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A Randomized Controlled Trial to Evaluate Approaches to Auditory Rehabilitation for Blast-Exposed Veterans with Normal or Near-Normal Hearing Who Report Hearing Problems in Difficult Listening Situations

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Abstract

Background: Blast exposure is a major source of injury among Service members in the Iraq and Afghanistan conflicts. Many of these blast-exposed veterans report hearing-related problems such as difficulties understanding speech in noise and rapid speech, and following instructions and long conversations that are disproportionate to their measured peripheral hearing sensitivity. Evidence is mounting that these complaints result from damage to the central auditory processing system.

Purpose: To evaluate the effectiveness of audiological rehabilitative interventions for blast-exposed veterans with normal or near-normal peripheral hearing and functional hearing difficulties.

Research Design: A randomized controlled trial with four intervention arms.

Study Sample: Ninety-nine blast-exposed veterans with normal or near-normal peripheral hearing who reported functional hearing difficulties.

Intervention: Four interventions were compared: compensatory communication strategies (CCS) education, CCS and use of a personal frequency modulation system (FM + CCS), CCS and use of an auditory training program (AT + CCS), and use of all three interventions combined (FM + AT + CCS).

Data Collection and Analysis: All participants tested before, and immediately following an 8-week intervention period. The primary outcome measures upon which the study was powered assessed speech understanding in noise and self-reported psychosocial impacts of the intervention. In addition, auditory temporal processing, auditory working memory, allocation of attention, and hearing and cognitive self-report outcomes were assessed.

Results: Use of FM + CCS resulted in significant benefit for speech understanding in noise and self-reported hearing benefits, and FM + AT + CCS provided more self-reported cognitive benefits than

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Aspects of this work have been presented at the 2013 American Speech Language Hearing Association Annual Convention, Chicago, IL, November 14–16; at the 2012 Phonak Advances in Audiology – Tomorrow's Solutions for Today's Challenges, Las Vegas, NV, December 2–5; and at the 2010 International Hearing Aid Conference (IHCON), Lake Tahoe, CA, August 11–15.

FM + CCS, AT + CCS, or CCS. Further, individuals liked and reported using the FM system, but there was poor adherence to and high attrition among individuals assigned to receive AT.

Conclusions: It is concluded that a FM system (or remote microphone via Bluetooth system) is an effective intervention for blast-exposed veterans with normal or near-normal hearing and functional hearing difficulties and should be routinely considered as an intervention approach for this population when possible.

Key Words: auditory processing disorder, rehabilitation, traumatic brain injury

Abbreviations: 4F-PTA = four-frequency pure-tone average; AC = across-channel; ANOVA = analysis of variance; AT = auditory training; ATTR = Adaptive Tests of Temporal Resolution; CCS = compensatory communication strategies; CONSORT = Consolidated Standards of Reporting Trials; CSRQ = Cognitive Self-Report Questionnaire; DS = Digit Span test; FHQ = Functional hearing questionnaire; FM = frequency modulation; HINT = Hearing-in-Noise Test; IRB = institutional review board; OEF = Operation Enduring Freedom; OIF = Operation Iraqi Freedom; PIADS = Psychosocial Impact of Assistive Devices Scale; SD = standard deviation; SNR = signal-to-noise ratio; SPL = sound pressure level; SSQ-C = Speech Spatial Qualities questionnaire–comparative version; SSW = Staggered Spondaic Word test; TBI = traumatic brain injury; TCST = Time-Compressed Speech Test; VHA = Veterans Health Administration; WC = within-channel

INTRODUCTION

Blast exposure and associated traumatic brain injuries (TBIs) are common among Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn veterans. Approximately 79% of injuries sustained during OEF/OIF deployment were associated with explosions from improvised explosive devices, landmines, mortars bombs, or grenades (Owens et al, 2008). As a result, >67,000 OIF and OEF service members seeking medical care through the Veterans Health Administration (VHA) during fiscal years 2010–2012 received diagnoses of TBI (Department of Veterans Affairs: Quality Enhancement Research Initiative, 2014), while many others reported signs of a persistent postconcussive state subsequent to blast exposure, though did not receive formal TBI diagnoses (Howe, 2009). Blast-related consequences to the brain following blast exposure can occur, regardless of an actual TBI diagnosis. These consequences include sleep disturbance (Verfaellie et al, 2015), headaches (Couch and Stewart, 2016), cognitive impairment (Rabinowitz and Levin, 2014), posttraumatic stress disorder (Kennedy et al, 2010), visual dysfunction (Capó-Aponte et al, 2016), and, most relevant here, hearing-related problems (Munjal et al, 2010; Belanger et al, 2011; Oleksiak et al, 2012; Saunders et al, 2015).

The vulnerability of the central auditory system to blast exposure and TBI has become more apparent with recent data showing poorer speech understanding in noise, binaural processing, temporal resolution, and speech segregation in blast-exposed individuals (Gallun, Lewis, et al, 2012; Vander Werff, 2012; Saunders et al, 2015). It is believed that these symptoms are the result of primary blast injuries that cause contusions (bruising) from the brain moving within the skull, hemorrhaging from the tearing of surface veins, and diffuse axonal injury as neurons are sheared and stretched. The specific areas of the brain thought to be damaged are the lower- and midbrain stem nuclei, the thalamus, and the corpus callosum (Rodriguez-Paez et al, 2005). Synaptic structures connecting nuclei in the central auditory system and the corpus callosum are also thought to be affected (Peru et al, 2003; Okie, 2005). The damage is thought to interfere with auditory and speech processing and likely contributes to trouble listening in background noise, difficulty following oral instructions, and/or difficulty understanding rapid or degraded speech. Audiologists at VHA often encounter blast-exposed veterans with normal or near-normal hearing seeking help for their hearing-related difficulties but are unsure of an appropriate approach to clinical management (Saunders et al, 2015). It is thus important to find ways to provide rehabilitative interventions for the many veterans with these central auditory processing problems.

A three-pronged approach to intervention for individuals with auditory processing difficulties is often proposed, consisting of environmental modifications, direct training of auditory skills, and the use of compensatory communication strategies (CCS; Bellis and Anzalone, 2008). The goal of intervention is not to cure the auditory processing disorder, but rather to develop strategies that minimize disability and maximize communication. The rationale for this three-pronged approach is as follows: (a) environmental modifications aim to improve the acoustic signal, allowing for more resources for higher-level processing being made available; (b) training of auditory skills will improve this higher level processing; and (c) CCS can build self-reliance and promote generalizability of skills into everyday activities.

Environmental modifications may address room acoustics or may involve the utilization of devices aimed at enhancing the acoustic signal of interest. A common and effective approach for improving signal quality is

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the use of a personal frequency modulation (FM) system, and more recently Bluetooth connectivity. With these approaches, the talker is provided with a microphone and transmitter which allow for a wireless FM or Bluetooth connection to a receiver worn by the listener. The use of wireless connectivity is very effective at improving the signal-to-noise ratio (SNR) at the listener's ear, resulting in well-documented improvements in speech understanding in noise by adults with hearing loss (Jerger et al, 1996; Boothroyd, 2004; Lewis et al, 2004) and children with hearing loss and/or auditory processing difficulties (Anderson and Goldstein, 2004; Schafer and Thibodeau, 2006). The most relevant research for the present work are documented improvements in speech understanding for those children with essentially normal peripheral hearing sensitivity and problems with auditory processing (Johnston et al, 2009; Sharma et al, 2012). While use of wireless technologies aimed at improving the SNR may provide an effective intervention for the population of interest here, there are several potential barriers to the acceptance and successful use of a FM system by adults. First, there are cosmetic concerns, as the FM receiver resembles a behind-the-ear hearing aid, and it may draw unwanted attention to the individual with the hearing difficulties. Second, an understanding of and willingness to use a FM system are both critical, and these efforts can easily be hindered by reluctance on the part of the user to ask a talker to use the transmitting microphone and/or reluctance on the part of the talker to accommodate the request (Boothroyd, 2004; Chisolm et al, 2007; Fabry et al, 2007). Given the benefits that are documented with the use of a FM (or other wireless systems), the use of technology for environmental modification is worthy of investigation as a rehabilitative intervention with blast-related hearing difficulties.

