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Intervention Research

The Baltimore HEARS Pilot Study: An Affordable, Accessible, Community-Delivered Hearing Care Intervention

Carrie L. Nieman, MD, MPH,[1,2] Nicole Marrone, PhD, CCC-A,[3] Sara K. Mamo, AuD, PhD,[1,2] Joshua Betz, MS,[2,4] Janet S. Choi, MPH,[1,2] Kevin J. Contrera, MPH,[1,2] Roland J. Thorpe Jr., PhD,[2] Laura N. Gitlin, PhD,[5,6] Elizabeth K. Tanner, PhD, RN,[2,5] Hae-Ra Han, PhD, RN, FAAN,[5] Sarah L. Szanton, PhD, ANP,[2,5,7] and Frank R. Lin, MD, PhD[1,2,8]

[1]Department of Otolaryngology-HNS, Johns Hopkins School of Medicine, Baltimore, Maryland. [2]The Johns Hopkins Center on Aging and Health, Johns Hopkins Medical Institutions, Baltimore, Maryland. [3]Department of Speech, Language, & Hearing Sciences, University of Arizona, Tucson. [4]Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland. [5]Department of Community Public Health, Johns Hopkins School of Nursing, Baltimore, Maryland. [6]Center for Innovative Care in Aging, Johns Hopkins School of Nursing, Baltimore, Maryland. [7]Department of Health Policy & Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland. [8]Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland.

Address correspondence to Carrie L. Nieman, MD, MPH, Department of Otolaryngology-HNS, Johns Hopkins School of Medicine, 601 N. Caroline St., 6th Floor, Baltimore, MD 21287. E-mail: cnieman1@jhmi.edu

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Abstract

Purpose of the Study: Age-related hearing loss negatively affects health outcomes, yet disparities in hearing care, such as hearing aid use, exist based on race/ethnicity and socioeconomic position. Recent national efforts highlight reduction of hearing care disparities as a public health imperative. This study a) describes a community engagement approach to addressing disparities, b) reports preliminary outcomes of a novel intervention, and c) discusses implementation processes and potential for wide-scale testing and use.

Design and Methods: This was a prospective, randomized control pilot, with a 3-month delayed treatment group as a waitlist control, that assessed feasibility, acceptability, and preliminary efficacy of a community-delivered, affordable, and accessible intervention for older adults with hearing loss. Outcomes were assessed at 3 months, comparing immediate and delayed groups, and pooled to compare the cohort's pre- and 3-month post-intervention results.

Results: All participants completed the study (n = 15). The program was highly acceptable: 93% benefited, 100% would recommend the program, and 67% wanted to serve as future program trainers. At 3 months, the treated group (n = 8) experienced fewer social and emotional effects of hearing loss and fewer depressive symptoms as compared to the delayed treatment group (n = 7). Pooling 3-month post-intervention scores (n = 15), participants reported fewer negative hearing-related effects (effect size = −0.96) and reduced depressive symptoms (effect size = −0.43).

Implications: The HEARS (Hearing Equality through Accessible Research & Solutions) intervention is feasible, acceptable, low risk, and demonstrates preliminary efficacy. HEARS offers a novel, low-cost, and readily scalable solution to reduce hearing care disparities and highlights how a community-engaged approach to intervention development can address disparities.

Keywords: Hearing loss, Age-related hearing loss, Hearing health care, Disparities, Minority health, Community engagement, Intervention development, Implementation

Age-related hearing loss is prevalent, increasing with each age decade, such that nearly 2/3 of older adults >70 years have a clinically significant hearing loss (Chien & Lin, 2012; Lin, Thorpe, Gordon-Salant, & Ferrucci, 2011). Yet, only 20% of older Americans, and only approximately 10% of minority and low-income older Americans, use hearing aids (Chien & Lin, 2012; Lin et al., 2011; Nieman, Marrone, Szanton, Thorpe, & Lin, 2016; Tomita, Mann, & Welch, 2001). Increasing epidemiologic evidence demonstrates that hearing loss is independently associated with significant adverse health outcomes: accelerated cognitive decline (Lin et al., 2013), incident dementia (Gallacher et al., 2012; Lin et al., 2011), declines in physical functioning (Dalton et al., 2003), and hospitalizations (Genther, Frick, Chen, Betz, & Lin, 2013). Hearing loss and access to hearing care are increasingly recognized as major public health issues (Lustig & Olson, 2014; National Academies of Sciences, Engineering, and Medicine, 2016; President's Council of Advisors on Science and Technology [PCAST], 2015).

Hearing care in the United States is typically delivered through clinic-based audiologic needs assessment, rehabilitative counseling, and sensory management with amplification, generally in the form of hearing aids (Valente et al., 2006). Traditionally, the process involves multiple fee-for-service visits to a clinician's office not covered by Medicare and demands mobility, transportation, and financial resources. The current model of care also requires a high degree of health literacy and executive function to navigate the involved systems, including hearing aid manuals and training materials, which have a mean reading grade level of 9.6 and the majority being unsuitable for older adults (Caposecco, Hickson, & Meyer, 2014).

Using a community-engaged approach, we designed and evaluated a community-delivered, affordable, and accessible hearing care intervention, HEARS (Hearing Equality through Accessible Research & Solutions). The intervention is theory driven and incorporates elements of Bandura's Social Cognitive Theory, specifically techniques to enhance self-efficacy (Bandura, 1977), as well as a human factors approach to design for older adults (Fisk, Rogers, Charness, Czaja, & Sharit, 2009) while mobilizing social support. Self-efficacy is one of the most commonly used concepts of Bandura's Social Cognitive Theory and one of the primary constructs associated with successful use of amplification, such as hearing aids (Bandura, 1977; Hickson, Meyer, Lovelock, Lampert, & Khan, 2014). With an emphasis on user-centered design, mobile technology, community engagement, and appropriate literacy level, the protocol was developed for delivery by community health workers to optimize its potential for implementation in a community setting. To evaluate the intervention's feasibility, acceptability, and preliminary efficacy, we conducted a two-group randomized control pilot study with a 3-month delayed treatment group as a waitlist control. The purpose of this paper is to describe our community engagement approach to addressing care disparities, report preliminary outcomes, and discuss implementation processes and potential for wide-scale testing and use.

