and provider. Sex was excluded from model because small number of female participants resulted in nonconvergence.

†Count model with Poisson distribution. Difference between two groups is interpreted as ratio of unplanned visits of individual to group. Ratio of unplanned visits for individual fitting to group fitting was 0.74, while ratio of unplanned visits for individual follow-up to group follow-up was 0.78.

‡Log normal model with log total cost as dependent variable. Cost per patient of individual fitting was 80% higher than group fitting, while cost per patient of individual follow-up was 12% higher than group follow-up.

CI = confidence interval, G = group visit, I = individual visit, LSM = least-squares-mean.

Table 4.
Session evaluation rations. Mean ± standard deviation.

Statement	Fitting			Follow-Up		
	I (*n*)	G (*n*)	*p*-Value	I (*n*)	G (*n*)	*p*-Value
1. Interaction with audiologist could be improved.	**1.8 ± 2.1 (314)**	**2.9 ± 3.0 (308)**	<0.001	**1.8 ± 1.8 (272)**	**2.4 ± 2.3 (288)**	<0.001
2. Wish I had more opportunities to practice with aids before taking it home.	**2.4 ± 2.4 (314)**	**2.9 ± 2.5 (308)**	0.01	2.7 ± 2.5 (272)	3.0 ± 2.5 (287)	0.12
3. If I wear aids, I expect it will be easier to communicate with people I don't know well.	7.7 ± 2.9 (313)	7.7 ± 2.8 (309)	0.91	7.7 ± 2.4 (272)	7.3 ± 2.7 (289)	0.06
4. I generally feel uncomfortable in social settings.	4.7 ± 3.1 (315)	4.5 ± 3.0 (309)	0.50	3.4 ± 2.8 (271)	3.3 ± 2.7 (289)	0.76
5. I wish I had more one-on-one time with my audiologist.	**2.8 ± 2.4 (314)**	**3.5 ± 2.7 (309)**	<0.001	**2.9 ± 2.5 (272)**	**3.8 ± 2.7 (289)**	<0.001
6. People will notice my hearing loss more if I wear hearing aids.	4.7 ± 3.0 (312)	4.8 ± 3.1 (310)	0.71	3.6 ± 2.8 (271)	3.9 ± 2.8 (288)	0.34
7. I feel less embarrassed about wearing hearing aids after my hearing aid training.	6.1 ± 3.4 (313)	6.4 ± 3.2 (309)	0.28	6.3 ± 3.3 (271)	5.9 ± 3.4 (287)	0.20
8. I would have liked more hands-on practice with my hearing aids before taking them home.	**2.5 ± 2.1 (312)**	**2.9 ± 2.4 (309)**	0.01	**2.9 ± 2.6 (270)**	**3.1 ± 2.5 (289)**	0.31
9. The experiences I have had with my hearing loss and hearing aids are normal.	6.4 ± 2.8 (308)	6.8 ± 2.7 (304)	0.08	7.3 ± 2.6 (271)	7.2 ± 2.5 (289)	0.93
10. Given a choice, I would choose to get hearing aid training one-on-one with an audiologist instead of in a group with other hearing aid users.	**7.1 ± 3.2 (310)**	**4.4 ± 3.1 (307)**	<0.001	**6.4 ± 3.4 (272)**	**4.2 ± 3.0 (288)**	<0.001
11. Given a choice, I would choose to get hearing aid training in a group with other hearing aid users instead of one-on-one with an audiologist.	**3.6 ± 2.9 (306)**	**5.8 ± 3.1 (307)**	<0.001	**3.7 ± 3.2 (271)**	**6.2 ± 3.2 (288)**	<0.001
12. I gained insight from hearing the experiences of other participants in my group.	—	6.7 ± 2.9 (300)	—	—	7.9 ± 2.3 (275)	—
13. Support from others in my group will help me use my hearing aids.	—	6.5 ± 2.9 (301)	—	—	7.1 ± 2.7 (275)	—
14. It would have been better if some topics today were discussed in private.	—	2.9 ± 2.6 (301)	—	—	2.3 ± 2.0 (275)	—
15. The slide show helped me learn how to use my hearing aids.	—	8.0 ± 2.41 (294)	—	—	7.7 ± 2.4 (271)	—

Note: 1 = strongly disagree, 10 = strongly agree. Comparisons conducted with the two-sample *t*-test; bolded numbers indicate statistically significant items. G = group, I = individual.

group format only. These results indicated a generally positive response to the group experience. Results from the information retention questions (**Table 5**), suggested that, overall, no systematic differences were found and that information retention was similar between visit formats for both types of visits.