Training of auditory skills can come in the form of person-to-person auditory rehabilitation sessions or, as is more common today, computer-based auditory training (AT). It is established that neural connections within the brain can reorganize and restructure in response to intrinsic conditions and/or sensory experiences (i.e., neuroplasticity) lending support to AT as rehabilitation for auditory processing deficits. Studies show that intensive auditory skills training can strengthen electrophysiological responses within the auditory cortex (Russo et al, 2005; Tremblay et al, 2009), potentially improving speech understanding. The outcomes of clinical trials on auditory skills training are somewhat mixed. While in general, improvements are found for on-task performance, only some studies have shown good generalization (Stecker et al, 2006; Sweetow and Sabes, 2006; Miller et al, 2007), whereas other studies show little or no generalization (Agnew et al, 2004; Burk and Humes, 2008; Burk et al, 2006; Ferguson et al, 2014; Saunders et al, 2016). Indeed, a systematic review (Henshaw and Ferguson, 2013) on the outcomes of computer-based AT for adults with hearing loss concluded that there was a need for further efficacy studies. Although the available evidence could not reliably guide AT intervention, the flexibility as well as the time- and cost-effectiveness of computer-based AT warrant further investigation as a tool for improving listening abilities of adults, including those with blast-related auditory processing difficulties.

Finally, CCS focus on the strengthening of higher-order central resources (e.g., language, cognition) and behavioral strategies that can help in the management of conversations and other communication situations. For example, an individual may learn how to most effectively ask for a repair when there is a communication breakdown, or one may learn how to position oneself to minimize the impact of background noise. Communication strategy training can occur in a one-on-one educational session, or it can be provided in a group setting. While adults with peripheral hearing losses, as well as those with auditory processing problems, could benefit from communication strategy training, in a survey of 962 adult hearing aid users, Sticka and Ross (2011) found that the percentage who received CCS education was very low, ranging from 10% for those seen by a hearing instrument specialist to 20% for those seen by an audiologist. Although CCS education does not appear to be provided regularly to adults with hearing difficulties, it is indeed another potentially effective approach for the population of interest in this study.

In sum, blast-related hearing difficulties are common among OIF/OEF veterans and in nature appear to reflect auditory processing deficits. While clinicians serving these populations need tools and rehabilitative interventions aimed at minimizing these hearing-related difficulties, research is needed to evaluate their effectiveness. To this end, a parallel-group randomized controlled trial was conducted to compare the outcomes of (a) CCS education alone, (b) use of a personal FM system plus CCS (FM + CCS), (c) provision of AT plus CCS (AT + CCS), and (d) the combination of all three interventions (AT + FM + CCS) in OEF/OIF blast-exposed veterans who report more hearing-related difficulties than would be expected based on their normal or near-normal peripheral hearing sensitivity.

MATERIALS AND METHODS

Study Synopsis

The parallel-group study was completed at two sites: the University of South Florida, Tampa, FL, and the VA Portland Health Care System, Portland, OR. Veterans with normal or near-normal peripheral hearing and functional hearing difficulties participated. All were

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randomly assigned to one of four intervention groups. Performance on behavioral and self-report measures was assessed before and immediately following an 8-week intervention period. The study methodology and results are reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines for reporting parallel group randomized trials (Schulz et al, 2010). The trial was registered with ClinialTrials.gov under identifier NCT00930774 and was approved by the institutional review boards (IRBs) and the research and development committees at each site: VA Portland Health Care System IRB ID #02386 and University of South Florida IRB ID #00000263.

Participants

Ninety-nine veterans participated in the study. They were recruited from the Portland VA Medical Center OR and the James A. Haley Veterans Hospital, Tampa, FL, between October 2010 and September 2012, with follow-up completed by November 2012. The number recruited was based on a power analysis that indicated the need to randomize 11 participants per site into each of the four intervention groups such that a 10% withdrawal rate would result in 90% power to detect differences between intervention groups on the Psychosocial Impact of Assistive Devices Scale (PIADS; Day and Jutai, 1996) and the Hearing-in-Noise Test (HINT; Nilsson et al, 1994). Participants were recruited from the audiology and speech pathology clinics, the OEF/OIF clinics, and the TBI clinics at both sites. Fliers describing the study were posted in each of these locations. The fliers provided study team contact information for potential participants. In addition, the study team gave presentations about the study to the staff at each clinic so the staff could make their patients aware of the study. To be eligible for participation, individuals had to meet the following inclusion criteria: (a) be a veteran of the OEF/OIF conflicts; (b) report exposure to one or more blasts during combat; (c) report problems understanding speech in difficult listening situations; (d) have air-conduction thresholds <40 dB HL at 500, 1000, 2000, 3000, and 4000 Hz in both ears with thresholds <30 dB HL at three of these frequencies; (e) have symmetrical air-conduction thresholds (a left-right difference not exceeding 15 dB HL at the frequencies of 500–4000 Hz); (f) have age- and education-appropriate scores on the Mini-Mental State Exam (Folstein et al, 1975; 1983); and (g) be able to see and read a computer screen so they could conduct AT, as determined by a best aided visual acuity score of at least 20/63 on the Smith-Kettlewell Institute Low Luminance card (Haegerstrom-Portnoy et al, 1997). Individuals were not eligible to participate if they failed to meet any of the above criteria, or exhibited any of the following: an active external ear disease or conductive component to their hearing loss; a confirmed diagnosis of dynamic cochlear pathology; a diagnosis of a neurological or psychiatric disorder that could reduce the likelihood of successful participation in the study, such as schizophrenia spectrum and other psychotic disorders, and bipolar and related disorders; or a comorbid disease that would interfere with ability to complete the study, and/or a history of auditory processing, reading, or language learning problems in school. Finally, if they used hearing aids or an FM system or had previously used an AT program, they were not eligible to participate.

Interventions

There were four intervention groups (CCS, FM + CCS, AT + CCS, and FM + AT + CCS), as described below.

CCS Education

CCS education was provided to participants in all intervention groups because it was the closest to standard of care that was being provided at the time the study was designed (Saunders et al, 2015). The CCS education consisted of a 10- to 15-min one-on-one session conducted by the Study Audiologist. Three patient brochures published by the National Center for Rehabilitative Auditory Research formed the basis for the talking points. The brochures addressed auditory processing, communication strategies, and hearing conservation. Participants were given a copy of each brochure to take home with them. These brochures were selected because they are disseminated nationwide by clinicians within the VHA Audiology Service and they addressed topics pertinent to the CCS education that were considered important and relevant to provide to the study population. The brochures can be found at http://www.ncrar.research.va.gov/ForVets/Index.asp.

Use of an FM System in Addition to CCS Education (FM + CCS)

In addition to receiving the CCS education, participants in this group were provided with bilateral Phonak iSense Micro Dynamic FM Receivers and a Zoom Link+ Dynamic Transmitter (Phonak, Switzerland) to use during the 8-week intervention period. Each device was tested in a Frye 7000 hearing aid test box to verify that the output met target specifications (maximum output sound pressure level [SPL] 90 of ±5 dB, high-frequency average output SPL90 of ±6 dB, high-frequency average full on gain at 50 dB of ±6 dB, equivalent input noise ≤5 dB, and harmonic distortion of ≤5%). Participants were provided with verbal and written instruction on device function and features, device care and maintenance, appropriate

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situational use, device benefits and limitations, troubleshooting, and self-advocacy for accommodating device use. Specifically regarding use, the audiologist had participants describe situations in which they were experiencing hearing difficulties. The audiologist then discussed how the FM system could be utilized in those particular situations. In addition, participants were encouraged to use the FM system in situations such as in a noisy restaurant, while driving in a car, and in a classroom/lecture type of setting. Orientation also included a demonstration during which the audiologist would speak to the participant from a distance while the FM system was in use.

AT + CCS Education (AT + CCS)

In addition to receiving the CCS education, participants were instructed to conduct AT 1 hr per day, 5 days/week during the 8-week intervention period, for a total of 40 hr of AT. The computer-based AT program selected was the Brain Fitness Program of Posit Science. This program was chosen first, because it trains skills such as temporal processing and auditory pattern recognition that have been found to be problematic in individuals with central auditory processing deficits (Atcherson et al, 2015; Bellis and Bellis, 2015) and following TBI/blast-exposure (Gallun, Diedesch, et al, 2012; Vander Werff, 2012). Second, it was chosen because studies have shown improved speech understanding in noise, memory, and attention following training with the program (Mahncke et al, 2006; Smith et al, 2009; Anderson et al, 2013). Brain Fitness consists of six auditory exercises ("High or Low," "Tell Us Apart," "Match It! Sound Replay," "Listen and Do," and "Story Teller") designed to train temporal resolution, gap detection, memory, and sound discrimination. Further description of these exercises and the adaptive algorithms used by the program can be found at http://www.positscience.com/sites/default/files/pdfs/bfp_coaches_guide.pdf. Participants were loaned a laptop computer and supra-aural headphones to take home for the duration of the training, along with detailed written instructions regarding equipment setup.