We hypothesized that participation in the HEARS intervention would be highly acceptable to participants and associated with decreased levels of hearing handicap, defined as fewer negative social and emotional effects related to hearing loss. In light of the 23 million older Americans with untreated hearing loss (Chien & Lin, 2012) and recent national efforts to develop additional models of hearing care, our study proposes a low-cost model of care that is potentially replicable and scalable and provides an example of how a community engagement approach may aid in developing interventions for health care disparities.

Design and Methods

The Baltimore HEARS pilot study was a prospective, randomized control pilot with a 3-month delayed treatment group as a waitlist control (clinicaltrials.gov NCT02045511). The study was approved by the Johns Hopkins Medicine institutional review board and written consent was obtained for every participant. Assessments in the immediate treatment group were obtained at baseline and repeated at 1 month and 3 months. Participants in the delayed treatment group were assessed at baseline and after 3 months, prior to receiving the intervention. After receiving the intervention, the delayed treatment group were assessed at 1 month and 3 months after the intervention (e.g., 6 months from baseline). The assessments were conducted in the participants' buildings by data collectors, who were trained graduate-level research assistants and not interventionists.

Recruitment and Randomization

Community-dwelling individuals were recruited in partnership with a nonprofit that provides subsidized, independent housing to low- and middle-income older adults in Baltimore, MD. Participants were recruited from three buildings that house predominantly low-income and minority, primarily African American, older adults. However, we did not utilize recruitment targets or exclusion criteria specific to self-identified race/ethnicity. The three buildings were selected because of their relatively large number of residents, close proximity to each other, and larger proportion of minority residents. Potential participants were referred by service coordinators and flyers posted in each building and were invited to information sessions held at each building. Interested individuals were contacted via phone by the study team and, if not successfully contacted by the study team, service coordinators followed up with interested individuals. Service coordinators provided additional assistance in contacting interested individuals if

phone calls were limited by hearing status (n = 2) or access to a reliable phone number.

Eligible participants were aged 60 years or older, English speaking, had a clinically significant hearing loss (mild hearing loss or greater), did not currently use a hearing aid, and had a communication partner who would participate in the study. Communication partners were any individual, aged 18 years or older, who spoke with the participant daily, including spouses, adult children, and friends. Participants and communication partners formed a dyad and completed the study as a dyad. Immediately following initial screening, the participant and communication partner completed an automated hearing testing protocol in a quiet room using a portable audiometer with TDH-39 headphones and Audiocups (Tremetrics RA300 Plus, Eden Prairie, MN). Hearing screening (Table 1) was utilized to determine whether a potential participant had a clinically significant hearing loss, which was defined as at least a mild hearing loss based on the averaged response at three test frequencies (1, 2, and 4 kHz) in the better hearing ear for each participant, also known as the Better Ear Speech Pure Tone Average (PTA). Mild hearing loss equated to Better Ear Speech PTA >25 dB HL and ≤40 dB HL based on American Speech-Language-Hearing guidelines. Individuals were excluded if unable to complete the automated protocol. After participants and their communication partners completed the screening visit and both deemed eligible for the study, each dyad was 1:1 randomized by random number generation to either treatment group. Figure 1 documents the flow of individuals through the study.

Table 1. HEARS Intervention Components, Details, and Associated Rationale

HEARS Component	Details	Rationale
Hearing screening—Delivered during study enrolment		
Basic ear examination	Otoscopy with conventional otoscope and iPhone-based otoscope	Referral for medical/audiologic evaluation for abnormal exams; iPhone-based otoscope allows for transmission of images for real-time supervision and monitoring by clinicians
Audiometric screening	Automated screening protocol in a quiet room (Tremetrics RA300+)	Simple screening audiometer; meets ANSI, OSHA standards; automated well-validated protocol
Ear and hearing history	Key history of ear or hearing problems that may require additional evaluation	Referral for complete medical and audiological evaluation with questionable or concerning history
Review limitations of HEARS	Review limitations of hearing screening, hearing aids vs personal sound amplifier products	Information on reasons to see a doctor and referrals to partner organizations for medical/audiological evaluation
Device provision and orientation—Delivered during training session		
Listening device selection	Introduction to device features and limitations. Discussion guided by user's needs. User selects own device	Hands-on exploration of each device, features, and limitations
Listening device fitting	Sound World Solutions CS-50 or Williams Sound Pocketalker	Both over-the-counter devices offer effective amplification and are readily available, affordable
Listening device orientation	Hands-on demonstration and real-life, functional practice based on daily use	Interactive, supportive, and mastery experiences enhance self-efficacy
Communication education and counseling—Delivered during training session		
Hearing loss basics	Discuss of how hearing works and why communication strategies are needed	Limitations of listening devices emphasize need for communication strategies, expectation management
Mini-aural rehabilitation session	Communication strategies, expectation management, and integration into daily life	Aural rehabilitation is an essential component of addressing communication difficulties
Provision of educational materials	Training workbook, a complete reference manual, and quick tips book	All materials written at ≤6th- to 7th-grade reading level. Large font. High black/white contrast. Use of icons/figures

Note: ANSI = American National Standards Institute; HEARS = Hearing Equality through Accessible Research & Solutions; OSHA = Occupational Safety and Health Administration.