DISCUSSION

We conducted a noninferiority, randomized clinical trial designed to determine if group hearing aid fitting and group hearing aid follow-up visits were at least as effective as individual fitting and follow-up visits over the 6 mo following the hearing aid fitting. Our results from 644 randomized participants showed no significant difference between individual and group hearing aid fit and follow-up in terms of hearing-related function, hearing aid adherence, and number of unplanned visits, nor for a number of other secondary outcomes, including hearing-related handicap, communication strategies, hearing aid-related outcomes, and hearing aid satisfaction. Importantly, however, we saw significant cost savings for both types of group visits. Our results demonstrate that routine use of group visits can maintain high-quality care while freeing scarce clinician-hours and funds that may well be used on other high-priority activities such as providing hearing aids to a larger number of patients, reducing wait times, or spending more time with patients who have more complex rehabilitation needs. For example, the VA Puget Sound staff saw about 830 new hearing aid users appropriate for group hearing aid visits in the year 2011.* Seeing these patients with group visits instead of individual would yield about approximately $88,000 of savings annually.

Randomized trials provide the best evidence about how well interventions work [29]. To the best of our

*Hanson, Emily R (VA Puget Sound Audiology Manager, Seattle, WA). Email to: Margaret P. Collins (Health Services Research & Development Center of Excellence, VA Puget Sound Health Care System, Seattle, WA). 2012 Mar 8.

Table 5.
Information retention. Percent of participants with correct answer.

Question	Fitting			Follow-Up		
	Individual (*n*)	Group (*n*)	*p*-Value	Individual (*n*)	Group (*n*)	*p*-Value
1. When I run out of batteries I should . . .	92.6 (212)	89.9 (308)	0.26	96.0 (273)	93.0 (286)	0.14
2. I can tell my right hearing aid from my left because . . .	87.4 (301)	86.4 (302)	0.81	85.5 (263)	87.0 (276)	0.71
3. While adjusting to my new hearing aids, I can expect . . .	**75.7 (305)**	**82.7 (294)**	0.04	**76.4 (267)**	**83.5 (285)**	0.04
4. If feedback occurs when I laugh, talk, or chew . . .	**24.3 (309)**	**34.9 (307)**	0.01	26.5 (272)	25.7 (288)	0.85
5. If my hearing aids gets wet, the first thing to do is . . .	84.2 (311)	85.2 (310)	0.82	84.8 (269)	84.5 (288)	0.63
6. When the Dri Aid Kit is saturated and needs rejuvenating . . .	85.2 (311)	86.2 (305)	0.73	**69.4 (271)**	**79.2 (289)**	0.01
7. If my hearing aid squeals when I talk on the telephone, I should . . .	**80.9 (309)**	**87.7 (309)**	0.03	80.7 (269)	79.4 (286)	0.75
8. My hearing aid battery should last at least . . .	86.9 (312)	93.5 (308)	0.01	94.1 (270)	93.1 (288)	0.73
9. To properly clean my hearing aids, I use . . .	94.9 (314)	98.7 (310)	0.01	97.1 (273)	97.9 (289)	0.59
10. If one of my hearing aids is not working, the first thing I do is . . .	45.9 (305)	51.5 (299)	0.19	64.0 (264)	69.3 (281)	0.93
11. With proper care, my hearing aids should last . . .	**76.8 (314)**	**63.5 (307)**	<0.001	54.0 (272)	58.0 (288)	0.35
12. My hearing aids will work best in . . .	34.1 (311)	41.6 (305)	0.06	**45.6 (272)**	**63.3 (289)**	<0.001

Note: Comparisons conducted with Fisher exact test. Bolded numbers indicate statistically significant items.

knowledge, the HEARING trial is the first randomized trial to examine group hearing aid visits. The findings in this randomized controlled trial confirm the importance of using randomized trial designs to understand the true effect of clinical interventions since prior nonrandomized studies (including ours) suggested we might find better outcomes for group visits [27–28]. Unlike this randomized trial, information content between visit formats was not controlled in previous studies. For example, the Collins et al. [28] observational study consisted of a similar participant cohort to ours, but no standard protocol was prescribed for the individual fitting, meaning the visit content could have varied between participants. Only participants in their group follow-up watched a 15 min video segment* discussing how to get the most benefit from new hearing aids, providing more learning opportunities. The use of this video highlights that one of the advantages of group visits in a nonresearch clinical setting is the ability to use a variety of educational tools to increase learning opportunities; therefore, the true clinical effectiveness of group sessions may be better than what we could demonstrate with this randomized controlled trial. In addition, for the nonrandomized studies, the group hearing aid orientation was conducted only by audiologists, versus a mixture of audiologists and technicians in this current investigation. Lastly, nonattendance was higher for Brickley et al.'s group sessions [27], possibly biasing results for the group visits toward more motivated and successful hearing aid users.

This is also the first randomized trial to examine the cost differences between individual and group hearing aid visits, considered not only in terms of immediate savings from reduced audiology clinician-hours, but also from the longer-term costs of unplanned visits that may be reduced if participants benefit with more learning and information retention. At the time of this trial, patients at the VA Puget Sound Audiology Clinic were welcome to return to the clinic on a walk-in basis during specified days and times. These patients would be seen by an audiologist or technician to address their specific needs. The similar unplanned visit rate found between visit formats was consistent with the similar outcomes described earlier and suggested that learning and information retention generally were similar between visit formats.

