



Randomized Controlled Trial of Hearing Aids

Versus

Combination Instruments for Tinnitus Therapy

James A. Henry, Ph.D.

SYNOPSIS

It's widely known that hearing aids provide a secondary benefit for tinnitus management. "Combination instruments" are hearing aids that have built-in noise/sound generators aimed at providing relief to tinnitus sufferers. Studies have not shown whether combination instruments are more effective than hearing aids alone for tinnitus management. To address this question, we conducted a randomized controlled trial to collect initial data aimed at finding out whether combination instruments do a better job than hearing aids at providing tinnitus relief. Thirty qualified hearing aid candidates who also experience tinnitus were enrolled and randomly received either hearing aids or combination instruments. Participants wore the devices for three months and completed the Tinnitus Functional Index before and after the intervention period. Both groups showed significant improvement, as indicated by reductions in their TFI scores. The group with combination instruments had a greater mean reduction in the TFI score than the hearing aid group had. These results suggest that both hearing aids and combination instruments are effective in managing reactions to tinnitus. More definitive results will require a larger controlled clinical trial.

STARKEY AUDIOLOGY SERIES

INTRODUCTION

Tinnitus can be caused by anything that causes hearing loss, the most common cause being noise exposure. The odds of experiencing tinnitus increase in direct proportion with degree of hearing loss (Coles, 2000). Epidemiology studies estimate the prevalence of tinnitus among adults in the U.S. to be 10 to 15 percent (Hoffman & Reed, 2004). Of those experiencing tinnitus, about 20 percent have a clinically significant condition, meaning clinical intervention would be warranted to address reactions to tinnitus. It is noteworthy that, in 2013, over 1.1 million military veterans were considered “disabled” by their tinnitus (Department of Veterans Affairs, Veterans Benefits Administration). Tinnitus is the number one disability affecting veterans and active-duty service members. It has been the most prevalent of all service-connected disabilities for veterans since 2007.

Audiologists have long known that hearing aids can provide secondary benefit for managing reactions to tinnitus (Saltzman & Ersner, 1947). However, research evidence does not strongly support this premise. Cochrane Reviews are considered a credible source for determining the evidence basis of interventions for different conditions — basing their reports on randomized controlled trials (RCTs) that are relevant to the condition (Keech et al., 2007). A number of Cochrane Reviews have been completed for methods of tinnitus intervention. The most recent of these evaluated the use of hearing aids for patients with hearing loss and bothersome tinnitus, concluding, “there is currently no evidence to support or refute their use as a more routine intervention for tinnitus” (Hoare et al., 2014, p.2).

Wearable ear-level devices were developed in the mid-1970s to provide broadband noise (BBN) to patients (Vernon, 1976). Their initial purpose was to replace the tinnitus percept with a more acceptable sound (i.e., to “mask” the tinnitus). The following decade, BBN was incorporated into hearing aids. With these “combination instruments,” incomplete (partial) masking was seen to be effective in providing relief from tinnitus (Vernon, 1988).

Since those early years of using ear-level devices for tinnitus management, numerous devices and techniques have been introduced — all using sound in some manner (“sound therapy”) to reduce the adverse effects of tinnitus. In spite of all this innovation, hearing aids and combination instruments have continued to be a mainstay for this purpose. Combination instruments, however, did not offer full hearing aid features until fairly recently. Most hearing aid manufacturers now produce combination instruments that include state-of-the-art hearing aids and numerous capabilities to “tailor” BBN to suit the individual patient.

Whereas it might be assumed that adding BBN to hearing aids enhances their benefit for tinnitus relief, RCTs are needed to provide evidence that this may actually be true. The present RCT was conducted to address this question.

