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Presented at the Annual Meeting of the American Auditory Society, Scottsdale, AZ, March 2018

## Introduction

The introduction of over-the-counter (OTC) hearing aids is intended to improve accessibility and affordability of hearing devices for individuals with mild to moderate hearing loss. While this undoubtedly will result in better access to more affordable hearing devices, it is unclear the extent to which user outcomes will be impacted for individuals who obtain these devices without traditional audiologic services. Further, research suggests that hearing aids might provide different benefits for consumers with varying cognitive ability<sup>1</sup>. However, no research on this topic is currently available for OTC hearing devices. As OTCs become more accessible to the general public, research is needed to better understand the relative benefits of traditional audiologic hearing aid services for consumers with varying cognitive abilities. This pilot research sought to determine how audiologist fitting and orientation practices might affect outcomes with OTC devices for novice adult hearing aid wearers with acquired mild to severe sensorineural hearing loss, and to explore how these effects might differ depending on consumers' cognitive abilities. The following questions were explored:

1. After a 1-week trial, do individuals fitted with OTCs using traditional audiologic practices:

- A) Have electroacoustic outputs that more closely approach evidence-based prescriptive targets compared to consumers' self-fitting practices?
- B) Have measureable improvements in their ability to use and benefit from OTCs?

2. Do these outcomes vary depending on users' cognitive abilities?

## Methods

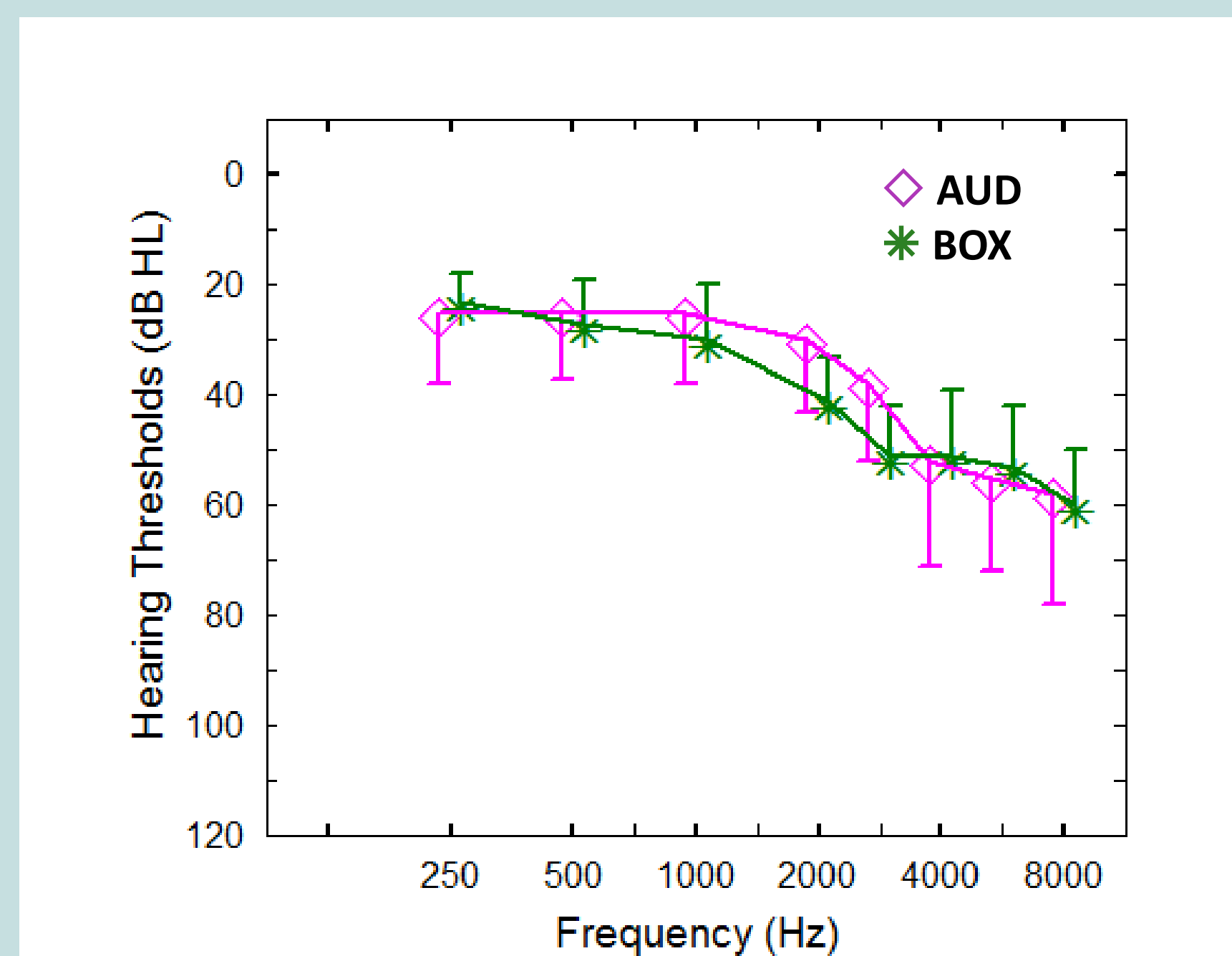
- **Design:** Double-blinded randomized control trial
- **Participants:** 17 adult novice hearing aid users with symmetrical mild to severe SNHL were randomized to one of 2 groups (AUD and BOX, described below). Demographics and mean composite audiograms are displayed for participations in each group. Error bars are one standard deviation.