FM + AT + CCS Education (FM + AT + CCS)

Participants in this intervention group received the CCS education and were asked to wear the FM system and to conduct AT over the 8-week intervention period. They received the same equipment and verbal and written instructions regarding equipment use as the FM + CCS and AT + CCS groups.

Randomization

Randomization was stratified by site and intervention to assure that each site enrolled an equal number of participants into each intervention. The study statistician provided each site with sequentially numbered randomization envelopes that contained the intervention arm to which the participant was randomized (CCS, FM + CCS, AT + CCS, FM + AT + CCS). For each participant the envelope was opened just before Visit 2 so that the study research team could ensure FM and/or AT equipment was available and prepared for the participant.

Baseline Measures

Audiometric Evaluation

Routine clinical audiometry, including air- and bone-conduction thresholds and word recognition testing using Maryland consonant-nucleus-consonant word lists, was used to assess peripheral hearing sensitivity. A binaural four-frequency pure-tone average (4F-PTA) (mean of thresholds at 500, 1000, 2000, and 4000 Hz) averaged across both ears was computed for each participant.

Functional Hearing Questionnaire (Myers, Personal Communication, October 5, 2010)

The Functional Hearing Questionnaire (FHQ) was used to assess reported functional hearing problems. It was developed for clinical use to quantify the degree and areas of perceived hearing difficulty among veterans with a mild TBI with normal or near-normal audiograms who were reporting hearing-related problems. The questionnaire consisted of nine items that assessed perceived hearing difficulties in nine communication situations (see Saunders et al, 2015 for more detail). Participants rated their degree of difficulty in each situation on a 4-point scale: Not at all true (1 point), Slightly true (2 points), Mostly true (3 points), or Very true (4 points). A total score was obtained by summing points on each item. Possible scores ranged from 9 points (no functional hearing problems) to 36 points (maximum functional hearing problems).

Infectious Conditions Questionnaire

An infectious conditions questionnaire was completed to rule out the presence of infectious diseases in the patient or patient's family. This was required to decrease the likelihood of cross-infection of participants via shared study equipment. The questionnaire listed 17 infectious conditions (e.g., chicken pox, tuberculosis, lice). Participants were asked to check any condition for which they or a member of their household were being treated for and if so, to specify a date of diagnosis.

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Patient Interview

A patient interview form was completed to characterize participants' blast exposure history, and the impacts of those exposures, in terms of auditory, vestibular, and cognitive sequelae.

Staggered Spondaic Word Test (Katz, 1998)

The Staggered Spondaic Word test (SSW) was used to assess ability to segregate competing speech signals. It was selected as a baseline measure because prior work has shown this measure to be sensitive to the deficit experienced by the study population (Gallun, Diedesch, et al, 2012; Saunders et al, 2015). Forty spondee word pairs (e.g., day-light, back-door) were presented through TDH-39 headphones (Telephonics Corporation, Huntington NY) at a level of 55 dB HL. On each trial, one spondee was presented to the left ear and one was presented to the right ear in a time-staggered manner such that the first syllable of the first spondee was presented in isolation, the second syllable of the first spondee was then presented at the same time as the first syllable of the second spondee, and finally the second syllable of the second spondee was presented in isolation. The listener's task was to repeat back each spondee. The total number of errors was used as the primary metric of interest, because it has been noted as the most appropriate metric when data are from individuals with normal hearing (Katz, 1998).

Outcome Measures

A behavioral (speech understanding in noise) and a self-report outcome measure (psychosocial outcomes) were selected as primary outcomes. These were supplemented by several secondary outcome measures. Further descriptions of each measure are provided below. Measures were selected because it was predicted that performance on each measure would be impacted positively by one or more of the interventions. Each outcome measure, the skill it assesses, and how performance on that measure is predicted to be impacted by each intervention are shown in Table 1. It was predicted that performance on the HINT and PIADS would be impacted by all three interventions; performance on the Stroop and Adaptive Tests of Temporal Resolution (ATTR) would be impacted by just AT; and performance on the Digit Span test (DS), Time-Compressed Speech Test (TCST), Story Recall, Speech Spatial Qualities questionnaire–comparative version (SSQ-C), and Cognitive Self-Report Questionnaire (CSRQ) would be impacted by both the FM system and AT.

Table 1. Outcome Measures

		Predicted Impact of Intervention		
Outcome Measure	Skill Assessed	FM	AT	CCS
Primary outcome measures				
HINT	Speech understanding in noise	+*: More positive SNR	+: Secondary to improved auditory skills	None
PIADS	Psychosocial impacts of intervention	+: Secondary to improved hearing	+: Secondary to improved auditory skills	+: Secondary to improved communication
Secondary outcome measures				
Stroop Color-Word test	Cognitive flexibility/ sensory gating	None	+: Secondary to improved auditory attention skills	None
ATTR	Gap detection	None	+: Trains gap detection	None
DS	Auditory working memory	+: Improved SNR may increase available cognitive capacity	+: Trains auditory working memory	None
TCST	Understanding of speeded speech	+: Improved SNR may increase available cognitive capacity	+: Trains speeded speech understanding	None
Woodcock Johnson Tests of Achievement-III Story Recall subtest	Working memory for spoken language	+: Improved SNR may increase available cognitive capacity	+: Trains auditory working memory	None
SSQ-C	Changes in reported hearing disability	+: Secondary to improved hearing	+: Secondary to improved auditory skills	None
CSRQ	Changes in cognitive difficulties	+: Secondary to improved hearing	+: Secondary to improved auditory skills	None

Note: *A positive impact of the intervention on the performance measure is predicted.

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Description of Primary Outcome Measures

HINT (Nilsson et al, 1994)

The HINT was used to assess ability to understand speech in noise. Speech understanding in noise was selected as the primary behavioral outcome measure because the most commonly reported complaint by the study population is difficulty understanding speech in noisy listening environments. Furthermore, both the FM system and the AT program could feasibly alter performance on this measure. For the HINT, the signal to SNR for 50% correct identification of sentences is obtained using an adaptive procedure, yielding a speech-reception threshold in noise. Sound field testing was conducted in a sound-attenuating booth for two conditions: (a) two loudspeakers at a distance of 1 m from the listener's head with speech presented from 0° azimuth, speech-shaped noise from 90° azimuth; and (b) two loudspeakers at a distance of 1 m from the listener's head with speech presented from 0° azimuth, speech-shaped noise from 270° azimuth. The level of the noise masker was fixed at 65 dB SPL; the level of the sentences was adjusted adaptively depending on performance. Any occasion for which the standard deviation (SD) of presentation levels met or exceeded the 95th percentile for the distribution of SDs, as defined in the HINT manual, was rerun. Results from the two conditions were averaged because all participants had symmetrical hearing.

PIADS (Day and Jutai, 1996)

The PIADS is a 26-item self-report scale that was used to measure the reported psychosocial impact of the received intervention. Respondents were shown a list of words or phrases (e.g., "efficiency," "happiness," "sense of control"). For each word or phrase they rated on a 7-point Likert scale the extent to which the intervention affected them. Scores for each item ranged from −3 (indicating maximum negative impact) through 0 (indicating no impact) to +3 (indicating maximum positive impact). The total PIADS score was computed by adding the responses to each item and dividing by the total number of items (n = 26). Questions were answered relative to the impact of the intervention; thus the questionnaire was completed only at the postintervention visit.