METHODS

The study was conducted at the National Center for Rehabilitative Auditory Research (NCRAR) which is located at the VA Portland Health Care System (VAPORHCS). Details of the study have been published (Henry et al., 2015). The present report provides a more concise description of the study. The primary outcome measure resulted in the Tinnitus Functional Index (TFI), which has been validated for measuring changes in tinnitus impact (responsiveness) resulting from intervention (Meikle et al., 2012). The TFI is scored from zero (no problem with tinnitus) to 100 (maximum problem with tinnitus). A score of at least 25 suggests the possible need for tinnitus-specific intervention. A reduction of at least 13 points in the TFI score following intervention indicates a meaningful reduction in the functional effects of tinnitus for the average person. To assess benefit from the devices on hearing ability, the 25-item Hearing Handicap Inventory for the Elderly (HHIE) was employed (Ventry et al., 1982). Twelve items measure the effect of hearing loss on social/situational functioning, and 13 items measure the emotional impact of hearing loss.

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At the final visit, participants completed both the TFI and the HHIE twice to indicate their responses with respect to when they were (1) using their devices (“with devices”), and (2) not using their devices (“without devices”). Consequently, three scores were obtained for both the TFI and the HHIE for each participant: one at baseline and two following the intervention.

Candidates were recruited from the VAPORHCS and from advertisements placed in the local newspaper. Telephone screening determined that candidates (1) were at least 18 years of age, (2) reported hearing difficulties, (3) did not wear hearing aids within the past 12 months, and (4) had no mental, emotional or health conditions that would prevent their participation. If they met these criteria, the Tinnitus and Hearing Survey (THS) was administered over the phone (Henry et al., 2015). The THS includes four items that address tinnitus problems that would not be confused with a hearing problem. To be invited to the NCRAR for a Visit 1 evaluation, a minimum total score of four was required for these four items; if the score was four to six, then at least one of the items required a score of at least three.

At Visit 1, candidates completed the TFI and the HHIE. Candidates with a minimum TFI score of 25 and who passed the Mini Mental State Exam (MMSE) (Bleecker et al., 1988) then underwent a standard audiologic evaluation. If indicated, a hearing aid assessment was performed. Thirty candidates met all qualifications and were enrolled and scheduled for a hearing aid fitting (Visit 2). They were randomized to either the Experimental hearing-aid-plus-BBN or Control hearing-aid-only group.

At Visit 2, all participants were fitted binaurally with a pair of Starkey Xino™ combination instruments. Real-ear measures were used to verify and adjust the amplification settings using the NAL-NL2 formula (Keidser et al., 2012). Participants then received counseling—following pages 31–64 in a flip-chart counseling book—describing how sound can be used in different ways to manage the effects of tinnitus (Henry et al., 2010).

For the Experimental group only, the BBN from the devices was activated and adjusted with the aim to provide “immediate relief from tinnitus.” Starting with an audiogram-based default algorithm, the research audiologist fine-tuned the amplitude- and frequency-modulated noise across 16 channels. (Although the software allowed participants to manipulate the settings across the 16 channels, this feature was not employed for this study.) Participants could select slow, medium, or fast modulation rates, or no modulation.

TINNITUS

OF PEOPLE WITH
TINNITUS
ALSO HAVE
HEARING LOSS.

Tinnitus can be caused by hearing loss, an ear injury or a circulatory system disorder.



Participants returned for a follow-up appointment one to three weeks after the fitting to check the instruments, retrieve the data-logging information and ensure participants were using the devices properly. Gain settings of the hearing aids were adjusted if needed. For the Experimental group, the audiologist offered to adjust the BBN to optimize tinnitus relief. Participants returned for their final visit three to four months after fitting, at which time a hearing aid check was completed and data-logging information was retrieved. This completed their participation in the study.

RESULTS

Overall Group (N=30). Mean age for the overall group was 67 years with 67 percent of the participants being male. The initial TFI mean score was 58.3, which was reduced at three months to 22.2 (*with devices*) and 44.8 (*without devices*). Both of these reductions were significant ($p < .0001$). Data logging information revealed the average number of hours per day participants had been using their devices: 8.8 hours prior to Visit 3, and 7.0 hours prior to Visit 4. Differences in device usage between Experimental and Control groups were not significant at either of the visits ($p > .05$).

Experimental Group (N=15) versus Control Group (N=15). For the Control group, the mean baseline TFI score was 60.5, which was reduced at three months to 27.6 (*with devices*) and 44.3 (*without devices*). Both of these reductions were significant ($p < .0001$ and $p = .002$, respectively). Effect sizes for the Control group were 2.1 (*with devices*) and 1.1 (*without devices*).