### Groups:

**Experimental group (AUD):** Received bilateral OTC devices that were fitted, adjusted, and verified using real-ear measures of amplified output. Also received comprehensive orientation to the devices and audiologic counseling.  
**Control group (BOX):** Received the manufacturer's box containing two OTC devices, a variety of coupling options, and the manufacturer's instruction packet and online resources. The control group received no additional training on their hearing devices.

### Procedures:

Outcomes were obtained by a blinded assessor after a 1-week trial.



	Partic ipants (#)	Age X (range)	PTA	SRT	WR	Reading Span Score
AUD	8	66 (54-83)	27	31	97	35
BOX	9	64 (47-76)	33	34	94	40

## Devices

OTC hearing devices used for this study were carefully chosen based on cost and capabilities. Devices were considered for inclusion if they:

- Were priced between \$100 and \$350 per aid.
- Implemented digital signal processing.
- Were styled similar to traditional hearing aids (e.g., mini behind-the-ear style hearing devices).

Devices used for this study had multiple coupling options (e.g., various tubing lengths, and styles and sizes of domes). Devices included a volume wheel and three manually accessible programs.

Electroacoustic characteristics of the 20 devices used for this study were compared against standards specified for personal sound amplification products published by the Consumer Technology Association<sup>2</sup>. Three devices were not issued to any participants due to excessive total harmonic distortion (500 Hz, 70 dB input, TDH 7-25%) and equivalent input noise (>60 dBA). Of the remaining 17, no devices met specified frequency bandwidth or response smoothness criteria, and all provided maximum acoustic output greater than 120 dB SPL. Despite these issues, 11 of 17 participants indicated a neutral to positive experience.

- **Preliminary analyses:** Two-way ANOVAS were used to test differences in outcomes.