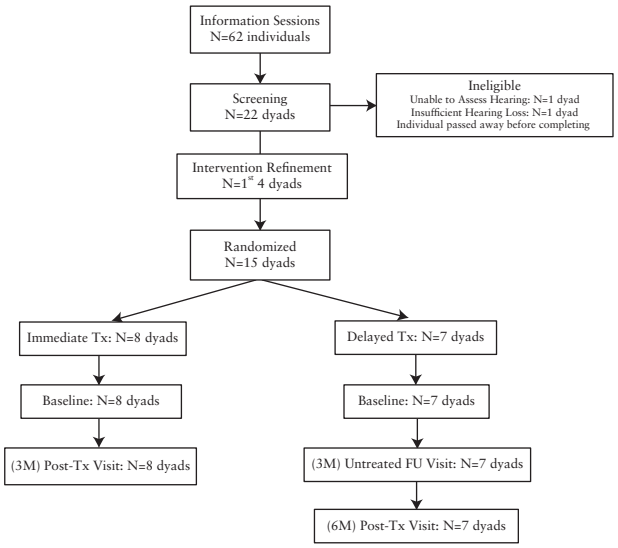

Figure 1. Flow chart of study participants.

HEARS Development and Intervention

The process of developing HEARS integrated principles of community-engaged research that involved community representatives, including low-income and minority older adults with hearing loss. We conducted a series of four separate focus groups that included a total of 23 different community representatives in order to explore perceptions of and barriers to hearing care along with preferences for learning new technology and desired intervention components and outcomes. Integrating lessons learned from the focus groups, the intervention includes a one-time training session to select and fit a listening device, learn how to use the device, and review essential education and counseling on age-related hearing loss and optimizing communication as a brief aural rehabilitation session (Table 1). Participant training materials developed from the focus groups include visual guides to be used during the training session and take-home references for later review. Materials were then reviewed by community representatives, who included service coordinators and volunteer resident leaders who were selected by the service coordinators as resident representatives. The community representatives provided feedback on the training materials and approach that was incorporated throughout the proof-of-concept process. The training session approach and materials were refined further in an iterative process based on the initial experience of the first four dyads, which were not included in the analytic cohort. Beyond the development of the intervention, regular meetings were held with community representatives throughout the pilot study. At the completion of the study, additional focus groups with the participants were held and the results of the study were shared with all participants in an open forum that also served as a graduation from the HEARS program. The open forum served as an important way to provide the study results to participants directly and obtain feedback on the interpretation and dissemination of the results, along with implications for future implementation.

In addition to a community engagement approach, we drew upon Bandura's Social Cognitive Theory and principles from a human factors approach to design. From Bandura's Social Cognitive Theory, the training session emphasizes strategies that enhance self-efficacy, utilizing: a) performance accomplishments, b) vicarious experience, c) verbal persuasion, and d) emotional arousal (Bandura, 1977). The training session follows a set structure: a) set a goal, b) model the behavior (vicarious experience), c) practice the behavior, and d) teach back (performance accomplishment). The HEARS training materials also incorporate principles of instruction for older adults from a human factors approach to design, which reinforce methods of enhancing self-efficacy: engage in solving meaningful problems, activate relevant previous experience, demonstrate problem solving techniques, use new skill to solve problems, and integrate new skill into daily life (Czaja & Sharit, 2012; Fisk et al., 2009). All materials use visuals to tell a story, simple and meaningful icons, large font size, high black/white contrast, arrows to highlight key information, and limit the use of jargon and the number of messages covered in a page (Czaja & Sharit, 2012; Fisk et al., 2009). Two forms of training materials were developed and provided to participants at the training session, a graphical version on how to use each listening device and highlights from the aural rehabilitation session intended for individuals with low literacy levels and a text/graphical version written at a 6th- to 7th-grade reading level with additional details.

Intervention Delivery

Each dyad, made up of the participant and communication partner, met with the trained interventionist (C. L. Nieman) for a one-time training session that included the selection of an over-the-counter personal sound amplification product (PSAP, also referred to here as a listening device), fitting and orientation to the device, education on age-related hearing loss, and elements of aural rehabilitation with a focus on communication strategies and expectation management and accompanying training materials (Table 1). In this initial pilot study, there was a single interventionist with training in audiology and otology who followed a protocol developed for a community health worker. The session is guided by the participant's primary goal for participation in the program and begins with selection of an over-the-counter listening device. Participants selected from two devices: the Sound World Solutions CS-50 (Park Ridge, IL; approximate retail price $350) or the Williams Sound Pocketalker Ultra Duo Pack (Eden Prairie, MN; approximate retail price $120). The devices were selected by the medical and audiological team based on their availability over-the-counter and relatively low cost compared to hearing aids along with their quality of output and older

adult-friendly features (Mamo, Reed, Nieman, Oh, & Lin, 2016). Each device was reviewed with the participant and each was able to try on the device.

The CS-50 is a Bluetooth-enabled, single-ear-worn device that can be paired to a smartphone and tailored to the individual's listening needs. The CS-50 may be programmed using a smartphone provided by the interventionist at the time of the fitting or the participant's personal phone. The participant does not need a smartphone to use the CS-50 on an ongoing basis and the device utilizes rechargeable batteries. The Pocketalker is a larger device that uses a remote microphone and headphones and has dials for volume and tone control. The Pocketalker runs on two AAA batteries and, as a larger, simpler device, was offered as an option for participants with limitations in manual dexterity. Features of both devices were reviewed along with the difference between an over-the-counter listening device and a hearing aid. Participants selected their own devices. Following device orientation, the remainder of the session focuses on understanding age-related hearing loss, understanding and practicing how to optimize communication, and a review of the resources available for reference and support.

All training sessions were conducted on an individual basis with the participant and his or her communication partner. The session was completed at the participant's building by a single interventionist, following a checklist of component tasks. The training session lasted a median of 1.8 hr (1.6–2 hr). Information regarding reasons to seek medical or audiological care were reviewed and resources provided. At the conclusion of the session, participants signed a waiver reviewing their understanding that they received a listening device and not a hearing aid and that they did not undergo a full medical and audiological evaluation. Referral resources for additional audiological and medical care were provided. Follow-up with the participants was performed with a phone call within ~5 days of the session in order to see if the participant had any initial questions or difficulties with listening device. The study team was also available by phone or in person for questions.