Description of Secondary Outcome Measures

Stroop Color and Word Test (Golden and Freshwater, 2002)

The Stroop Color and Word test assessed cognitive flexibility and sensory gating—the neurological processes of filtering out redundant or unnecessary stimuli in the brain from all possible environmental stimuli (Freedman et al, 1987). This was included because the AT program has been shown to improve attention (Smith et al, 2009) and thus may improve the ability to filter out irrelevant external stimuli. Participants were shown 100 test items in each of three conditions: a Word page, a Color page, and a Color-Word page. The Word page consisted of the words "red," "blue," and "green" printed in black ink. The Color page consisted of the item "XXXX" printed in red, blue, or green ink. The Color-Word page consisted of the words from the Word page printed in the colors from the Color page. For the Word page, participants read the words as quickly as they could, while for the Color page and the Color-Word page, participants named the color of the ink as quickly as they could. A Stroop Interference *t*-score is the difference between the Color-Word and predicted interference scores originally modeled by Golden (1978). This was obtained using computerized scoring software available from Stoelting (http://www.stoeltingco.com/stroop-color-word-test-kit-for-adults-2270.html). *t*-scores have a mean of 50 and an SD of 10.

ATTR (Lister et al, 2006)

The ATTR was used to measure gap detection thresholds using an adaptive two-interval forced-choice paradigm. The measure was included because the AT program trains gap detection ability, and thus it should be sensitive to changes following the AT intervention. The listener was presented with two bursts of noise each of 150 msec in duration, one of which had a silent gap embedded in it. The listener's task was to identify the interval that contained the embedded silent gap. The test paradigm targeted the 70.7% correct gap detection threshold. Within-channel (WC) and across-channel (AC) gap detection thresholds were measured. Testing was conducted binaurally through Sennheiser HD 201 headphones (Sennheiser, Wedemark, Germany) at a comfortable listening level. Two repetitions in each condition were measured. If the geometric means of the two repetitions differed by more than a factor of two, a third run was completed, and the two closest thresholds were averaged for the final gap detection threshold.

DS

A modified recorded version of the subtest of the Wechsler Adult Intelligence Scale-third edition (Psychological Corporation, 1997) was used to assess auditory working memory. It was included because the AT program trains auditory working memory for speech, and thus the DS test should be sensitive to changes following the AT intervention. Further, there is a positive

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relationship between auditory working memory and SNR (Rönnberg et al, 2014), and thus DS scores may improve when using an FM system. DS-Forward (memory for digits repeated in the sequence they were presented) and DS-Backward (memory for digits repeated in the reverse sequence they were presented) scores were obtained for a signal of 55 dB HL, and then combined. The combined scores were converted into DS-scaled scores, using the age-appropriate conversion table in the Wechsler Adult Intelligence Scale-third edition administration and scoring manual. Scaled scores have a mean of 10 and an SD of 3. For the current study, the DS stimuli were modified by (a) making a recording (in lieu of live voice presentation) of a female speaking the digit sequences, and (b) replacing the digit 7 (bisyllabic) with the digit 10 (monosyllabic).

TCST (Vaughan et al, 2006)

The TCST assesses the ability to understand time-compressed speech. It was used as a secondary outcome measure because the AT program trains ability to follow rapidly modulated sounds (i.e., speeded speech), and thus the TCST should be sensitive to change following the AT intervention; further, as with auditory working memory, improved SNR from the FM could result in greater availability of auditory processing resources and thus improved TCST performance when using the FM system. The TCST consists of Institute of Electrical and Electronics Engineers sentences (Rothauser et al, 1969) that have been time compressed at 50% and 60% using custom software (Vaughan et al, 2006). Participants are presented with ten sentences at each compression rate through a loudspeaker located at 0° azimuth 1 m from the listener's location at a presentation level of 55 dB HL. Sentences were scored in terms of the number of key words repeated correctly (five key words per sentence), and a percent correct score computed for each condition.

Story Recall

The Story Recall subtest of the Woodcock Johnson Tests of Achievement-III (Schrank and Woodcock, 2007) was used to assess working memory for spoken language. It was included as a secondary outcome measure because the AT program trains working memory, and thus performance on this measure might improve following use of the AT intervention. Further, the improved SNR with use of an FM may result in increased story recall content due to increased available cognitive capacity. Listeners had to recall the content of stories that ranged in length and content complexity from 2 sentences with 3 content units, to 5 sentences with 21 content units. Recordings of the stories were presented at a comfortable listening level through a loudspeaker located at 0° azimuth 1 m from the listener. Participants' responses were recorded for later transcription and scoring. Scores were converted into a standard score, using the Woodcock Johnson Tests of Achievement scoring software. Standard scores have a mean of 100 and an SD of 15.

SSQ-C (Gatehouse and Noble, 2004; Jensen et al, 2009)

The SSQ-C was used to assess changes in reported hearing disability in three domains: Speech understanding, Spatial hearing (direction, distance, and movement) and Sound quality (ease of listening, naturalness, clarity). It was included as an outcome measure because it was thought that scores on each scale might improve secondarily to improved hearing/auditory skills following use of the FM and AT interventions. The questionnaire consisted of 50 items (e.g., "You are outside. A dog barks loudly. Can you tell immediately where it is, without having to look?") to which participants responded on a 11-point scale ranging from −5 (much worse) through 0 (unchanged) to +5 (much better). Scores were averaged across all items for each domain separately. Questions were answered relative to hearing at the start of the study; thus the questionnaire was completed only at the postintervention visit.

CSRQ (Spina et al, 2006)

The CSRQ assesses changes in cognitive difficulties on eight dimensions: Attention, Executive function, Memory, Language, Vision, Hearing, Energy, and Satisfaction. It was included as an outcome measure because it was thought that scores on the Hearing, Memory, and Attention scales might improve secondarily to improved hearing and auditory skills following use of the FM and AT interventions respectively. The questionnaire consisted of 64 statements (e.g., "My ability to remember phone numbers is . . . .") to which participants responded on a 3-point scale to specify whether they believe they improved (1-point), remained the same (0-points), or got worse (-1 point) due to the intervention they received. Scores were averaged across all items on each dimension separately. Questions were answered relative to difficulties at the start of the study; thus the CSRQ was completed only at the postintervention visit.

Participant Payment

Participants attended three study visits and were compensated $20 for each visit. In addition, all individuals were given $100 bonus if they returned all loaned equipment, or, if in the CCS group, when they attended their final study visit.

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Procedures

Visit 1

Participants underwent a written consent process and signed a consent form to confirm that they understood the study purpose and procedures. Inclusion-exclusion assessments were then completed. The audiometric evaluation was conducted in a sound-attenuating booth using clinically recommended procedures (ASHA, 2005). All other tests were conducted in a quiet, well-lit room. The patient interview and FHQ were completed in interview format, while the infectious conditions questionnaire was completed with a pen and paper. The visit lasted between 1 and 1.5 hr.

Assignment to Intervention

Each site was provided with sequentially numbered randomization envelopes that specified the intervention to which a participant was assigned. A block randomization scheme with a block size of eight (two individuals per intervention group) with stratification across test sites was used. Envelopes were opened by the study audiologist after Visit 1 but before Visit 2, so that the necessary equipment for the assigned intervention could be prepared. Participants were not informed of the intervention to which they had been assigned until Visit 2.

Visit 2

Visit 2 took place within 3 weeks of Visit 1. Performance on the outcome measures was assessed. The order in which they were administered was counterbalanced across participants, and performance tests were purposely interleaved with questionnaires to minimize fatigue and boredom. With the exception of the Stroop Test, all testing was conducted in a sound-attenuating booth. The HINT, DS test, TCST, and Woodcock Johnson Story Recall were conducted in the sound field; the ATTR was administered via headphones. The HINT, DS test, TCST, and Woodcock Johnson Story Recall were conducted in the sound field; the ATTR was administered via headphones. For the HINT, DS test, TCST, and Woodcock Johnson Story Recall, all signals were routed from a Sony High Density Linear Converter Compact Disc Player through a calibrated Grason Stadler Inc. GSI 61 audiometer to a GSI 61 loudspeaker (Grason Stadler Inc., Eden Prairie MN). For the ATTR, signals were generated from a laptop computer and presented to the participant via Sennheiser HD125 headphones. The Stroop test was conducted in a quiet, well-lit room. Once all testing was completed, the assigned intervention was revealed to participants. All participants received CCS education, which took ~10–15 min. Those in the FM + CCS, AT + CCS, and FM + AT + CCS groups were then loaned the necessary equipment and were provided with verbal and written instructions for setting up and using the equipment (this took between 10 and 20 min). In total, Visit 2 lasted between 1.5 and 2.5 hr.