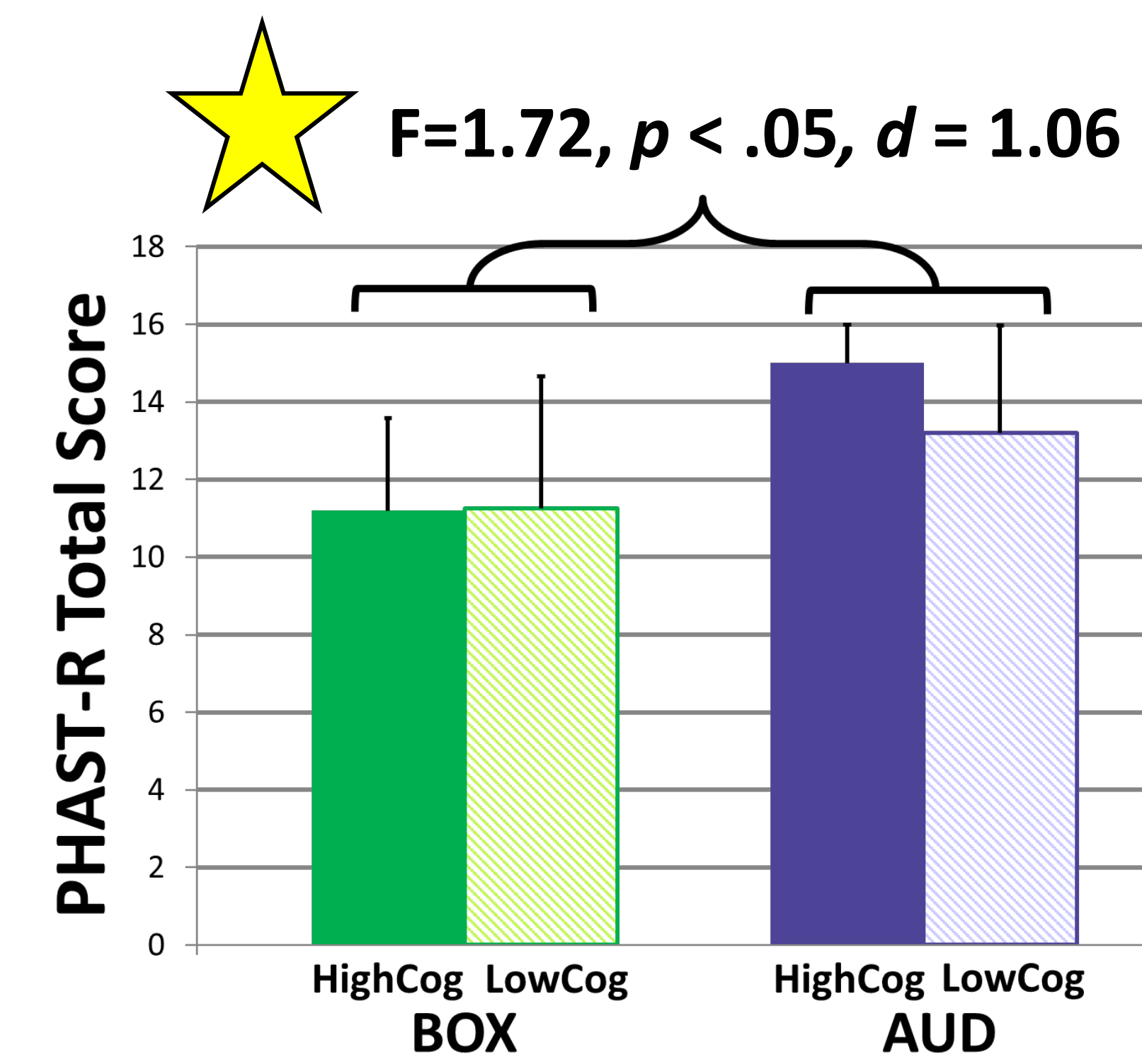
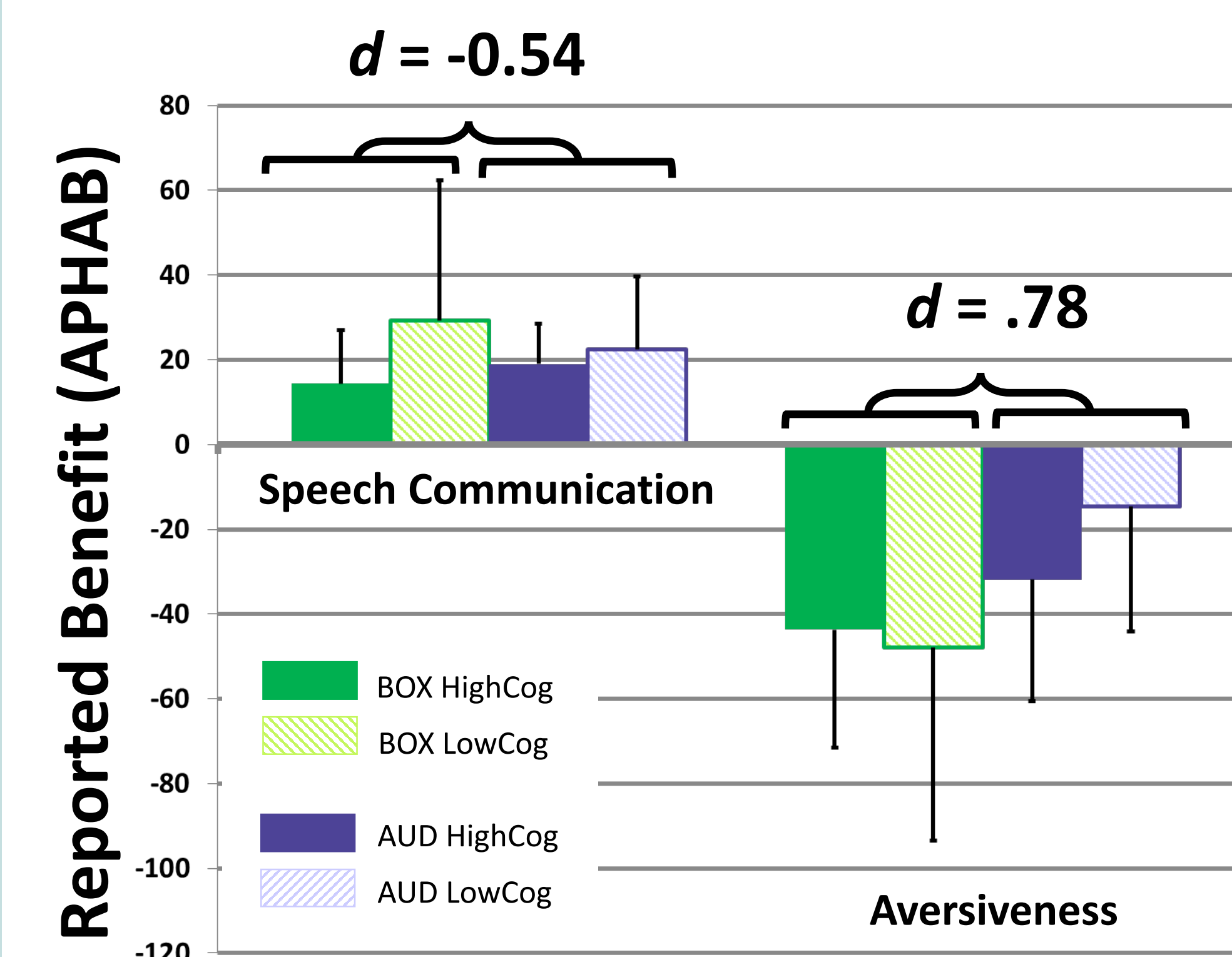