However, results from the session evaluation questions revealed some factors that may be considered when designing and conducting a group session. For example, care should be taken to ensure that participants are offered ample hands-on practice with their hearing aids and opportunities to ask questions, and the audiologist should take care to give sufficient direct one-on-one interaction with each participant during the visit. In theory, longer group sessions would allow for more interaction and practice, so negative perceptions may be related to participants' desire for a one-on-one visit. That is, less one-on-one interaction with the audiologist was perceived as poorer interaction and less hands-on practice. Interestingly, when asked which type of format was preferred, those who received an individual visit would have chosen an individual visit and those who received a

*Koop CE, Gans S, Gorsuch P, Rogers C, producers. Getting the most out of your hearing aids [Videotape]. Burke (VA): CDR Communications; 1994.

group visit would have chosen a group visit. This was true for both the fitting and follow-up, suggesting that regardless of the format, participants found the session valuable and did not want the other format with which they were not familiar.

There are potential limitations to our study. Most importantly, our findings may not be generalizable to non-Veterans since Veterans receiving hearing aids do not have the financial barrier faced by most non-Veterans and, therefore, may pursue hearing aids at an earlier age and with less perceived handicap than their private sector counterparts. Age and handicap may affect an individual's receptiveness to group intervention. Because of their experiences in military service and/or their hearing loss severity, Veterans may have responded differently to the group setting. Another limitation was that the treatment could not be blinded to either participants or providers, and participants may have been biased by their preconceived ideas about group visits. We also note that the loss to follow-up rates were higher in the participants randomized to group fitting; however, these losses did not result in clinically or statistically significant differences in primary outcome measures. We also defined group visits as being no more than six individuals for fittings and five individuals for follow-ups. Therefore, outcomes may not generalize to much larger groups. Finally, we also recognize that there may be some unmeasured selection bias in our cohort since we were unable to track patients who were offered participation by clinicians but declined to enroll. We had attempted to track these patients, but asking busy clinicians to maintain these lists proved excessively burdensome.

We considered the possibility that our outcomes were not sensitive enough to detect a difference between study arms. The data presented in **Tables 4** and **5** suggest that less satisfactory interactions with audiologists were sometimes observed with participants randomized to group visits. However, despite these occasional data, our results suggest that there were no clinically or statistically meaningful differences between groups. The fact that none of a host of hearing aid measures detected a difference lends credence to our findings.

Hearing aid technicians conducted many of the group hearing aid orientations and audiologists conducted all of the individual orientations; therefore, outcomes may have been influenced by differences in provider type rather than session format. However, adjusted analyses showed no effect of clustering, suggesting that provider type did not affect outcomes. More and more clinics, particularly within VA, are implementing Systems Redesign principles and utilizing technicians at increasing rates for a range of activities, including hearing aid orientation [40].[*†‡]

This trial provides important evidence that outcomes are not hindered when technicians conduct these activities and that this staffing mix is an effective way to increase the number of audiologist-hours available for more complex clinical activities.

Although this trial considered costs from VA's perspective, there are also costs associated with patients' time, which were not captured by the study. Most patients will likely prefer a shorter visit and one for which they do not need to wait between hearing aid programming and orientation. We believe that the preference for shorter visits is mitigated by providing a high-quality orientation, leaving patients with a sense of confidence about how to use their hearing aids. To eliminate wait times between programming and orientation, larger clinics with more staff, space, and equipment may be able to simultaneously conduct programming for more than three individuals. Subsequent to this study, VA Puget Sound began programming in groups of four. Smaller clinics can conduct smaller groups or elect to ask patients to wait. More importantly, group visits use fewer clinical hours than individual visits, with 4.5 versus 7.5 h for fittings and 1.25 versus 2.5 h for follow-ups. More patients can be seen in a given time, reducing delays in actually receiving hearing aids. This study shows that audiology group visits could improve patient access to audiology services by increasing capacity of audiology clinics without reducing quality of care.

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[‡]AudiologyOnline, VA audiology clinic selected for a VHA National Systems Redesign Champion Award. AudiologyOnline. 2011 Sep 16. Available from: https://www.audiologyonline.com/news/news_detail.asp?news_id=4881

CONCLUSIONS

Group hearing aid visits for new hearing aid users were at least as effective as individual visits in terms of hearing-related function, adherence, and number of unplanned visits, as well as a number of other secondary outcomes measured at 6 mo after the hearing aid fitting. Importantly, the group visits yielded substantial cost savings. These results support routine use of group hearing aid fitting and follow-up visits in order to provide quality care at reduced cost and may be an effective tool for minimizing strain on resources and improving patient wait times.

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