Intervention Period

The intervention period was 8 weeks in duration. During this period participants in the FM + CCS, AT + CCS, and FM + AT + CCS groups were instructed to use the FM system and/or complete the AT. Within 1 week of Visit 2, a member of the study team telephoned all participants. All were asked whether they had read the brochures they had been given and whether they had questions or wanted to discuss anything. Individuals with a FM system were asked whether they had been using the FM system, if it was proving helpful, whether it seemed to be working properly, and about the existence and nature of any problems they had encountered with the system. Individuals assigned to conduct AT were asked whether they had been able to set up the equipment and had found a quiet location for training, and whether and when they were doing the training. Participants having problems with equipment were encouraged to return for further instruction and training.

Visit 3

Visit 3 took place 8–12 weeks after Visit 2 (mean = 70 days, SD = 14.1 days). Performance on the behavioral outcome measures was reassessed using the same procedures used for Visit 2 with two exceptions: (a) participants in the FM + CCS and FM + AT + CCS groups wore their FM system when conducting the HINT, DS test, TCST, and Story Recall. When testing with the FM system, the Zoom Link transmitter was placed 6 inches from the center cone of the loudspeaker from which the stimuli were presented. Testing of behavioral measures was conducted in the same order as for Visit 2. Participants also completed the self-report questionnaires. The CSRQ and PIADS were completed in pencil and paper format, the SSQ-C was completed in computerized format, and the FHQ was completed in interview format. Finally, a brief structured exit interview was conducted to assess participants' opinions about the interventions. Visit 3 lasted between 1.5 and 2 hr.

RESULTS

Analyses

Analyses were conducted to compare the effectiveness of CCS, FM + CCS, AT + CCS, and FM + AT + CCS in terms of auditory rehabilitation outcomes. Scores from

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all test measures were entered into a database and were double-checked by two individuals. Descriptive statistics were used to describe the study population, and analyses of variance (ANOVAs) and χ^2 analyses were used to compare the characteristics of participants in each intervention group. Scores on each outcome measure were compared in general linear model ANOVAs to examine outcome across groups. Significant main effects and interactions were analyzed further by post hoc examination, using Bonferroni corrections for multiple comparisons. The significance level for each ANOVA and post hoc analysis was set to $p < 0.05$. Data from both test sites were combined for all analyses because there were no significant between-site differences in terms of participant age, gender, word recognition score, or education level. There was a between-site difference in the mean 4F-PTA of individuals recruited at the two sites (Portland: mean = 10.7 dB HL, Tampa: mean = 13.6 dB HL; $F = 8.020$, $p = 0.006$); however, the difference was deemed as being unlikely to have any meaningful clinical impact. Statistical analyses were conducted using the Statistical Package for the Social Sciences (SPSS) Version 22.0 (IBM).

Attrition

As seen from the CONSORT participant flow diagram (Figure 1), complete data were available for 99 participants at baseline and 87 participants at postintervention follow-up, for an overall attrition rate of 12.1%, which is just slightly higher than the anticipated 10% attrition rate. One-way ANOVAs showed no differences in baseline peripheral hearing, age, or reported hearing-related difficulties measured with the FHQ between those who completed the study and those who did not. However, χ^2 analysis revealed a significant difference in attrition rate across intervention groups ($\chi^2 = 18.7$, $p < 0.001$), with a greater rate of attrition among the AT + CCS group than any of the other groups. Specifically, attrition rates were 0.0%, 4.0%, 36.0%, and 8.3% of participants in the CCS, FM + CCS, AT + CCS, and FM + AT + CCS groups, respectively.

The reason for the high drop-out rate among individuals in the AT + CCS group is unclear. Exit interviews with those in the AT + CCS group who completed the study revealed that most participants found the AT boring, repetitive, and too time-consuming. It is thus probable that the individuals dropped out because they did not want to continue the training. Since it appears the data are missing not at random, and because we cannot develop an appropriate model to account for the missing data, analyses were conducted using list-wise deletion.

Demographic Data and Baseline Performance

Table 2 summarizes the participant demographic and baseline data broken out by intervention group and the results of between-group comparisons. Data are shown for age, gender, 4F-PTA, total FHQ score, binaural word recognition in quiet measured using 50 Maryland consonant-nucleus-consonant words presented at 40-dB sensation level relative to the participant's three-frequency PTA, SSW performance, education level, and race. There were no significant differences between intervention groups on any of these variables. For further description and discussion of the baseline characteristics of the group as a whole, see Saunders et al (2015).

Adherence to Interventions

Adherence to the recommended use of each intervention was examined for each intervention separately; thus all participants provided input on the CCS, individuals in the FM + CCS and FM + AT + CCS groups provided information on use of the FM system, and individuals in the AT + CCS and FM + AT + CCS groups provided information about use of AT. As regard CCS, participants were asked whether they had read the brochures and applied the recommendations. With regard to the FM system, participants were asked how often and for how many hours on average they used their FM system. With regard to the AT, the number of AT sessions completed was available from the training program.

Most (74.7%) participants said they had read the brochures, but less than half (48.3%) reported using the suggestions, or found the suggestions helpful (43.7%). Interestingly, the number of participants in each group reading, using and finding the brochures differed significantly (Table 3). Overall adherence with use of the FM systems was good, with 15.6% of individuals using their system 7 days/week, 82.2% using it 2 or 3 days a week, and just one individual (2.2%) not using it at all. FM use per week did not differ between the FM + CCS and FM + AT + CCS groups (FM + CCS: 3.42 days/week, FM + AT + CCS: 3.1 days/week), but daily use did ($F = 6.592$, $p = 0.014$), with those in the FM + CCS group using the system 3.6 hr and those in the FM +AT +CCS group using it 2.1 hr. Overall adherence with the recommended 40 AT training sessions was extremely poor. Only 8.1% of participants completed 30 or more of the recommended 40 training sessions, with 27% completing between 11 and 29 sessions and the remaining 64.9% completing 10 or fewer sessions. As noted above, exit interview data indicate adherence was poor with the AT because participants found it boring, repetitive, and too time-consuming. The average number of training sessions completed by participants in the AT + CCS group was 12.1, and was 9.4 by participants in the FM + AT + CCS group. These group differences were not significant ($F = 0.633$, $p = 0.431$).

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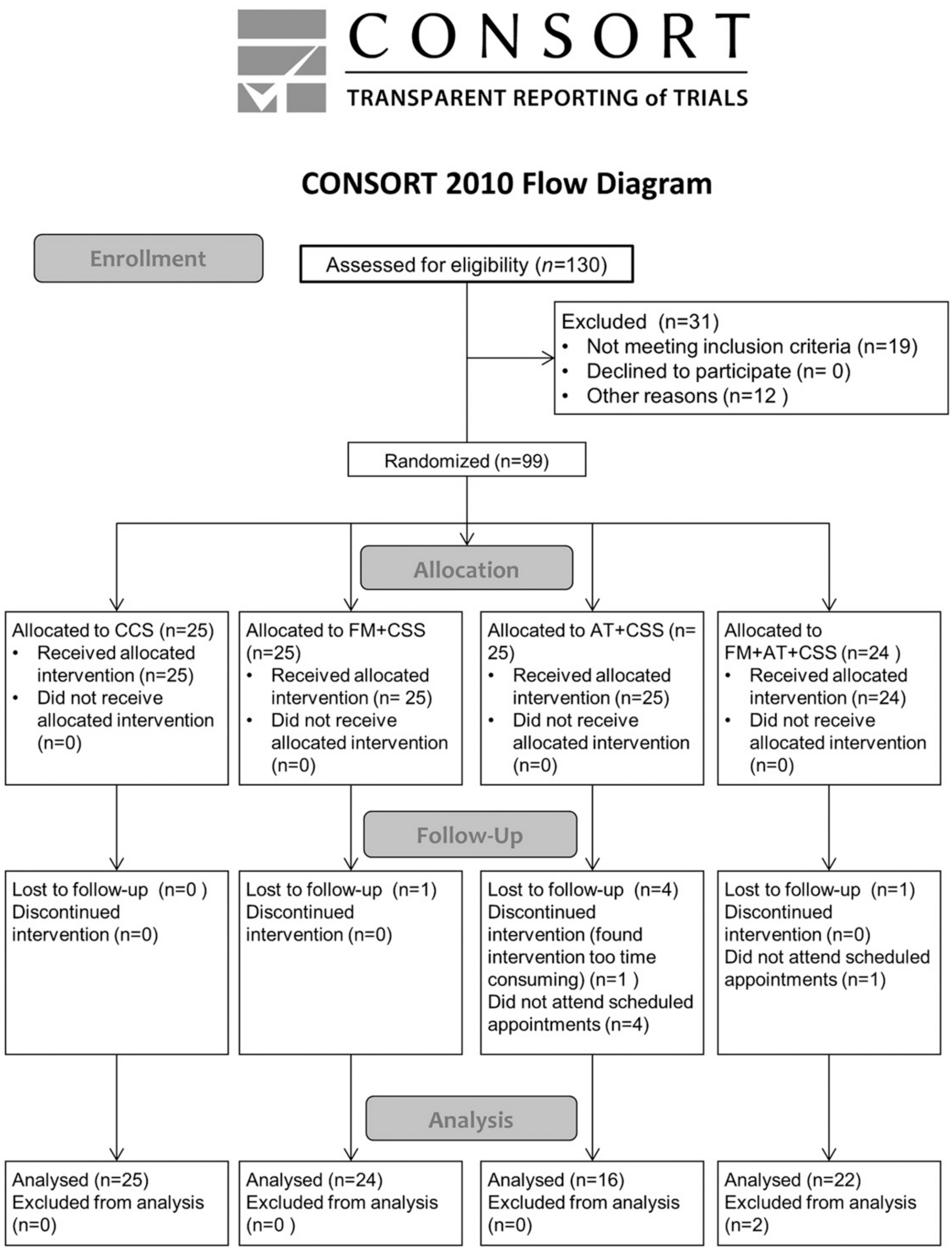