Measures

Baseline measures included questions on demographics and potential covariates, including hearing history, technology use (Communication Technology Use; Elliot, Mooney, Douthit, & Lynch, 2014), health literacy (REALM-R, Rapid Estimate of Adult Literacy in Medicine; scored 0–11, ≤6 means at-risk for poor health literacy; Bass, Wilson, & Griffith, 2003), and cognition (MoCA, Montreal Cognitive Assessment; scored 0–30, higher meaning better performance; Nasreddine et al., 2005). Self-efficacy was measured as hearing-related self-efficacy (The Line from the Ida Institute; scored 0–10, higher meaning higher level of self-efficacy; Jeppesen, 2015) and technology self-efficacy (adapted ATCQ, Attitudes Toward Computers Questionnaire; 5 items scored 1–5 and added, higher meaning higher level of self-efficacy; Jay & Willis, 1992).

Outcomes included communication function, capturing the social and emotional effects of hearing loss and related communication difficulties (HHIE-S, Hearing Handicap Inventory for the Elderly-Screening; 10 items, scored 4, 2, or 0 points depending on degree of hearing handicap, >8 suggests some degree of hearing handicap; Ventry & Weinstein, 1983; Weinstein, 1986; revised QDS, Quantified Denver Scale of Communication Function; 5 items, scored 1–5 and totaled, higher score, greater communication dysfunction; Tuley, Mulrow, Aguilar, & Velez, 1990), social-emotional function (revised UCLA Loneliness Scale; 20 items, scored 1–4, higher scores mean more severe loneliness; Peplau & Cutrona, 1980; PHQ-9, Patient Health Questionnaire; 9 items, scored 0–3, higher scores mean more severe depressive symptoms; Kroenke, Spitzer, & Williams, 2001) along with health-related quality of life (SF-36, Short-Form General Health Survey; 36 items, higher score means better quality of life; Stewart, Hays, & Ware, 1988). The primary outcome was self-reported hearing handicap (HHIE-S). Scores from a series of eight questions on the social and emotional effect of hearing loss (e.g., do you feel handicapped by a hearing problem?, do you feel that any difficulty with your hearing limits or hampers your personal or social life?, etc.) were summed, with higher scores equating to higher levels of hearing handicap.

Acceptability was measured as use and satisfaction with the HEARS program and listening device with the International Outcome Inventory-Alternative Interventions (IOI-AI; 7 items, scored 1–5, higher score means greater benefit derived; Laplante-Lévesque, Hickson, & Worrall, 2012; Noble, 2002) and self-reported willingness to pay (Yueh et al., 2001). Components of the IOI-AI include self-reported use and benefit from the device and communication strategies, residual activity limitations related to his or her hearing loss, satisfaction with the device and program, residual participation restriction secondary to his or her hearing loss, impact of his or her hearing loss on others following the program, and change in quality of life given the device and program participation.

Statistical Analyses

Statistical analysis was performed according to the intention to treat principle. Continuous variables were summarized using the median and interquartile range (IQR = 75th percentile–25th percentile; including age, monthly household income, adjusted MoCA Score, and hearing thresholds) or mean and standard deviation (including hearing help self-efficacy, computer self-efficacy, and listening device self-efficacy) along with Wilcoxon rank-sum test, which was used to compare outcome measures between the immediate and delayed treatment group. Categorical variables were summarized by frequency and compared using Fisher's exact test. Hypothesis tests were not performed

given that the trial was a small feasibility pilot. The primary outcome was change in hearing handicap score. Effect sizes were calculated using the mean change from baseline to 3-month follow-up in each group divided by the common (unpooled) standard deviation. In addition to these estimated effect sizes, estimates of the effect size using posttreatment data from all participants were calculated using baseline to posttreatment changes. The change from baseline to posttreatment in the delayed treatment group was adjusted by subtracting the mean change from baseline to 3-month follow-up to account for changes in the outcome due to pretreatment study participation. This adjusted difference was then divided by the common (unpooled) standard deviation of baseline to posttreatment change to give a pooled estimate of the effect size from all participants. Regarding missing data, two participants declined to share their monthly household income, which was taken into account in calculating the median monthly household income. No other missing data occurred. All analyses were performed in R version 3.2.1 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Sample Characteristics

The analytic cohort consisted of 15 participants. Participants primarily self-identified as racial/ethnic minorities, which included African Americans and a small number of Native Americans (Table 2). Participants had low income and many had inadequate health literacy (Table 1). The median degree of hearing loss was mild, ranging from mild to severe (Table 1). At baseline, the cohort had relatively high levels of communication difficulties, high levels of hearing- and technology-related self-efficacy, and moderate levels of technology use (Table 2). The cohort had high levels of loneliness and depression and low health-related quality of life (Table 2).

Three-Month Outcomes: Immediate Versus Delayed Treatment Groups

The median hearing handicap from baseline to 3 months decreased for the immediate and delayed treatment groups, but the median decrease for the immediate treatment group (19 to 10 points), following participation in the intervention, was greater than for the delayed treatment group (20 to 16 points) (Table 3). Greater improvements in hearing handicap were observed in those with higher levels of baseline hearing handicap (Figure 2). Similar improvements were seen with decreased communication difficulties (revised QDS; Table 3). For loneliness, median scores on the revised UCLA Loneliness Scale increased for both treatment groups over the same time period (Table 3). Depressive symptoms improved for both groups, with a greater improvement in the immediate treatment group and for participants with more depressive symptoms at baseline (Table 3, Figure 3). Median scores for mental and physical quality of life varied (Table 3).

We found strong to moderate effect sizes in the mean change from pre- to post-intervention, comparing the immediate and delayed groups (Table 4). The strongest effect sizes were seen with improvements in communication function and depressive symptoms. The mean change in hearing handicap for the immediate treatment group was −8.5 points compared to 0.3 points for the delayed (untreated) group and an effect size of −0.80 (Table 4). Similarly, the mean change in communication function was greater for the immediate compared to the delayed group and an effect size of −0.67 (Table 4). The mean change in depressive symptoms decreased to a greater degree among the treated, immediate group compared to the delayed treatment group and an effect size of −0.74 (Table 4). Smaller effect sizes were seen for loneliness and quality of life (Table 4).