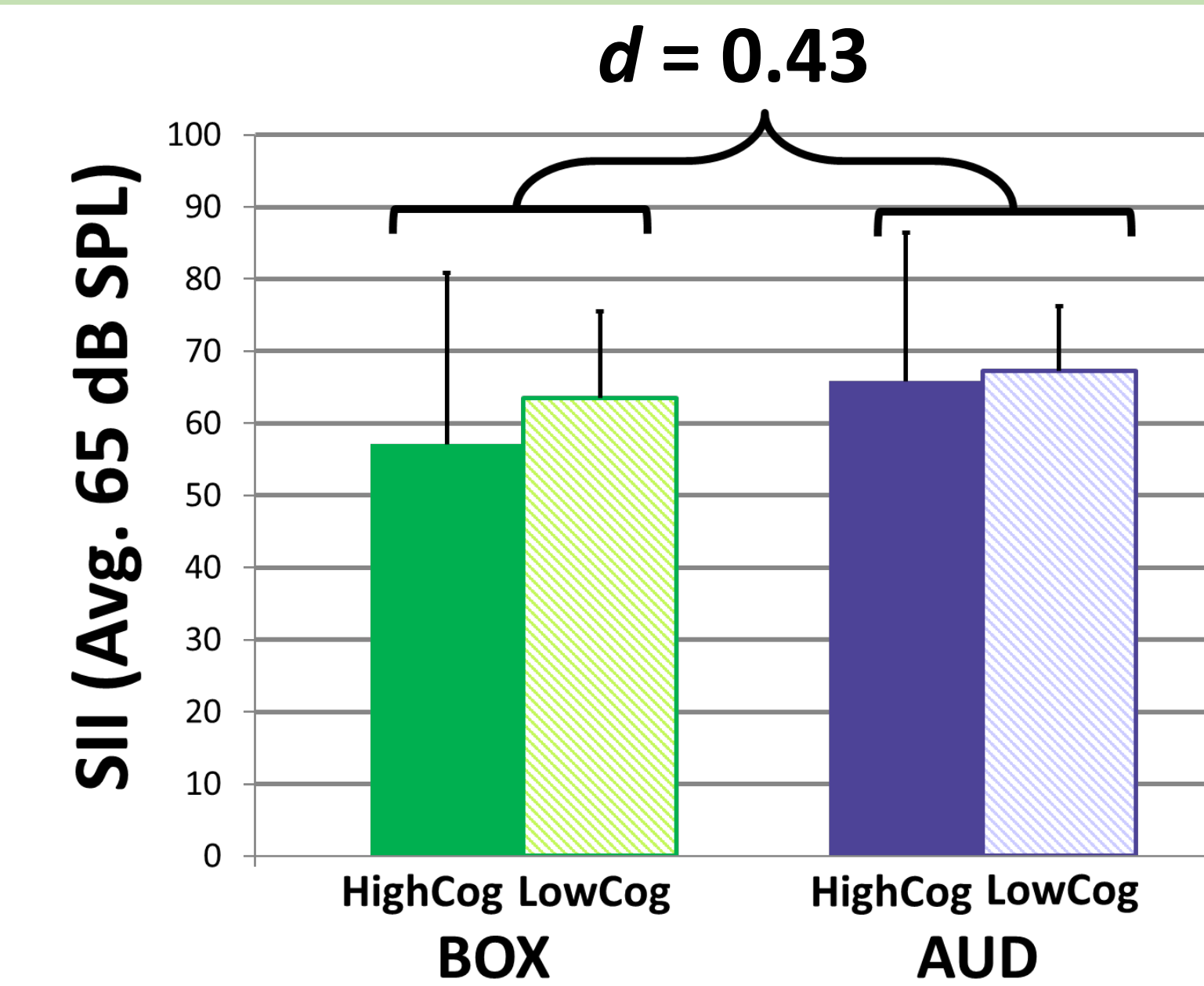