Figure 1. Study participant flow.

Intervention Outcomes

General linear modeling ANOVAs were used to compare group performance on these measures—the results of which are described below. Figures 2–5 illustrate data for variables on which between-group differences were identified, while Table 4 shows data for variables on which there were no between-group differences in outcome.

Outcome Measures Showing Significant Between-Group Differences

HINT

A repeated-measures ANOVA, comparing HINT scores at baseline and postintervention by intervention group, showed a significant main effect of visit (baseline versus postintervention; F = 17.7,

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Table 2. Participant Characteristics by Intervention Group

Characteristic	CCS (n = 25)	FM + CCS (n = 25)	AT + CCS (n = 25)	FM + AT + CCS (n = 24)	Between-Group Comparison
Age (years)	33.7 (8.0)	34.4 (7.8)	33.9 (9.2)	33.9 (7.7)	$F = 0.032$ $p = 0.992$
Gender					
Male	22 (88%)	20 (80%)	22 (88%)	24 (100%)	$\chi^2 = 5.0$
Female	3 (12%)	5 (20%)	3 (12%)	0 (0%)	$p = 0.169$
4F-PTA (dB HL)	12.1 (4.4)	12.3 (6.1)	12.0 (5.3)	12.9 (5.4)	$F = 0.129$ $p = 0.943$
FHQ total	22.8 (6.8)	21.0 (5.8)	23.7 (5.7)	22.2 (6.1)	$F = 0.839$ $p = 0.476$
Word recognition as % correct	95.6 (3.9)	95.5 (5.8)	95.2 (5.4)	97.3 (2.8)	$F = 0.899$ $p = 0.445$
SSW total errors	9.2 (14.5)	8.0 (9.0)	6.5 (11.5)	9.9 (15.5)	$F = 0.309$ $p = 0.819$
Race					
Caucasian	17 (68%)	18 (72%)	21 (84%)	17 (71%	$\chi^2 = 17.7$
Black	4 (16%)	4 (16%)	2 (8%)	1 (4%)	$p = 0.473$
Hispanic	4 (16%)	1 (4%)	1 (4%)	4 (17%)	
Other	0 (0%)	2 (8%)	1 (4%)	2 (8%)	
Education level					
High school	5 (20%)	2 (8%)	5 (20%)	2 (8%)	$\chi^2 = 17.8$
Current student	1 (4)	1 (4%)	1 (4%)	3 (13%)	$p = 0.121$
Some college	9 (36%)	15 (60%)	16 (64%)	17 (71%)	
College degree	10 (40%)	7 (28%)	3 (12%)	2 (8%)	

Notes: For continuous variables, data are mean scores (SD). For categorical variables, data are the number of cases (percent of cases).

$p < 0.001$) and intervention ($F = 0.9.33$, $p < 0.001$), and a significant interaction between visit and intervention ($F = 28.16$, $p < 0.001$). From Figure 2, it can be seen that participants in all intervention groups obtained better scores (lower speech-reception thresholds in noise) postintervention relative to baseline but that participants in the FM + CCS and FM + AT + CCS groups improved more than those in the AT + CCS or CCS groups. Post hoc testing confirmed that these intervention group differences were statistically significant; however, the performance of individuals in the CCS and AT + CCS groups did not differ, nor did the performance of individuals in FM + CCS and FM + AT + CCS groups. It is concluded that use of an FM system was effective at improving speech understanding in noise, but that AT did not improve speech understanding in noise. These data support the predictions in Table 1 that the performance of participants who received an FM system would improve on this measure.

ATTR

A repeated-measures ANOVA showed significant main effects of visit ($F = 7.66$, $p = 0.007$) and of ATTR condition (WC versus AC; $F = 244.8$, $p < 0.001$), but not of intervention ($F = 0.32$, $p = 0.601$). More importantly, there was a significant interaction between visit and intervention ($F = 3.61$, $p = 0.017$) and between visit and ATTR condition ($F = 4.85$, $p = 0.030$). Figure 3 illustrates that with the exception of the CCS group on the WC condition, performance improved (i.e., gap thresholds decreased) between baseline and postintervention, and that, as expected, (Grose et al, 2001) shorter gaps were detected in the WC condition than in the AC condition. Participants in the FM + AT + CCS group showed the greatest improvement in both conditions. Paired comparison post hoc testing showed the change in performance from baseline to postintervention to be statistically significant in the AC condition for the FM + AT + CCS group

Table 3. Participant Use of Brochures for Each Intervention Group Separately

Participants	CCS (n = 25)	FM + CCS (n = 24)	AT + CCS (n = 16)	FM + AT + CCS (n = 22)	χ^2 Comparisons
Read brochures	100.0%	62.5%	68.8%	63.6%	$\chi^2 = 12.1$, $p = 0.007$
Used suggestions	72.0%	37.5%	56.3%	27.2%	$\chi^2 = 11.5$, $p = 0.010$,
Found suggestions helpful	64.0%	33.3%	50.0%	27.2%	$\chi^2 = 8.21$, $p = 0.042$

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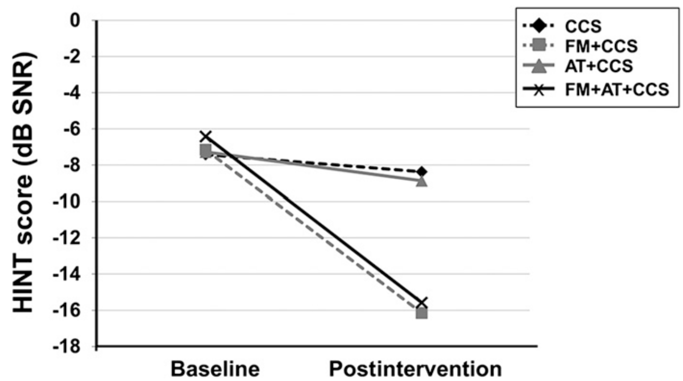

Figure 2. HINT scores at baseline and postintervention by intervention group.

only (t = 2.88, p = 0.009). This suggests that the combined use of an FM system, AT, and CCS resulted in improved gap detection. If, as was predicted in Table 1, AT is the explanation for this improvement, then participants in the AT + CCS group would also have shown improved ATTR performance. They did not. Instead, it seems more likely the improved performance of participants in the FM + AT + CCS group is associated with the fact that participants in this group had poorest performance at baseline and thus had the most room for improvement. Note also that the performance of participants in the FM + AT + CCS group was highly variable, with the SD of this group being twice that of the other groups. As a result, it is concluded that AT is not the explanation for the findings here.

SSQ-C

A multivariate ANOVA comparing intervention groups on each SSQ-C subscale showed a main effect of intervention for the Speech scale (F = 5.94, p = 0.001) and the Qualities scale (F = 4.23, p = 0.008) but not for the Spatial scale (F = 1.78, p = 0.157). On both the Speech and Qualities scales, post hoc testing using Bonferroni correction for multiple comparisons showed that participants in the FM + CCS and FM + AT + CCS groups had significantly better outcomes (higher scores, $p < 0.05$) than those in the AT + CCS and CCS groups. These data are plotted in Figure 4. As predicted in Table 1, use of an FM system, whether alone or in combination with AT, resulted in better outcome on the SSQ-C than not using an FM system, while neither AT + CCS or CCS alone improved outcome on the SSQ-C.