Treatment Effects for All Participants

We investigated the change from baseline to 3-month posttreatment, pooling pre- to posttreatment data for both groups. The mean change in hearing handicap was a decrease in of 9.49 points and an effect size of −0.96 (Table 4). For communication function and depression, the mean changes and effect sizes were smaller with an improvement of 1.46 points in communication function and an effect size of −0.32 and a mean decrease in depressive symptoms of 1.93 points and an effect size of −0.43 (Table 4). The results for loneliness and quality of life remained varied and smaller (Table 4).

Feasibility and Acceptability

All participants completed the study and there were no adverse events. Overall use and satisfaction with the HEARS program was high (Table 5). Most participants used their device and communication strategies regularly, reported significant benefit, felt the device and program were worth the effort, and improved their enjoyment of life (Table 5). When participants were asked how much they would be willing to pay to participate in the HEARS program, including the provision of a listening device, the median one-time fee reported was $87.50 or 7.9% of the median monthly household income.

Participants rated their experience positively; 93% benefited from the program, 87% reported they would not be able to use their listening device as well without the program, 80% felt more connected with others, 67% felt less lonely, 80% found having a communication partner go through the program to be helpful. Regarding the device and program, 100% would recommend the listening device and program to others. When asked about their interest in helping others with hearing loss, 67% reported interest in training others.

Table 2. Baseline Characteristics of Participants by Group

	Immediate treatment group, *n* = 8	Delayed treatment group, *n* = 7	Overall, *n* = 15
Demographics			
Age (years), median (IQR)	69.9 (67.2–79.8)	72.2 (69.9–74.2)	70.1 (68.6–76.4)
Sex, *n* (%)			
Female	5 (62.5)	3 (42.9)	8 (53.3)
Race/ethnicity, *n* (%)			
African American or other	4 (50)	5 (71.4)	9 (60)
Living arrangement, *n* (%)			
Live alone	8 (100)	4 (57.1)	12 (80)
Education, *n* (%)			
Less than high school	2 (25)	2 (28.6)	4 (26.7)
High school graduate	1 (12.5)	3 (42.9)	4 (26.7)
Greater than high school	5 (62.5)	2 (28.6)	7 (46.7)
REALM (reading level), categories, *n* (%)			
6th grade or below	4 (50)	3 (42.9)	7 (46.7)
Monthly household income, median (IQR)	$862 ($731–1,118.20)	$1,235 ($1,050–2,600)	$1,100 ($824–1,600)
Adjusted Montreal Cognitive Assessment Score, median (IQR)	23 (21.2–27.2)	24 (21–28)	23 (21–28)
Hearing and hearing health care			
Hearing thresholds (dB HL)[a], median (IQR)	45.8 (38.8–59.2)	31.7 (30–43.3)	40 (32.5–53.3)
Hearing loss category (Better Ear Speech PTA[a]), *n* (%)			
Mild[b]	3 (37.5)	5 (71.4)	8 (53.3)
Moderate[c]	4 (50)	2 (28.6)	6 (40)
Severe[d]	1 (12.5)	0 (0)	1 (6.7)
Hearing screening, *n* (%)			
<1 year ago	1 (12.5)	1 (14.3)	2 (13.3)
1–4 years ago	4 (50)	1 (14.3)	5 (33.3)
5–9 years ago	1 (12.5)	0 (0)	1 (6.7)
10 or more years ago	2 (25)	2 (28.6)	4 (26.7)
Never	0 (0)	3 (42.9)	3 (20)
Hearing help self-efficacy, mean (*SD*)	8.6 (2.1)	8 (1.7)	8.3 (1.9)
Ever worn a hearing aid, *n* (%)			
Yes	1 (12.5)	0 (0)	1 (6.7)
Ever used a listening device, *n* (%)			
Yes	2 (25)	1 (14.3)	3 (20)
Occupational noise exposure, *n* (%)			
Yes	3 (37.5)	4 (57.1)	7 (46.7)
Technology use and self-efficacy			
Owns a cellphone, *n* (%)	6 (75)	6 (85.7)	12 (80)
Owns a smartphone, *n* (%)	1 (12.5)	5 (70.5)	6 (40)
Used a computer within the past month, *n* (%)	3 (37.5)	5 (70.5)	8 (53.3)
Used text or e-mail within the past month, *n* (%)	3 (37.5)	4 (57.1)	7 (46.7)
Computer self-efficacy, mean (*SD*)	20 (3.6)	20.6 (2.4)	20.3 (3)
Listening device self-efficacy, mean (*SD*)	19 (4.5)	21.7 (2.1)	20.3 (3.7)
Outcome measures			
Communication function			
HHIE-S[e], median (IQR)	19 (14.5–27.5)	20 (17–20)	20 (16–22)
Revised QDS[f], median (IQR)	16 (14–20.2)	16 (12.5–16.5)	16 (13.5–18)
Social-emotional function			
Revised UCLA[g], median (IQR)	46 (43.8–54)	46 (37.5–55.5)	46 (41.5–55.5)
PHQ-9[h], median (IQR)	9.5 (4.8–13.8)	8 (3–8.5)	8 (4–11.5)

Table 2. *Continued*

	Immediate treatment group, *n* = 8	Delayed treatment group, *n* = 7	Overall, *n* = 15
Quality of life			
SF-36 mental component[i], median (IQR)	50.9 (38–57.2)	56.6 (49.7–59.3)	54.4 (41.9–58.6)
SR-36 physical component[i], median (IQR)	41.5 (40.1–47)	50.6 (47.5–60)	46.3 (41.5–59.9)