For the Experimental group, the mean baseline TFI index score was 56.1 which was reduced at three months to 16.8 (*with devices*) and 45.3 (*without devices*) (Figure 1). The mean three-month reduction on the TFI was significant *with devices* ($p < .0001$) but not significant *without devices* using the Bonferroni correction ($p = .034$). Effect sizes for the Experimental group were 2.2 (*with devices*) and 0.6 (*without devices*).

For both groups, repeated measures ANOVA revealed that answering the TFI questions with respect to when they were wearing hearing aids (*with devices*) resulted in significantly better TFI scores than when they were not wearing hearing aids (*without devices*).

The number (and percentage) of participants showing improvement in TFI scores that would be considered a meaningful reduction (≥ 13 -point reduction) (Meikle et al., 2012) was determined. For the *with-devices* condition, 13 of 15 (87 percent) Control participants and 13 of 15 (87 percent) Experimental participants showed at least a 13-point improvement in their TFI scores. For the *without-devices* condition, eight of 15 (53 percent) Control participants and six of 15 (40 percent) Experimental participants had at least a 13-point improvement.

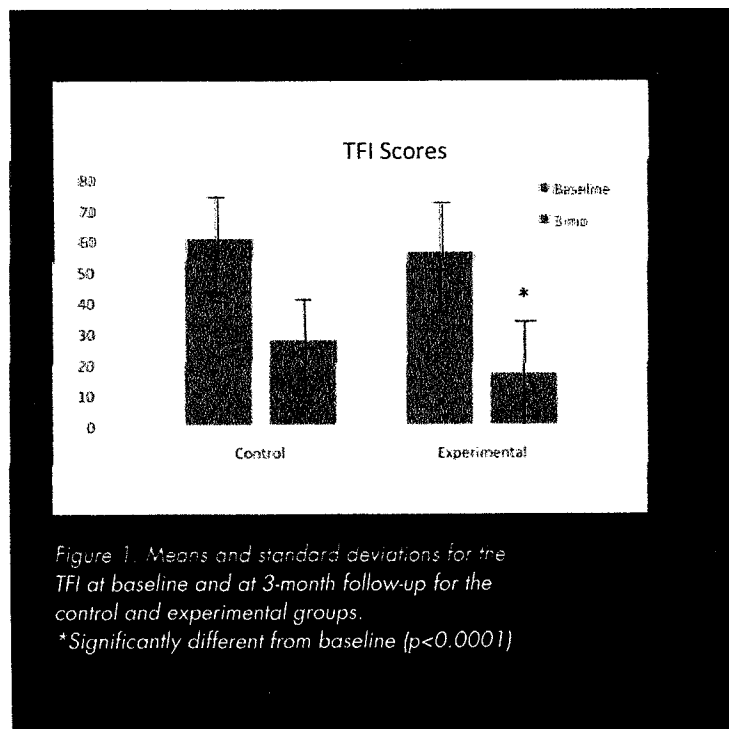


Figure 1. Means and standard deviations for the TFI at baseline and at 3-month follow-up for the control and experimental groups.
*Significantly different from baseline ($p < 0.0001$)

Most hearing aid manufacturers now produce combination instruments that include state-of-the-art hearing aids and numerous capabilities to **tailor BBN to suit the individual patient.**

Hearing Handicap Inventory for Elderly

(HHIE). For the overall group (N=30), the initial mean HHIE index score was 52.6, which was reduced at three months to 23.6 (*with devices*) and 47.5 (*without devices*). Paired t-tests showed the mean three-month reduction on the HHIE *with devices* as significantly different ($p<.0001$) and *without devices* as not significantly different ($p>.05$).

For the Control group, the mean baseline HHIE score was 55.3. At three months, the mean score was 26.9 (*with devices*) and 47.5 (*without devices*) (Figure 2). The mean three-month reduction *with devices* was significant ($p<.0001$) but *without devices* was not significant using the Bonferroni correction ($p=.04$). Effect sizes for the Control group were 1.8 (*with devices*) and 0.5 (*without devices*).