CSRQ

Figure 5 shows group mean scores on each scale of the CSRQ. It is seen that the best scores were obtained by individuals in the FM + AT + CCS group, and that the poorest scores were obtained by those in the CCS group. A multivariate ANOVA showed a significant main effect

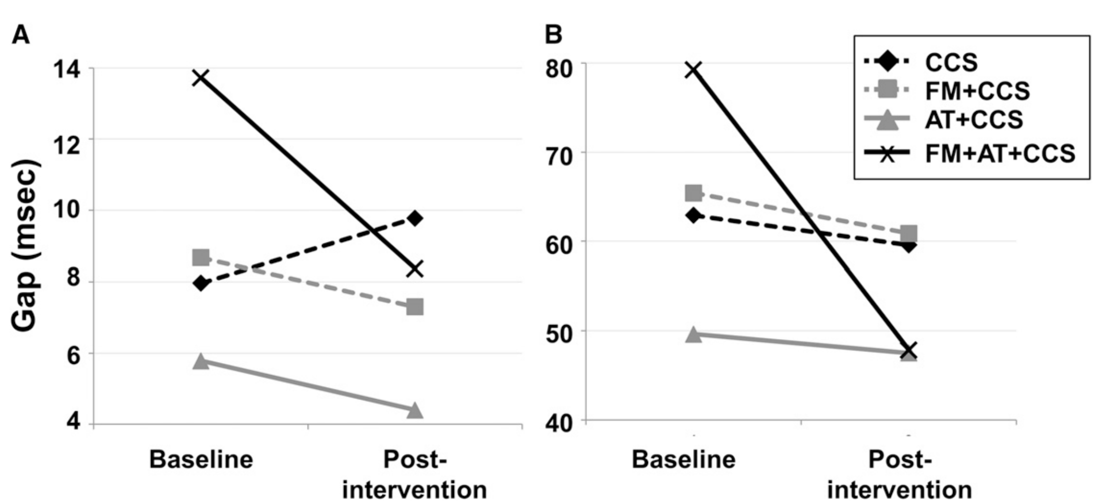

Figure 3. ATTR performance at baseline and postintervention by intervention group for WC and AC gap detection separately. (A) WC gap detection data; (B) AC gap detection data.

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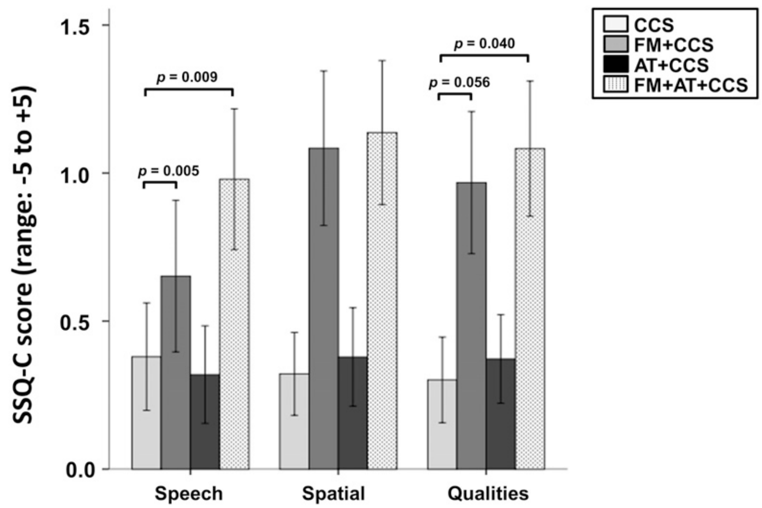

Figure 4. SSQ-C data for each scale and intervention group separately along with ±1 standard error bars and horizontal bars showing statistically significant between-group findings.

of intervention group ($F = 6.343$, $p = 0.001$), with post hoc testing showing the scores of individuals in the FM + AT + CCS group were significantly better than those of the CCS group on the Attention, Executive Function, Memory, Language, Vision, and Hearing scales. In addition, the FM + AT + CCS group had better scores than the AT + CCS group on the Executive Function scale, and better scores than the FM + CCS on the Memory scale, and the FM + CCS group had better scores than the CCS group on the Hearing scale. These data suggest that the combination of FM + AT + CCS yielded more benefits relative to CCS education alone. These findings are supportive of the prediction that both the FM and AT but not CCS would impact CSRQ scores (Table 1).

Outcome Measures Not Showing Significant Between-Group Differences

Table 4 shows the means and SDs by intervention group for variables on which there were no between-group differences in outcome by visit. This was the case for the PIADS, Stroop Color and Word test, DS, and the TCST or Story Recall subtest, Woodcock Johnson Tests of Achievement-III. In each case, between-intervention group ANOVAs showed $p > 0.5$. It is thus concluded that the interventions did not significantly impact psychosocial outcomes (PIADS), cognitive flexibility or sensory gating (Stroop Color and Word test), auditory working memory (DS), ability to understand time-compressed speech (TCST), or working memory for spoken

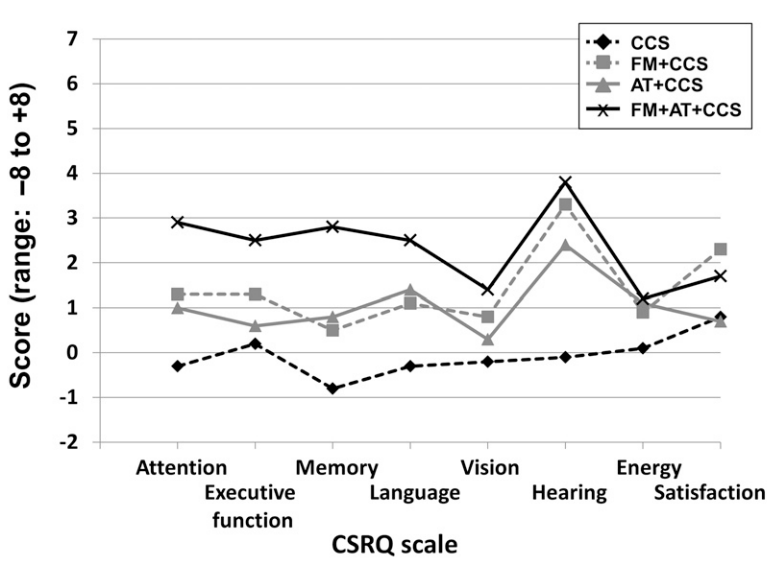

Figure 5. CSRQ data for each scale and intervention group separately.

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Table 4. Means (SDs) for Scores at Baseline (V2) and Postintervention (V3) on the Outcome Measures That Did Not Show Significant Between-Intervention Group Differences ($p > 0.05$)

Test Measure (Unit)	Data Collection Visit	CCS (n = 25)	FM + CCS (n = 24)	AT + CCS (n = 16)	FM + AT + CCS (n = 22)
PIADS total	V3*	0.4 (0.8)	0.5 (0.6)	0.3 (0.5)	0.6 (0.6)
Stroop test (*t*-score)	V2	51.5 (9.5)	50.2 (8.9)	52.9 (7.8)	52.1 (5.9)
	V3	53.1 (7.4)	51.5 (8.5)	53.3 (7.7)	53.2 (7.3)
DS (scaled score)	V2	8.2 (0.5)	8.7 (0.5)	9.1 (0.6)	8.8 (0.6)
	V3	9.6 (0.6)	9.2 (0.6)	10.2 (0.7)	9.4 (0.6)
TCST 50% CR (%)	V2	91.1 (10.5)	92.8 (7.2)	93.0 (5.8)	88.1 (13.3)
	V3	93.2 (8.1)	95.4 (3.3)	95.6 (3.4)	91.7 (9.9)
TCST 60% CR (%)	V2	84.6 (13.4)	83.7 (9.8)	88.0 (6.5)	83.0 (13.8)
	V3	88.6 (11.3)	90.2 (7.7)	91.9 (5.7)	87.4 (10.6)
WJ III Standard score	V2	96.9 (10.2)	101.1 (8.9)	103.5 (11.9)	89.5 (11.9)
	V3	98.9 (10.7)	101.9 (11.0)	103.3 (12.1)	93.7 (14.8)

Notes: *Data collected at V3 only. CR = compression ratio; V2 = Visit 2; V3 = Visit 3; WJ III = Story Recall subtest of the Woodcock Johnson Tests of Achievement-III.

language (Woodcock Johnson Tests of Achievement-III). This indicates that the hypotheses in Table 1 pertaining to these variables are not supported.