Notes: IQR = interquartile range; PTA = Pure Tone Average; REALM = Rapid Estimate of Adult Literacy in Medicine.
[a]Hearing thresholds are defined as the averaged response at three test frequencies (1, 2, and 4 kHz) in the better hearing ear for each participant, also known as the Better Ear Speech PTA.
[b]Mild hearing loss equates to Better Ear Speech PTA >25 dB HL and ≤40 dB HL based on American Speech-Language-Hearing guidelines, collasped into fewer categories to assist with analysis.
[c]Moderate hearing loss equates to Better Ear Speech PTA >40 dB HL and ≤70 dB HL based on American Speech-Language-Hearing guidelines, collasped into fewer categories to assist with analysis.
[d]Severe hearing loss equates to Better Ear Speech PTA >70 dB HL based on American Speech-Language-Hearing guidelines, collasped into fewer categories to assist with analysis.
[e]Hearing Handicap Inventory for the Elderly-Screening; 10 items, scored 4, 2, or 0 points depending on degree of hearing handicap, >8 suggests some degree of hearing handicap.
[f]Revisied Quantified Denver Scale of Communication Function; 5 items, scored 1–5 and totaled, higher score, greater communication dysfunction.
[g]Revised UCLA Loneliness Scale; 20 items, scored 1–4, higher scores mean more severe loneliness.
[h]Patient Health Questionnaire; 9 items, scored 0–3, higher scores mean more severe depressive symptoms.
[i]Short-Form General Health Survey; 36 items, higher score means better quality of life.

Discussion

The HEARS intervention is a novel, theory-driven, community-delivered hearing care intervention for older adults that was developed through a community engagement process. This process entailed initial formative meetings with community representatives, focus groups with participants and their communication partners, and further refinement of the intervention based on feedback from the first dyads to complete the intervention in order to assure relevance and acceptability. Our results demonstrated that a one-time training session including immediate provision of an over-the-counter listening device and interactive aural rehabilitative training reduces hearing handicap, improves communication function, and decreases depressive symptoms with moderate to large effect sizes. For a cohort of minority, urban-dwelling, and low-income older adults, the intervention was positively received and proposes an additional model of care to address disparities in hearing care and illustrates the potential power of community-engaged research in designing and testing interventions to address disparities.

The primary outcome of interest was change in hearing handicap or change in the negative social and emotional effects of hearing loss. The mean change in hearing handicap among all participants and the effect size compares to improvements seen with hearing aids (Chisolm et al., 2007; Newman, Jacobson, Hug, Weinstein, & Malinoff, 1991; Vuorialho, Karinen, & Sorri, 2006a, 2006b). Improvements in communication function, as measured by reductions in hearing-related communication difficulties, were greater than improvements reported with hearing aids, including programmable aids (Yueh et al., 2001). Although preliminary, our results suggest that a community-delivered hearing care intervention that incorporates over-the-counter technology and aural rehabilitation may achieve similar improvements in communication function to hearing aids and usual care.

Depression is a key outcome associated with hearing care (Acar, Yurekli, Babademez, Karabulut, & Karasen, 2011; Boi et al., 2012; Mulrow et al., 1990) and has been independently associated with hearing loss (Li et al., 2014). Following participation in the HEARS program, participants had a mean improvement in their depression scores that approaches the effect of other community-delivered, nonpharmacologic interventions for depression among older adults (Gitlin et al., 2013). Unlike depression, the HEARS intervention did not improve the mean loneliness scores of participants on objective measures but subjective measures demonstrated some improvement. The inconsistent effect of the program on loneliness is similar to other studies that found inconclusive findings on the effect of hearing aids and aural rehabilitation on loneliness and may have been complicated by the high rate of participants living alone (Cattan, White, Bond, & Learmouth, 2005; Tesch-Römer, 1997).

The effect of the HEARS intervention on health-related quality of life was inconsistent and relatively weak. Similar findings have been found with hearing aids (Bess, 2000; Mulrow et al., 1990; Stark & Hickson, 2004) and aural rehabilitative programs (Abrams, Chisolm, & McArdle, 2002; Hickson, Worrall, & Scarinci, 2007). Generally, disease-specific functional and quality of life measures (e.g., HHIE-S, revised QDS, and IOI-AI) capture benefits related to hearing care interventions, whereas generic quality of life measures (e.g., SF-36) remain unchanged or inconclusive

Table 3. Outcomes at Baseline and 3-Month Follow-Up by Group

	Median (IQR)	
	Immediate	Delayed
Communication function		
HHIE-S[a]		
Baseline	19 (14.5–27.5)	20 (17–20)
3-month follow-up	10 (10–14.5)	16 (14–22)
Revised QDS[b]		
Baseline	16 (14–20.2)	16 (12.5–16.5)
3-month follow-up	10.5 (6–14.2)	13 (11–14.5)
Social-emotional function		
Revised UCLA[c]		
Baseline	46 (43.8–54)	46 (37.5–55.5)
3-month follow-up	51.5 (38.8–56)	48 (31–50)
PHQ-9[d]		
Baseline	9.5 (4.8–13.8)	8 (3–8.5)
3-month follow-up	5 (3–9.2)	5 (3–7.5)
Quality of life		
SF-36 mental component[e]		
Baseline	50.9 (38–57.2)	56.6 (49.7–59.3)
3-month follow-up	51.7 (39.9–57.2)	53.8 (53.1–59.5)
SF-36 physical component[e]		
Baseline	41.5 (40.1–47)	50.6 (47.5–60)
3-month follow-up	47.6 (42.4–53.1)	50.3 (45.6–60.5)

Notes: IQR = interquartile range.
[a]Hearing Handicap Inventory for the Elderly-Screening; 10 items, scored 4, 2, or 0 points depending on degree of hearing handicap, >8 suggests some degree of hearing handicap.
[b]Revisied Quantified Denver Scale of Communication Function; 5 items, scored 1–5 and totaled, higher score, greater communication dysfunction.
[c]Revised UCLA Loneliness Scale; 20 items, scored 1–4, higher scores mean more severe loneliness.
[d]Patient Health Questionnaire; 9 items, scored 0–3, higher scores mean more severe depressive symptoms.
[e]Short-Form General Health Survey; 36 items, higher score means better quality of life.

given a lack of sufficient sensitivity (Bess, 2000; Hickson et al., 2007).