For the Experimental group, the mean baseline HHIE score was 49.3. Three months following the hearing aid fitting, the mean score was 20 (*with devices*) and 47.5 (*without devices*). The mean three-month reduction *with devices* was significant at $p=.001$ but *without devices* was not significant after the Bonferroni correction ($p=.04$). Effect sizes for the Experimental group were 1.8 (*with devices*) and 0.1 (*without devices*).

For both the Control and Experimental groups, answering the HHIE questions with respect to when they were wearing hearing aids (*with devices*) resulted in significantly better HHIE scores than when they were not wearing hearing aids (*without devices*).

The number (and percentage) of participants showing an improvement of ≥ 19 points in the HHIE score that would be considered significant change (Weinstein et al., 1986) was determined. For the *with-devices* condition, nine of 15 (60 percent) Control participants and ten of 15 (67 percent) Experimental participants showed at least a 19-point improvement in their HHIE scores. For the *without-devices* condition, three of 15 (20 percent) Control participants and one of fifteen (7 percent) Experimental participants had at least a nineteen-point improvement.

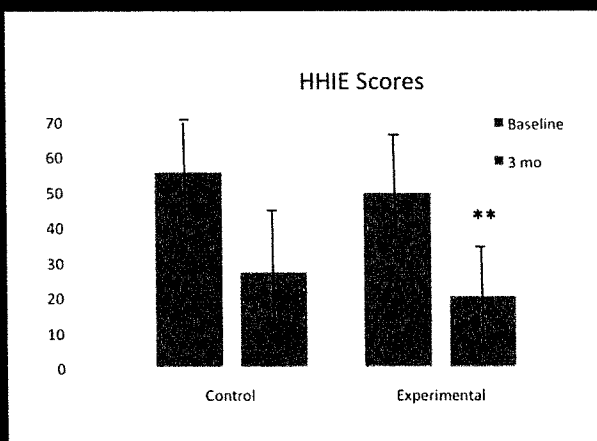


Figure 2. Means and standard deviations for the HHIE at baseline and at 3-month follow-up for the control and experimental groups.
*Significantly different from baseline ($p<0.0001$)

“Hearing aids and combination instruments were **more effective both for tinnitus management and reducing hearing handicap** when the devices were being worn (versus not worn).”

DISCUSSION


For this RCT, both the Control and Experimental groups improved significantly based on reductions in mean TFI scores. These results suggest that using hearing aids alone or combined with BBN can significantly reduce effects of tinnitus.

Although differences in mean TFI scores between groups at three months were not statistically significant, it is of note that the mean reduction in the TFI score (*with devices*) for the Experimental group was 6.4 points greater than for the Control group. This difference approached statistical significance ($p=.09$), suggesting that more participants may have resulted in a significant improvement for the combination instruments relative to hearing aids alone. The effect sizes, however, indicate that after controlling for variation a significant difference between groups seems less likely. Thus, the primary question of whether adding BBN to hearing aids provides improved tinnitus benefit remains unanswered. A larger RCT would answer this question more definitively.

The HHIE results showed that self-perceived hearing handicap was reduced by about the same amount for both groups, suggesting that adding BBN to

amplification does not compromise hearing aid effectiveness. Participant's impressions regarding the hearing aids were generally positive for both groups.

A unique aspect of this study was the evaluation of outcomes in two conditions: while wearing devices (*with devices*) and while not wearing devices (*without devices*). Differences in TFI and HHIE mean scores between these conditions were statistically significant for both Control and Experimental groups. Hearing aids and combination instruments were more effective both for tinnitus management and reducing hearing handicap when the devices were being worn (versus not worn). Although this might be expected, no previous study has confirmed such a result.

In summary, results of this study revealed that both hearing aids and combination instruments provided significant benefit for relief of tinnitus, although differences between Experimental and Control groups were not significant. Importantly, 26 of the 30 participants (86.7 percent) reported meaningful improvement in their reactions to tinnitus. What is still uncertain is the degree of benefit provided by BBN when added to amplification. 