Qualitative Reports about the Interventions

A brief, structured exit interview was conducted during the final visit. All participants were asked whether they had read the brochures and whether they had found them useful (Table 3). Participants who had used an FM system were asked to specify situations in which they had found the FM system useful and when it was not useful, and participants who had used the AT program were asked what they thought of the program, whether they had noticed change in their hearing since training, and whether they had any other input.

Users of the FM systems reported finding the equipment useful in the expected listening situations: during work meetings, at restaurants, while riding public transport, during lectures at school, while traveling in a car, and when watching TV. Likewise, the situations in which they reported the FM system was not helpful were also predictable: when using the telephone, when in quiet places, and when it was "extremely noisy." Some participants were creative in their use of the FM system. For example, one individual was a maintenance worker who needed to communicate with colleagues who worked a little distance away, so he left the FM transmitter at a central location while he was working elsewhere on maintenance tasks. The colleagues would speak into the transmitter when they needed him. Another used a similar arrangement for communicating between the upstairs and downstairs of his home. Three individuals reported that the FM system was too bulky to carry around routinely, two reported feeling uncomfortable to be seen using it, and one noted, quite appropriately, that it "messed up" his ability to localize sounds. However, 6 of the 20 participants at the National Center for Rehabilitative Auditory Research site who had used an FM system wanted to obtain one from the VA audiology clinic so they could continue using it. A similar number in Tampa received low-gain hearing aids with remote microphones (equivalent to an FM system) from the Tampa VA audiology clinic.

As noted above, adherence to the AT regimen was extremely poor, with only 3 of 38 individuals completing 30 or more of the recommended 40 training sessions. Reasons given for the lack of adherence were associated with the time required to train (ten individuals), the program being boring (seven individuals), and the type of reinforcement provided (three individuals). A further seven did not like the animations during training, noting they were too juvenile and uninteresting, and three encountered computer/technical issues and thus stopped training. In terms of positive comments, seven said they enjoyed the program a lot, and two noted that they enjoyed the computer animations during training.

DISCUSSION

The purpose of this study was to compare the effectiveness of CCS education, use of a personal FM system (FM + CCS), CCS and use of an AT program (AT + CCS), and use of all three interventions combined (FM + AT + CCS) for improving behavioral and self-reported hearing difficulties in a population of blast-exposed OEF/OIF veterans. Two primary outcome measures were selected. The HINT was chosen as a primary outcome measure because difficulties understanding speech in noise is the primary hearing-related difficulty reported by the study population. The second measure, the PIADS, was selected because all three interventions had the potential to positively impact PIADS scores.

With regard to the HINT, the data showed that use of the FM system alone and in combination with AT significantly improved HINT performance. In both instances the improvement was almost identical, suggesting that AT did not further supplement speech understanding

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in noise over and above that of FM system use alone. Further evidence for this is the finding that AT alone did not result in significantly improved speech understanding in noise. Given that the AT program used by study participants targeted temporal processing and auditory working memory, it is not surprising that no effect was observed.

As with other studies (Anderson and Goldstein, 2004; Chisolm et al, 2007; Johnston et al, 2009; Thibodeau, 2010; Rodemerk and Galster, 2015), this study confirmed that FM systems are, in the laboratory at least, highly effective at improving speech understanding in noise. Study participants provided positive feedback in regard to FM system use, and about one-third of them acquired or intended to acquire similar technology through VA Audiology following study participation. Taken together, these results lend support to the potential incorporation of FM technology in clinical practice for veterans with normal or near-normal hearing reporting difficulties with speech understanding in noise. However, use of an FM system is not appropriate for every individual: three participants did not like the need for "bulky equipment," two had cosmetic concerns, and one did not like the way the system negatively impacted sound localization. As with any listening device, these "lifestyle costs" should be identified and appropriately discussed before any dispensing decisions.

There was limited evidence that any of the interventions had positive psychosocial outcomes for the participants as assessed by the PIADS, although individuals who used an FM system (those in the FM + CCS and FM + AT + CCS groups) had higher PIADS scores (although not statistically significantly so) on all scales than did those in the AT + CCS and CCS groups. One explanation for this finding is that intervention benefits were not great enough to be reflected by the PIADS; however, another consideration is that positive psychosocial changes may become evident only after months rather than weeks.

Scores on the SSQ-C told a different story. As with the HINT, participants using an FM system with or without AT and CCS showed greater benefit on the SSQ-C Speech and Qualities scales than did those in the AT + CCS and CCS groups. This suggests the FM system provided subjective improvement for listening to speech and to the quality of sound. There were no between-group differences on the SSQ-C Spatial scale, which is to be expected because an FM system does not provide the binaural cues necessary for sound localization. Likewise, there are several interesting findings in the CSRQ data that assessed cognitive difficulties on various dimensions. First, the scores of the CCS group on all scales were essentially zero—a finding that was to be expected since, with the exception of the hearing scale, CCS does not attempt to address any of the dimensions measured by the CSRQ. A second noteworthy point was that individuals in the FM + CCS and FM + AT + CCS groups scored most highly on the hearing scale, presumably because the FM system provides significant hearing-related benefit. Finally, the scores of individuals in the FM + AT + CCS group were significantly better than those of the CCS group on six of the eight scales, and were higher (although not significantly so) than those of the FM + CCS and AT + CCS groups on all scales except satisfaction. The fact that scores of the FM + CCS and AT + CCS did not differ and that their score fell midway between those of the CCS group and those of the FM + AT + CCS group indicates that in terms of self-reported cognition, there is benefit to combining use of an FM system with AT. This is most likely because the improved speech understanding gained from the FM independently supplements the effects of temporal processing and auditory working-memory training.

There was just one secondary behavioral outcome measure on which the impact of the interventions differed significantly—the ATTR. For both the WC and AC conditions, participants in the FM + AT + CCS condition showed greater improvement than participants in any of the other intervention groups. A reasonable explanation for this is that the AT program, which focused on training of temporal abilities, underlies this. If this were the case, however, the AT + CCS group would be expected to show as much improvement as the AT + FM + CCS group and more than the FM + CCS and CCS groups—something that was not observed. The finding may therefore be a function of the poorer and more variable baseline performance of individuals in the FM + AT + CCS group relative to individuals in the other intervention groups. Contrary to the predictions in Table 1, none of the other secondary behavioral outcome measures showed significant effects of any intervention.

Limitations

There are several limitations with this study that should be noted. First and foremost is the poor adherence to the recommended AT protocol and the high attrition rate for individuals assigned to the AT + CCS group. While this study is not alone in reporting poor adherence to an AT regimen (Sweetow and Sabes, 2010; Abrams et al, 2015), it leaves open the question of whether the program would be efficacious if it were presented in a format that would be more engaging for the user. Indeed, since this study was completed, the manufacturers of the program have made changes to the software interface and training protocol, and thus data about this might be forthcoming if the program is used in future studies. Second, because this was a randomized controlled trial, analyses investigating individual differences and predictors of benefit are not

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appropriate. It would be worthwhile for future studies to determine whether there are particular baseline deficits that result in better outcomes from one intervention or another, or whether there are individual characteristics that make a particular intervention more appropriate for a particular individual.

Clinical Implications

It was interesting to observe that for all interventions there was an inverse relationship between adherence to the intervention and the number of interventions received. Specifically, more individuals in the CCS group read the brochures and used the suggestions than in the other groups, daily FM use was higher among the FM + CCS group than the FM + AT + CCS group, and individuals in the AT + CCS group completed more (although not significantly so) AT sessions than individuals in the FM + AT + CCS group. The clinical implication of this is that more is not necessarily better. There is a need to consider whether the patient can handle multiple simultaneous approaches to a problem, and/or if one intervention at a time is more appropriate. However, it is concluded that FM system use (or remote microphone via Bluetooth system) is an effective intervention for blast-exposed veterans with normal or near-normal hearing and functional hearing difficulties, and should be routinely considered as an intervention approach for this population when possible.

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