Participants' use and satisfaction with the listening devices and program are an important comparison to usual care. Participants reported favorable attitudes toward the device and program. Participants' mean scores compare to and, in many cases, exceed older adults' attitude toward hearing aids, including low-cost versions and home-based aural rehabilitation (Cox, Alexander, & Beyer, 2003; Kramer, Allessie, Dondorp, Zekveld, & Kapteyn, 2005; McPherson & Wong, 2005; Parving & Christensen, 2004). Furthermore, participants were willing to pay for the program, including the device and accompanying education and counseling, despite their relatively low income, demonstrating a promising potential for a sustainable model of care.

Our preliminary pilot study has limitations. The analytic cohort was small with 15 older adults as a convenience sample in this feasibility pilot, preventing inference testing or statistical comparisons. All participants lived in an urban environment and participated in services through a

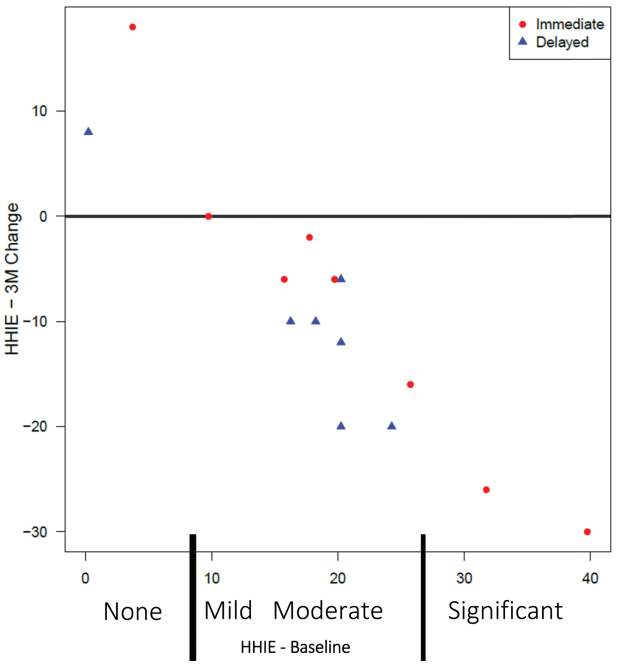

Figure 2. Change in hearing handicap vs baseline hearing handicap score by treatment group. Change in hearing handicap was measured as the change from baseline to 3-month follow-up in the immediate treatment group and from baseline to 6-month follow-up, 3 months after receiving the intervention, in the delayed treatment group.

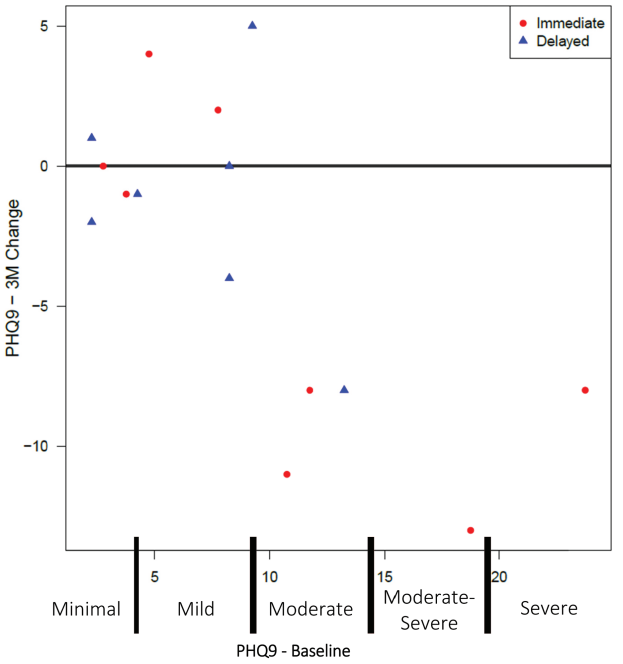

Figure 3. Change in depressive symptoms vs baseline depression score by treatment group. Change in depressive symptoms was measured as the change from baseline to 3-month follow-up in the immediate treatment group and from baseline to 6-month follow-up, 3 months after receiving the intervention, in the delayed treatment group.

Table 4. Mean Change in Outcome Measures and Effect Sizes From Before Intervention to 3 Months After Intervention

	Unpooled, baseline to follow-up			Pooled, untreated to treated	
	Immediate	Delayed			
	Mean change (*SD*)		Effect size	Mean change	Effect size
Communication function					
HHIE-S[a]	−8.5 (15.4)	0.3 (4.5)	−0.80	−9.49	−0.96
Revised QDS[b]	−5.9 (6.8)	−2.1 (4.3)	−0.67	−1.46	−0.32
Social-emotional function					
Revised UCLA[c]	−2.1 (10.8)	−4 (5.2)	0.23	1.4	0.31
PHQ-9[d]	−4.4 (6.4)	−1 (1.7)	−0.74	−1.93	−0.43
Quality of life					
SF-36 mental component[e]	2.1 (14.7)	1.7 (14)	0.02	−1.77	−0.18
SF-36 physical component[e]	3.6 (5.8)	−1.3 (5.4)	0.88	1.36	0.15

Notes: [a]Hearing Handicap Inventory for the Elderly-Screening; 10 items, scored 4, 2, or 0 points depending on degree of hearing handicap, >8 suggests some degree of hearing handicap.
[b]Revisied Quantified Denver Scale of Communication Function; 5 items, scored 1–5 and totaled, higher score, greater communication dysfunction.
[c]Revised UCLA Loneliness Scale; 20 items, scored 1–4, higher scores mean more severe loneliness.
[d]Patient Health Questionnaire; 9 items, scored 0–3, higher scores mean more severe depressive symptoms.
[e]Short-Form General Health Survey; 36 items, higher score means better quality of life.

nonprofit housing association, limiting the generalizability of the results. Participants were required to have a communication partner, someone they spoke with daily who was willing and eligible to complete the study, which may have selected for participants with stronger social networks and did not capture those most at-risk for negative social-emotional consequences. Participants had a range of hearing loss, but primarily mild to moderate hearing loss, and may not represent the experience of individuals with more severe hearing loss. However, larger improvements in hearing handicap and depressive symptoms were generally seen among participants with greater hearing handicap and more depressive symptoms. As an initial feasibility trial, only one trained interventionist delivered the program, who had advanced training, which does not reflect the level of education and training of community health workers, who will serve as future interventionists and are currently undergoing training. All services, including the listening device, were provided without cost, as compensation for participation in a research study. Use and satisfaction with an listening device may vary based on who covered the costs (Cox et al., 2003).