References

- Bleecker, M.L., Bolla-Wilson, K., Kawas, C., and Agnew, J. (1988). *Age-specific norms for the Mini-Mental State Exam*. *Neurology* 38, 1565-1568.
- Coles, R.R.A. (2000). Medicolegal issues. In *Tinnitus Handbook*, R.S. Tyler, ed. (San Diego, Singular), pp 399-417.
- Department of Veterans Affairs, Veterans Benefits Administration Annual Benefits Report for Fiscal Year 2014. Accessed October 27, 2015 at: <http://www.va.gov/budget/report/>
- Henry, J.A., Frederick, M., Sell, S., Griest, S., and Abrams, H. (2015). Validation of a novel combination hearing aid and tinnitus therapy device. *Ear Hear* 36, 42-52.
- Henry, J.A., Griest, S., Zaugg, T.L., Thielman, E., Kaelin, C., Galvez, C., and Carlson, K.F. (2015). Tinnitus and hearing survey: a screening tool to differentiate bothersome tinnitus from hearing difficulties. *Am J Audiol* 24, 66-77.
- Henry, J.A., Zaugg, T.L., Myers, P.M., and Kendall, C.J. (2010). *Progressive Tinnitus Management: Counseling Guide*. (San Diego, CA: Plural Publishing).
- Hoffman, H.J., and Reed, G.W. (2004). Epidemiology of tinnitus. In *Tinnitus: Theory and Management*, J.B. Snow, ed. (Lewiston, NY, BC Decker Inc.), pp 16-41.
- Hoare, D.J., Edmondson-Jones, M., Sereda, M., Akeroyd, M.A., and Hall, D. (2014). Amplification with hearing aids for patients with tinnitus and coexisting hearing loss. *Cochrane Database Syst Rev* 1, CD010151.
- Hoffman, H.J., and Reed, G.W. (2004). Epidemiology of tinnitus. In *Tinnitus: Theory and Management*, J.B. Snow, ed. (Lewiston, NY, BC Decker Inc.), pp 16-41.
- Keech, A., Gebiski, V., and Pike, R. (2007). Interpreting and reporting clinical trials. A guide to the CONSORT statement and the principles of randomised controlled trials. In: Sydney, MJA Books.
- Keidser, G., Dillon, H., Carter, L., and O'Brien, A. (2012). NAL-NL2 empirical adjustments. *Trends Amplif* 16, 211-223.
- Meikle, M.B., Henry, J.A., Griest, S.E., Stewart, B.J., Abrams, H.B., McArdle, R., Myers, P.J., Newman, C.W., Sandridge, S., Turk, D.C., et al. (2012). The tinnitus functional index: development of a new clinical measure for chronic, intrusive tinnitus. *Ear Hear* 33, 153-176.
- Saltzman, M., and Ersner, M.S. (1947). A hearing aid for relief of tinnitus aurium. *Laryngoscope* 57, 358-366.
- Ventry, I.M., and Weinstein, B.E. (1982). The hearing handicap inventory for the elderly: a new tool. *Ear Hear* 3, 128-134.
- Vernon, J. (1976). The use of masking for relief of tinnitus. In *Neurological Surgery of the Ear: Volume II*, H. Silverstein and H. Norrell, eds. (Birmingham, Aesculapius Publishing Co.), pp 104-118.
- Vernon, J. (1988). Current use of masking for the relief of tinnitus. In *Tinnitus Pathophysiology and Management*, M. Kitahara, ed. (Tokyo, Igaku-Shoin), pp 96-106.
- Weinstein, B.E., Spitzer, J.B., and Ventry, I.M. (1986). Test-retest Reliability of the Hearing Handicap Inventory for the Elderly. *Ear Hear* 7, 295-299.

Infographic Sources

- Mayo Clinic Staff (2013). Tinnitus. Retrieved from: <http://www.mayoclinic.org/diseases-conditions/tinnitus/basics/definition/con-20021485>
- Mayo Clinic Staff (2013). Tinnitus. Retrieved from: <http://www.mayoclinic.org/diseases-conditions/tinnitus/basics/definition/con-20021486>
- Mayo Clinic Staff (2013). Tinnitus. Retrieved from: <http://www.mayoclinic.org/diseases-conditions/tinnitus/basics/definition/con-20021487>