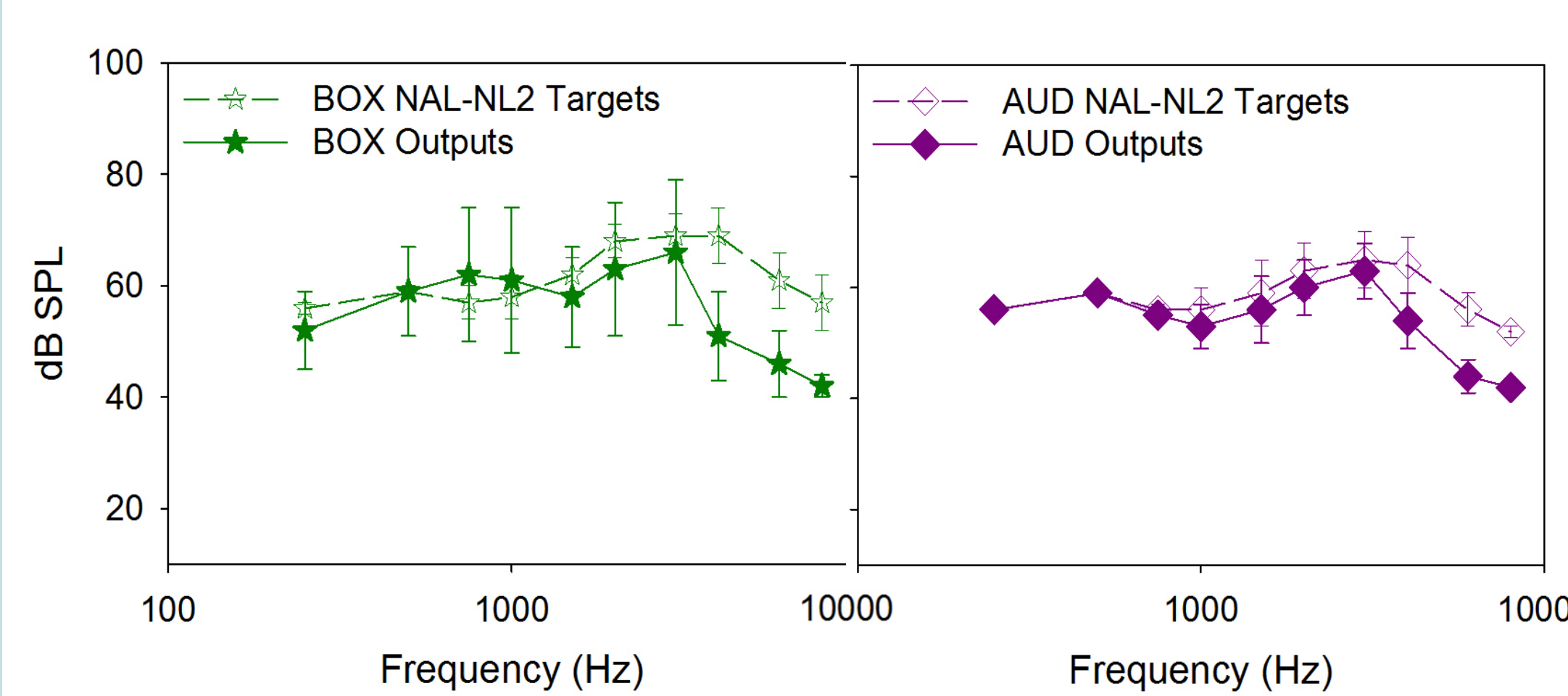
Independent variables:

- **Type of fitting:** audiologic fitting and orientation (AUD) or provided with a box of OTC devices (BOX)
- **Cognition (working memory):** HighCog (Reading Span Score > 36) and LowCog (Reading Span Score ≤ 36)

Dependent variables:

- **Acoustic fitting for Average Speech inputs (65 dB SPL):** Difference between real-ear outputs and prescriptive targets; Speech Intelligibility Index (SII)
- **Self-reported benefit:** Abbreviated Profile of Hearing Aid Benefit (APHAB)
- **Skills and ease of use:** Practical Hearing Aid Skills Test – Revised (PHAST-R)

## Results



This poster is available for download at [www.harlmemphis.org](http://www.harlmemphis.org)

## Q&A

1. **Did audiologists' recommendations for OTC hearing device configuration and use settings result in electroacoustic characteristics that more closely approached evidence-based prescriptive targets compared to consumers' self-fitting practices after a 1-week field trial?**
  - **Statistically, no.** However, even with limited flexibility in fitting these devices, it can be seen that outputs and SII values for conversational inputs were clinically superior for the audiologic fitting.
2. **Did the audiologic fitting and orientation process provide measureable improvements in participants' abilities to use and benefit from OTC hearing devices after a 1-week field trial?**
  - **Yes and no.** Participants fitted by an audiologist had better PHAST-R scores indicating better ability to use their devices following audiologic orientation and counseling ( $p < .05$ ,  $d = 1.06$ ). This group also had fewer self-reported problems with aversiveness in their daily lives. However, this large effect was not statistically significant due to this study's limited sample size ( $p > .05$ ,  $d = .78$ ). No differences in speech communication benefit were noted between groups.
3. **Did cognition mediate the effects of audiologic fitting and orientation practices with these devices?**
  - **Maybe.** Although comparisons across cognitive groups did not reach statistical significance, a trend was observed wherein individuals with lower cognition reported greater speech communication benefit. This might be due to more unaided problems with speech communication for the LowCog group (difference in global unaided APHAB score,  $d = -.6$ ). Audiologic intervention appeared to reduce this difference between cognitive groups.
  - As cognition improved, the relative benefit obtained from audiologic intervention increased in terms of electroacoustic output (average SII) and ability to use the devices (PHAST-R). This interaction did not reach statistical significance.

## Discussion

- Previous research by Humes et al.<sup>3</sup> compared traditional audiologist-fitted HAs with a simulated OTC process that included lab-produced instructional materials for self-selecting and fitting HAs. Similar to that research, participants with audiologist fittings in this study also demonstrated better ability to use their devices. The OTC devices used for this research had limited flexibility for audiologic adjustments; however, the AUD-fitted participants had outputs that were slightly closer to prescriptive targets. This translated to less aversiveness to daily environmental sounds, but no differences in perceived speech communication improvements.
- Results of this study hint that cognition might influence outcomes with OTC fittings. Specifically, those with higher cognition might receive greater benefit from audiologic fitting and orientation practices.
- **Limitations:** It could be argued that all participants in this study benefitted from audiologic expertise: all received an audiometric evaluation and medical referral when needed, and devices were screened to ensure "acceptable" electroacoustic characteristics. Several individuals with a BOX fitting seriously misused their devices (e.g., using multiple domes on a single device, tolerating reportedly painful acoustic feedback, and sleeping while aided). Many of these problems occurred regardless of cognition. A lack of power prevented us from seeing statistical differences, despite potentially important effects.

## References

1. Gatehouse, S., Naylor, G., & Elberling, C. (2003). Benefits from hearing aids in relation to the interaction between the user and the environment. *International Journal of Audiology*, 42, 77-85.
2. Consumer Technology Association (CTA). (2017). ANSI/CTA Standard. Personal Sound Amplification Performance Criteria. ANSI/CTA-2051.
3. Humes, L. E., Rogers, S. E., Quigley, T. M., Main, A. K., Kinney, D. L., & Herring, C. (2017). The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial. *American Journal of Audiology*, 26(1), 53-79.