Implications for Implementation and Sustainability

Key national discussions are poised to redefine access to hearing care (Cassel, Penhoet, & Saunders, 2016; Lustig & Olson, 2014; National Academies of Sciences, Engineering, and Medicine, 2016; PCAST, 2015). Although small and preliminary, our pilot study raises critical questions around the future implementation and sustainability of an additional model of hearing care delivered outside of a clinical setting, in the community, that utilizes over-the-counter technology with oversight by a medical and audiological team. Through the lens of Murray's Normalization Process Theory, components of coherence, cognitive participation, collective action, and reflexive monitoring must be considered (Murray et al., 2010).

In terms of coherence, the intervention was clearly understood by participants and community partners. However, explanation of the distinction between hearing aids and over-the-counter devices and the indications and available resources for audiological and medical follow-up is necessary. The alignment of our sense of purpose with our community partners in providing tools and training that were previously inaccessible strengthened our collaboration. For cognitive participation, participants and partners appreciated the use of only devices that are currently available to consumers and incorporated rechargeable or commonly used batteries (e.g., AAA batteries) to limit ongoing costs of using their new devices. Although increasing numbers of older adults own smartphones, only devices that could operate without the use of a smartphone were used in the intervention so that participants were not limited by their access to technology. Regarding collective action, all devices and training sessions were provided at no cost, as compensation for participation in the study. Although participants report a willingness to pay a mean $87.50 for the program and device or 7.9% of their monthly household income, consumer behavior may differ. The current retail cost of the devices ($120–350) compared to participants' willingness to pay underlines the need for subsidization and continued innovation to decrease the cost of hearing care to within range of all older adults. Compared to the $2,000–4,000 in out-of-pocket costs associated with hearing aids and usual care, the HEARS intervention and devices represent a relative low-cost option. In order to build on a potential model

Table 5. Percent Distribution and Mean Scores to Responses on the International Outcome Inventory-Alternative Intervention

Device use[a]		Program use[b]		Benefit[c]		Residual activity limitations[d]		Satisfaction[e]		Residual participation restrictions[f]		Impact on others[g]		Quality of life[h]	
None	13%	None	7%	Not at all	7%	Very much	7%	Not at all	0%	Very much	7%	Very much	0%	Worse	0%
<1 hr/day	27%	Rarely	13%	Slightly	13%	Quite a lot	0%	Slightly	13%	Quite a lot	0%	Quite a lot	7%	No change	27%
1–4 hr/day	**33%**	Sometimes	27%	Moderately	27%	Moderate	7%	Moderately	0%	Moderate	27%	Moderately	7%	Slightly	13%
4–8 hr/day	13%	**Often**	**40%**	Quite a lot	20%	**Slight**	**60%**	Quite a lot	20%	**Slight**	**47%**	Slightly	40%	**Quite a lot**	**33%**
>8 hr/day	13%	Almost always	13%	**Very much**	**33%**	None	27%	**Very much**	**67%**	None	20%	**Not at all**	**47%**	Very much	27%
Mean score															
2.9		3.4		3.6		4		4.4		3.7		4.3		3.6	

Notes: HEARS = Hearing Equality through Accessible Research & Solutions. The ordinal response scale for each item below is ordered vertically from least benefit to greatest benefit. The most commonly provided response is bolded (n = 15).

[a]Device use: Think about how much you used the listening device over the past 2 weeks. On an average day, how many hours did you use it?

[b]Program use: Think about how much you used the listening device and what you learned in Baltimore HEARS over the past 2 weeks. On an average day, how many hours did you use them?

[c]Benefit: Think about the situation where you most wanted to hear better, before doing the Baltimore HEARS program. Over the past 2 weeks, how much has Baltimore HEARS helped in that situation?

[d]Residual activity limitations: Think again about the situation where you most wanted to hear better. When you use the listening device and what you learned in Baltimore HEARS, how much difficulty do you STILL have in that situation?

[e]Satisfaction: Considering everything, do you think participating in the Baltimore HEARS program is worth the trouble?

[f]Residual participation restrictions: Over the past 2 weeks, using the listening device and what you learned in Baltimore HEARS, how much have your hearing difficulties affected the things you do?

[g]Impact on others: Over the past 2 weeks, with your listening device and using what you learned in Baltimore HEARS, how much were other people bothered by your hearing difficulties?

[h]Quality of life: Considering everything, how much has your listening device and using what you learned in Baltimore HEARS changed your enjoyment of life?

of hearing care through community-delivered care, training materials designed for community health workers to deliver the intervention are currently under development and will provide essential insight into the feasibility, acceptability, and efficacy of the program as delivered by a peer. Initial interest from the majority of participants to serve as trainers and support from focus group discussions for program delivery by non-health care professionals demonstrate preliminary acceptability. Finally, important questions related to reflexive monitoring are currently unanswered in terms of the need for ongoing support, booster training, and durability of devices.

Conclusion

Our pilot demonstrated that a community-delivered, user-centered hearing care intervention designed for older adults that integrates low-cost, over-the-counter technology in a one-time training session is acceptable, feasible, low risk, and may improve outcomes similar to hearing aids and the usual standard of care. We must replicate our results in additional contexts and larger communities to evaluate outcomes along with the barriers and paths to more rapid scaling. Although preliminary, the HEARS intervention's results in delivering care to an at-risk older adult population highlight the value of a community engagement research approach in addressing disparities. Our work demonstrates the value of developing interventions through community engagement and serves as a model for addressing disparities in hearing loss, particularly for low-income older adults.

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